HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

UTILITY PATENT APPLICATION TRANSMITTAL *(Only for new nonprovisional applications under 37 CFR 1.53(b))*	Attorney Docket No.	4147.1020-002 (15-089)
	First Named Inventor	Seyed M. A. Salehizadeh
	Express Mail Label No.	

Title of Invention	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria, VA 22313-1450

1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent)
2. ☒ a. Applicant Asserts Small Entity Status
   See 37 CFR 1.27
   ☐ b. Applicant Certifies Micro Entity Status
   See 37 CFR 1.29
3. ☒ Specification **Total Pages 77**
   Both the claims and the abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ Drawing(s) (35 U.S.C. 113) **Total Sheets 25**
5. ☐ Inventor's Oath or Declaration **Total Sheets**
   (including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))
   a. ☐ Newly executed (original or copy)
   b. ☐ Copy from a prior application (37 C.F.R. 1.63(d))
6. ☒ Application Data Sheet
   See 37 CFR 1.76 *(PTO/AIA/14 or equivalent)*
7. ☐ Large Table or Computer Program (*Appendix*)
   a. ☐ CD-ROM or CD-R in duplicate b. ☐ Text file attached herewith
8. ☐ Nucleotide and/or Amino Acid Sequence Submission
   a. ☐ Computer Readable Form (CRF)
   b. ☐ Specification Sequence Listing on:
      i. ☐ CD-ROM or CD-R (2 copies); or
      ii. ☐ Text file attached herewith *(electronic filing)*
      iii. ☐ Paper [ ] **Pages**
   c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers. *(Do not submit when e-filing application)*
   Name of Assignee: _____
10. ☐ Power of Attorney
    ☐ Transmittal for Power of Attorney to One or More Registered Practitioners
11. ☐ English Translation Document (*if applicable*)
12. ☐ Information Disclosure Statement (Listing of References *(PTO/SB/08 or PTO-1449)*)
13. ☐ Preliminary Amendment
14. ☐ Return Receipt Postcard *(Check this box if going by express mail)*
15. ☐ Certified Copy of Priority Document(s). (If foreign priority is claimed)
16. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must indicate in ADS.
17. ☒ Other: Petition to Accept Color Drawings

***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
(2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

18. CORRESPONDENCE ADDRESS

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Signature	/Mark B. Solomon, Reg. No. 44348/	Date	6/9/2016
Submitted by Typed or Printed Name	Mark B. Solomon	Reg. Number	44,348

2370512

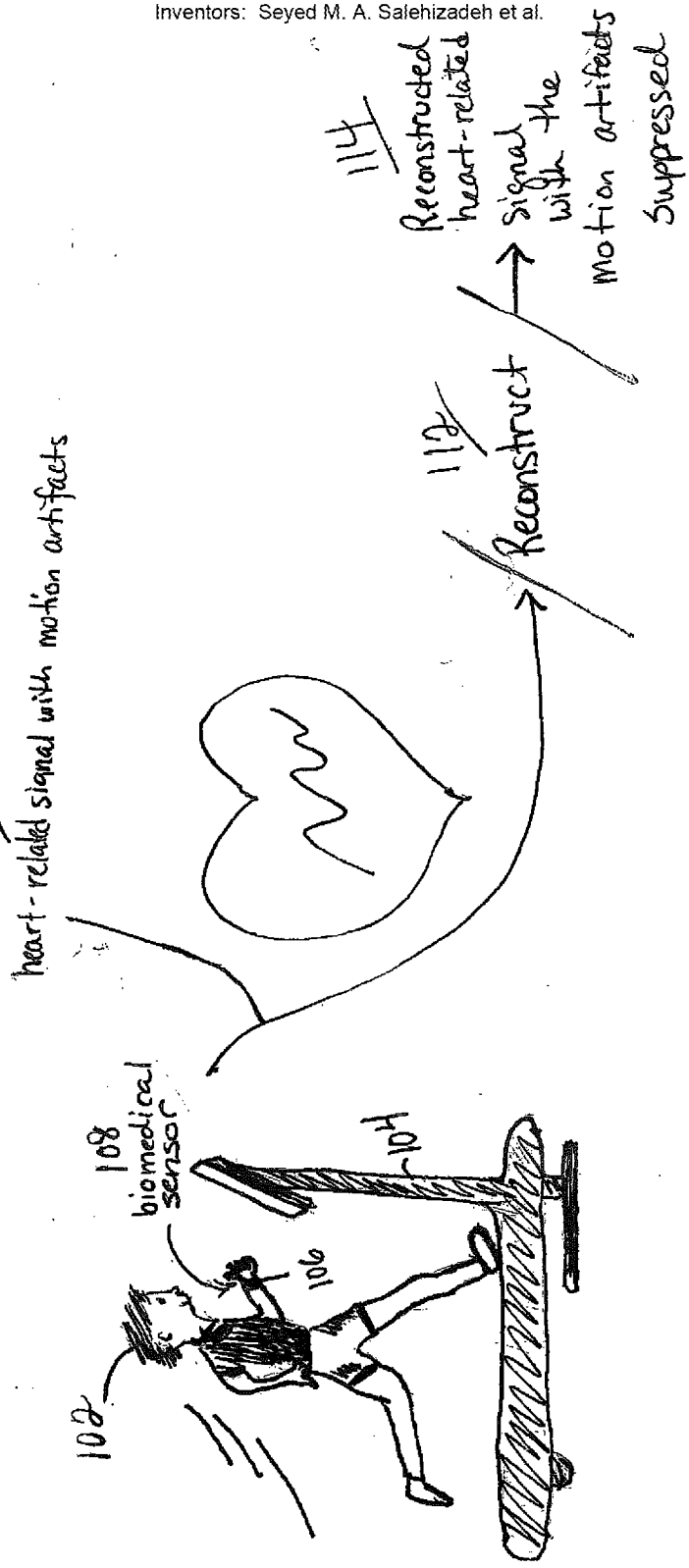

100
110
heart-related signal with motion artifacts
108
biomedical sensor
104
106
102
112
Reconstruct
114
Reconstructed heart-related signal with the motion artifacts suppressed

FIG. 1

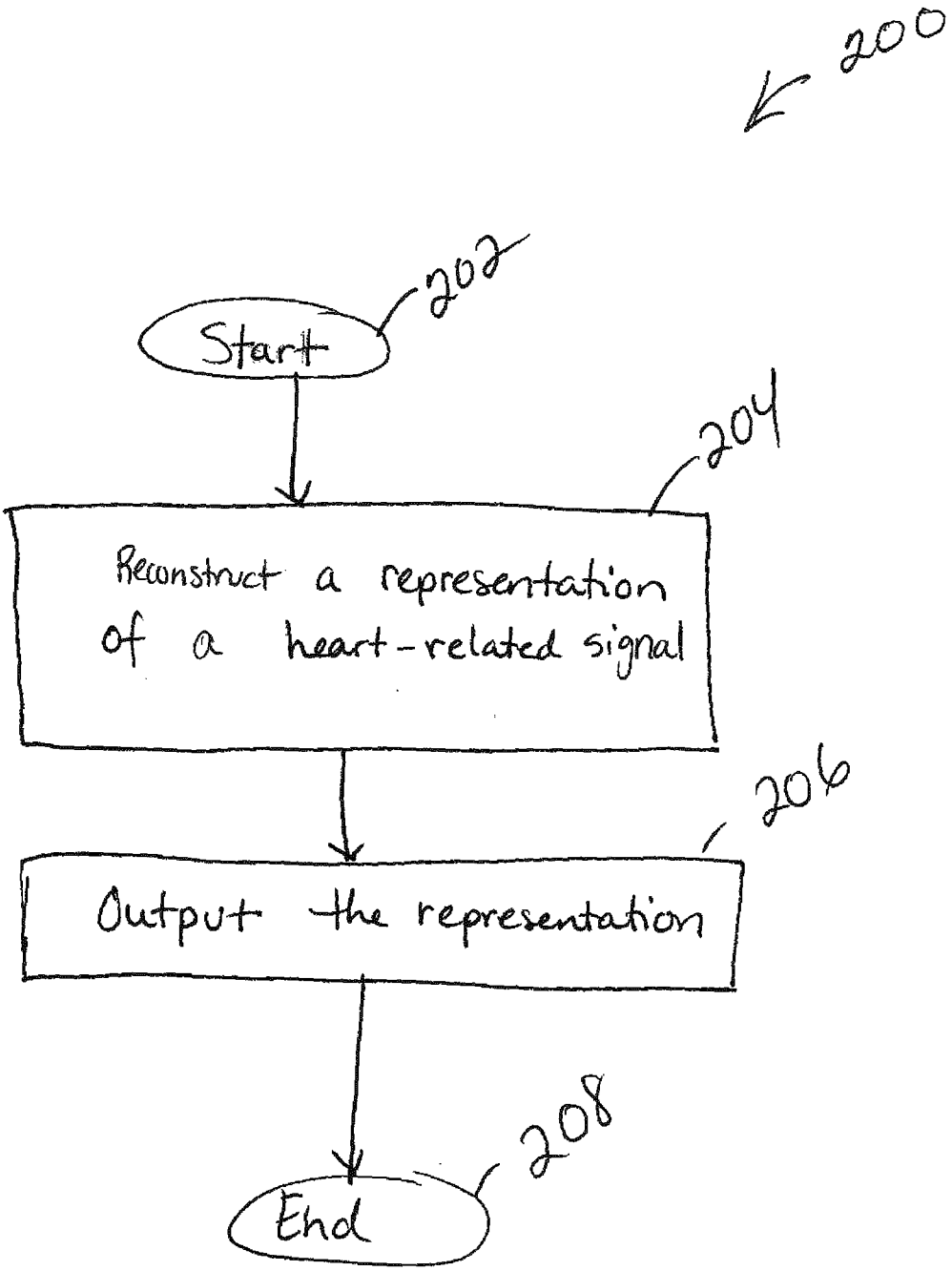

200
202
Start
204
Reconstruct a representation of a heart-related signal
206
Output the representation
208
End

FIG. 2

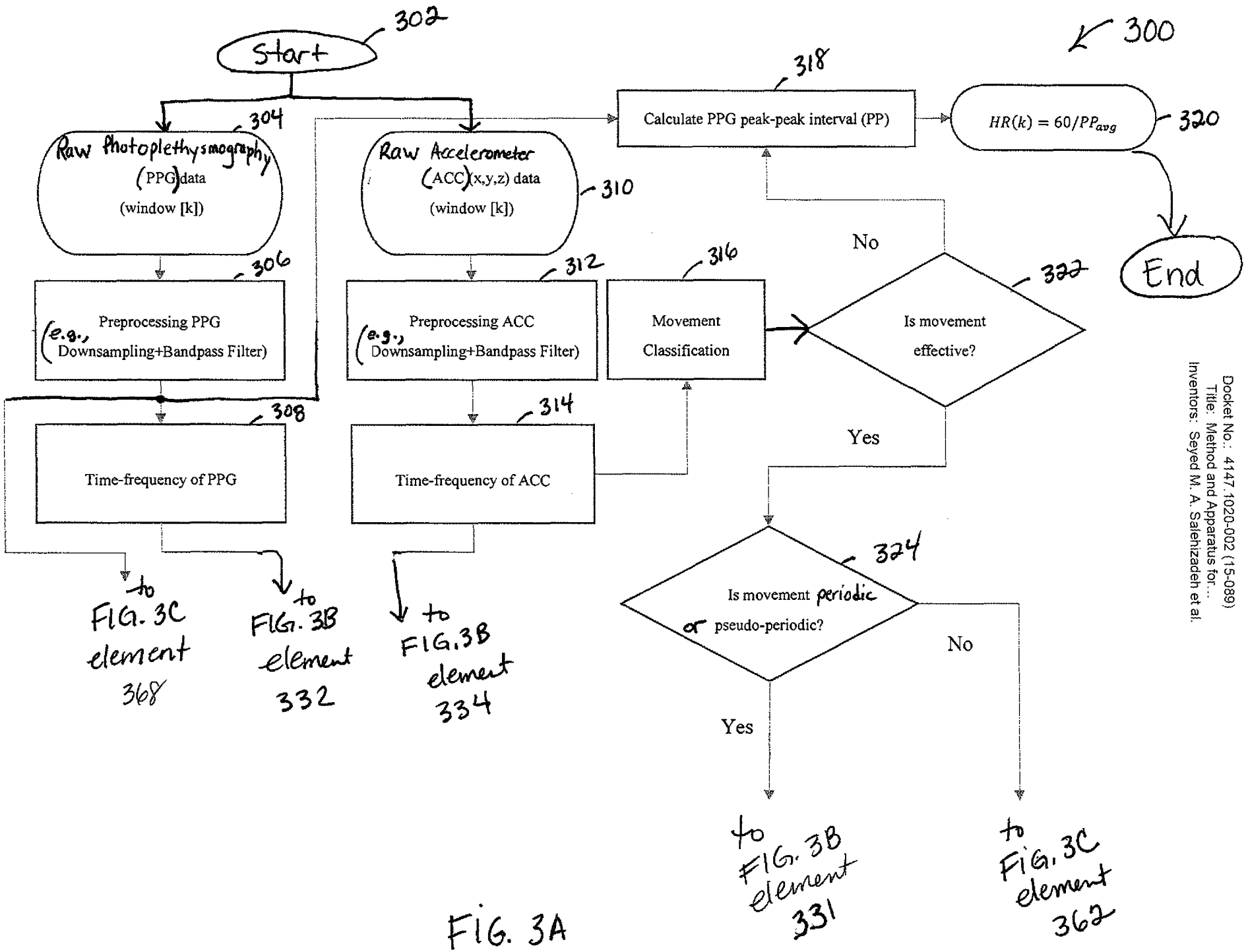


FIG. 3A

Docket No.: 4147.1020-002 (15-089)
Title: Method and Apparatus for...
Inventors: Seyed M. A. Salehizadeh et al.

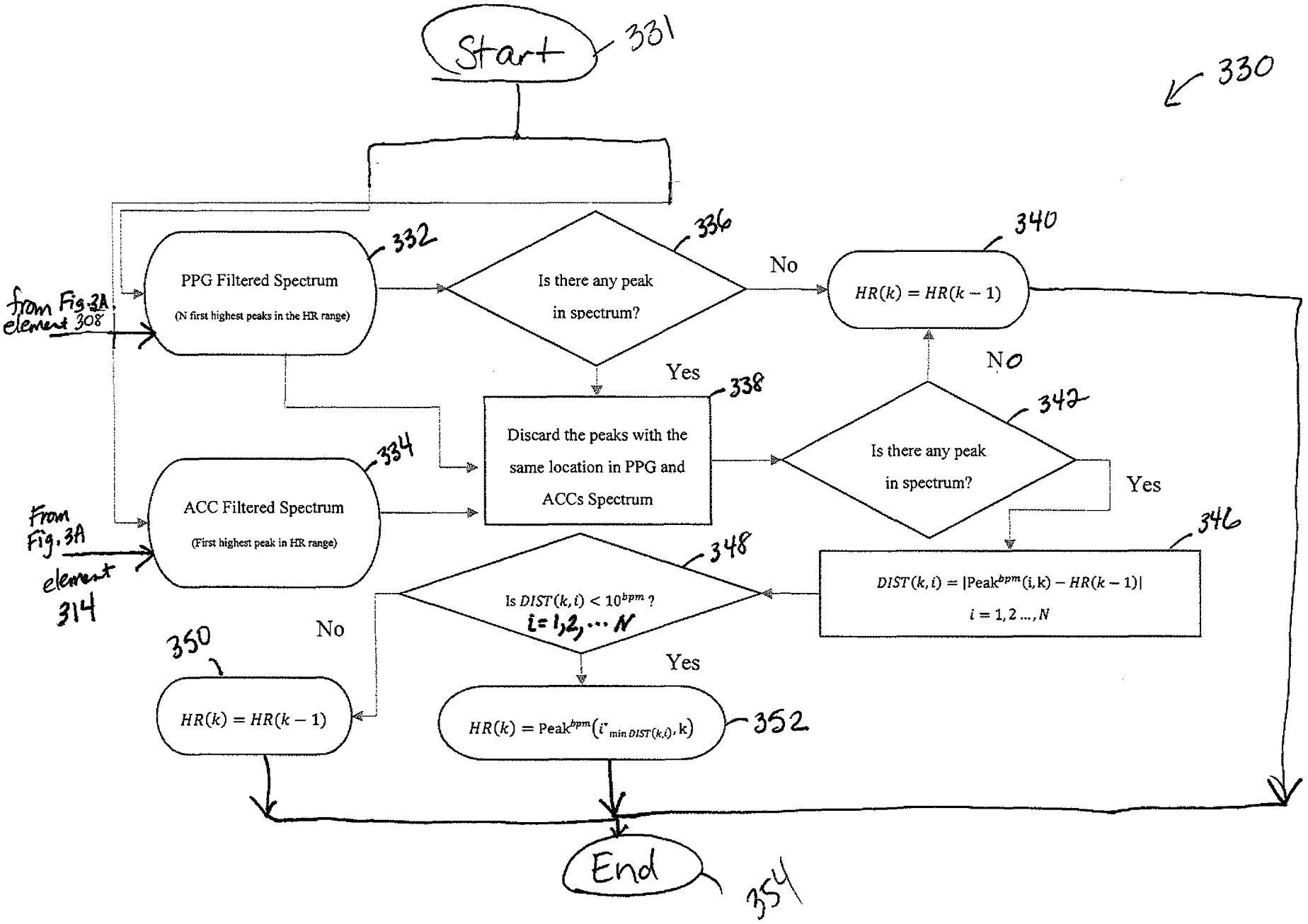


FIG. 3B

Docket No.: 4147.1020-002 (15-089)
Title: Method and Apparatus for...
Inventors: Seyed M. A. Salehizadeh et al.

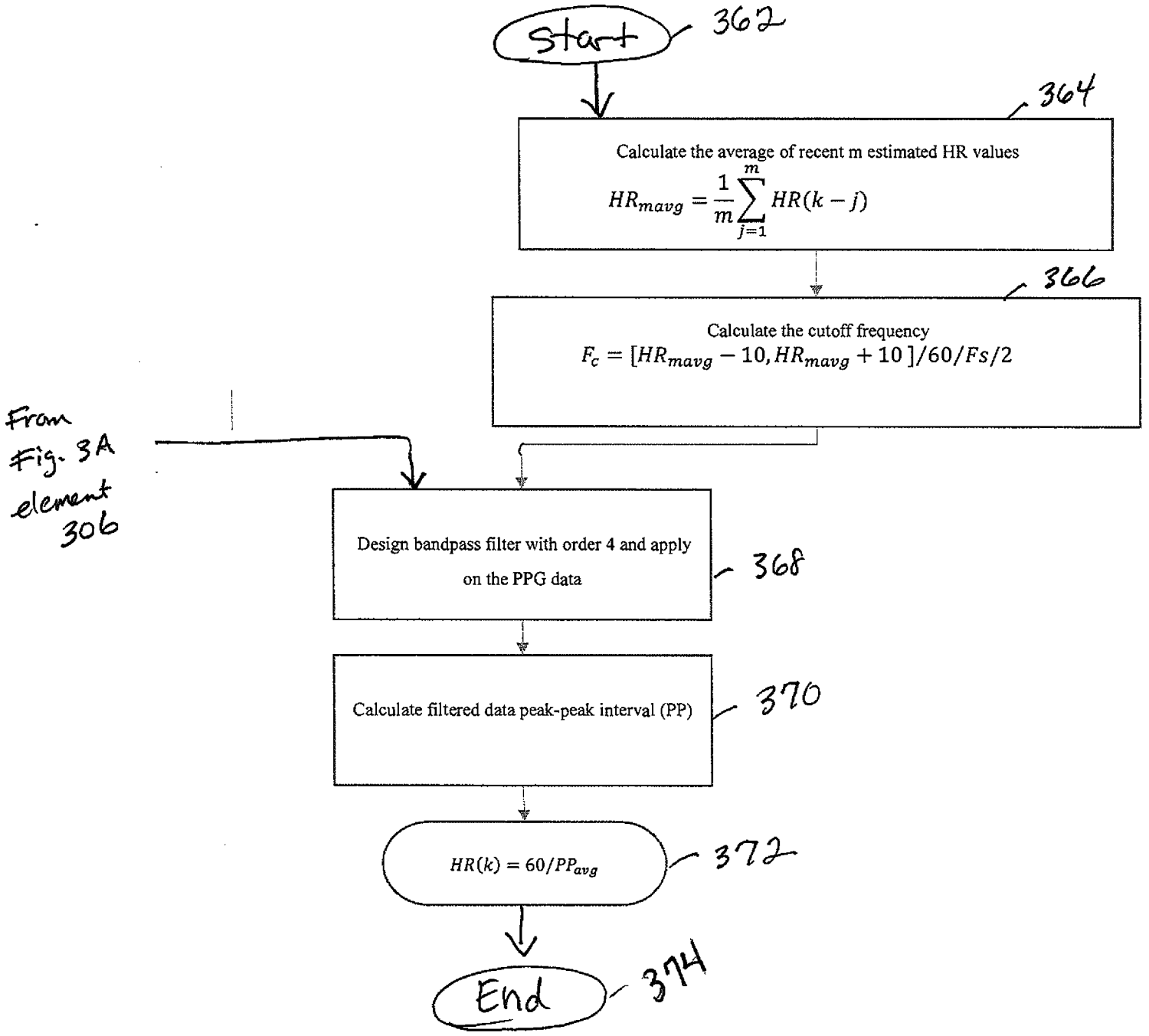


FIG. 3C

Docket No.: 4147.1020-002 (15-089)
Title: Method and Apparatus for...
Inventors: Seyed M. A. Salehizadeh et al.

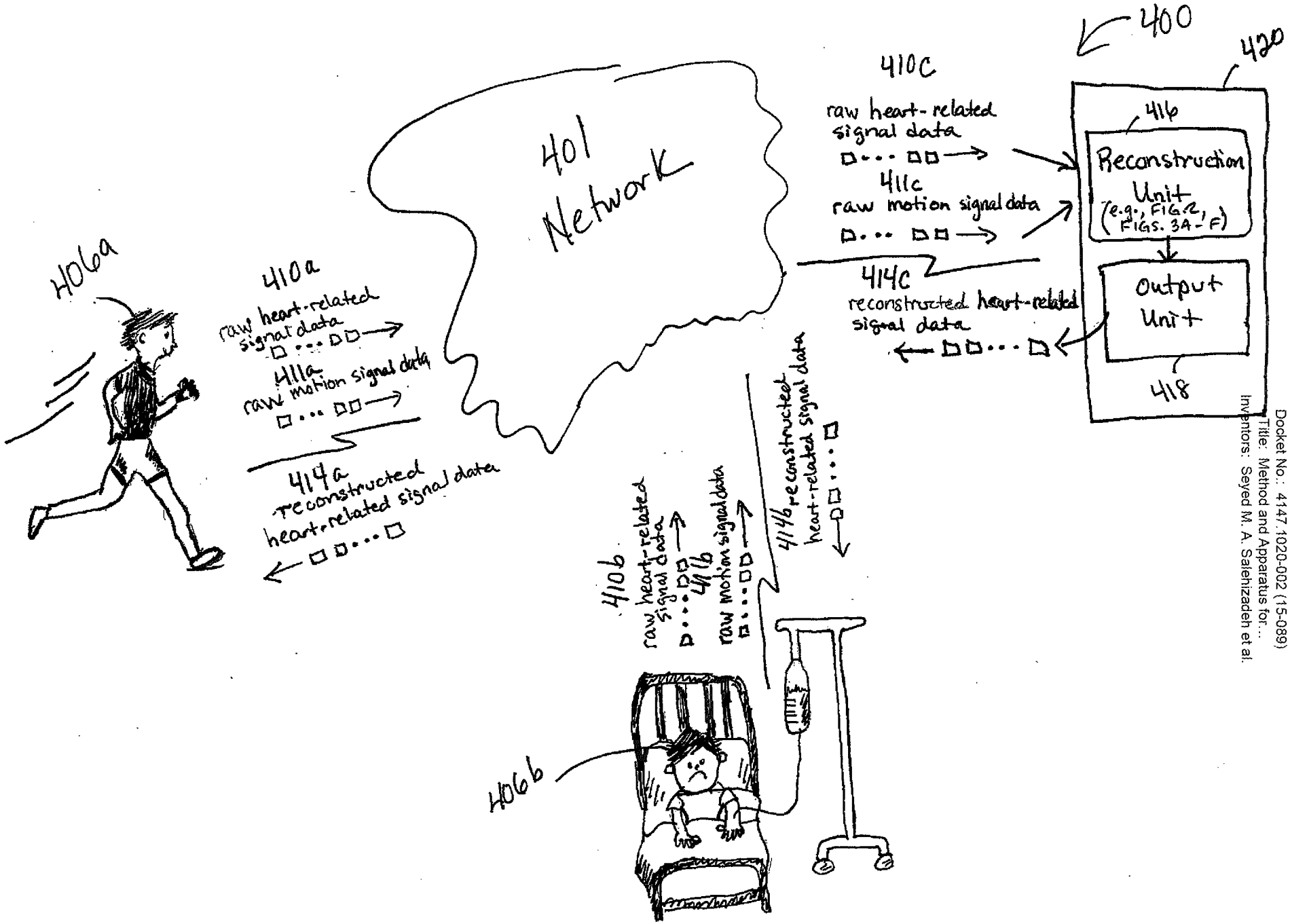


FIG. 4

Docket No.: 4147.1020-002 (15-089)
Title: Method and Apparatus for...
Inventors: Seyed M. A. Salehizadeh et al.

Petitioner Ex-1004, 0007

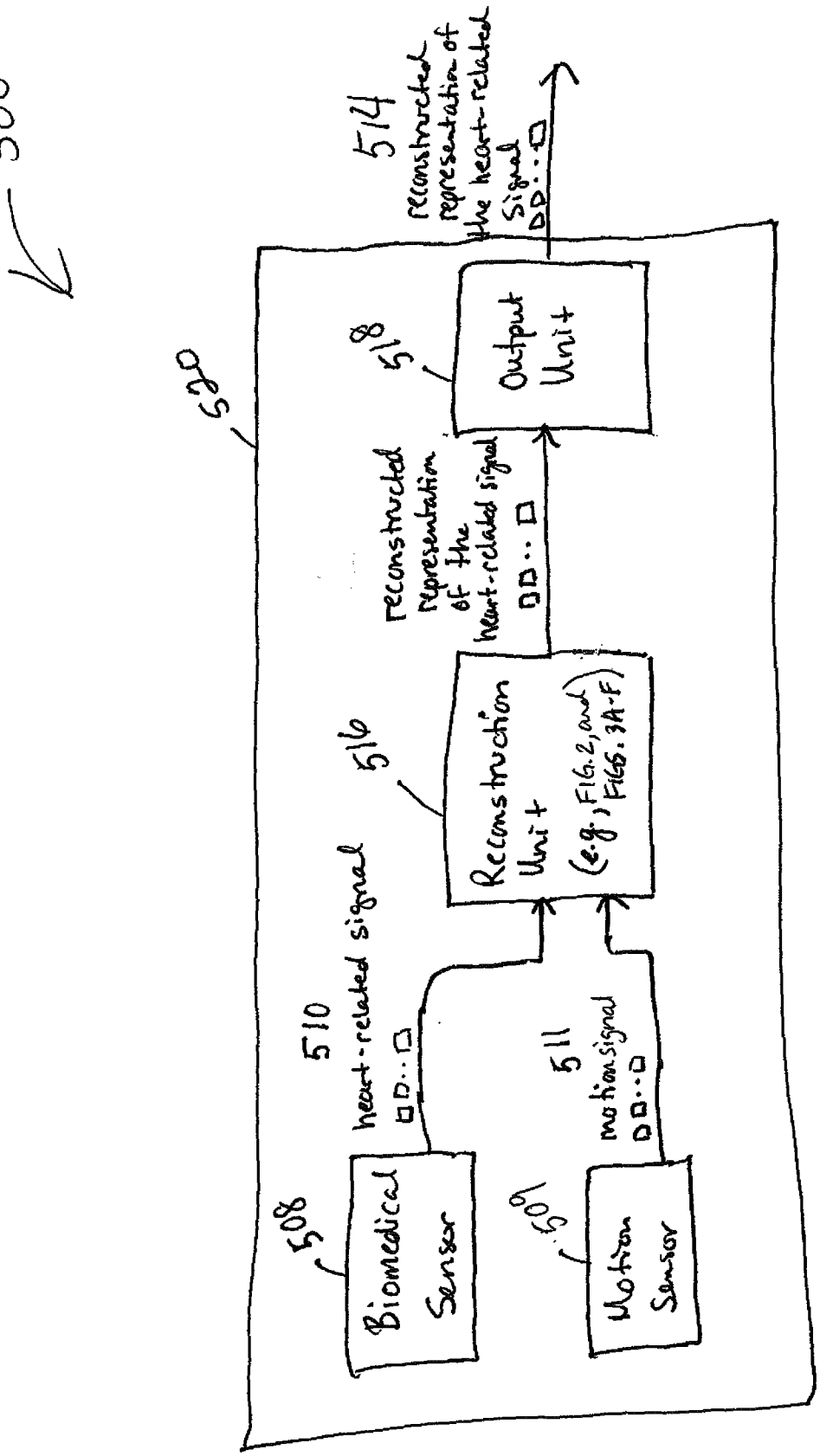

500
520
514
Reconstructed representation of the heart-related signal
518
Output Unit
Reconstructed representation of the heart-related signal
516
Reconstruction Unit (e.g., FIG. 2, and FIGS. 3A-F)
510
heart-related signal
511
motion signal
508
Biomedical Sensor
509
Motion Sensor

FIG. 5

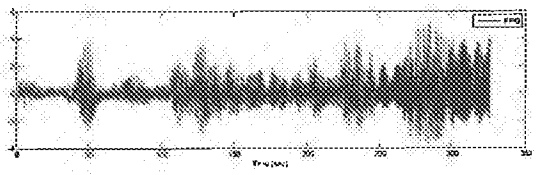


FIG. 6A

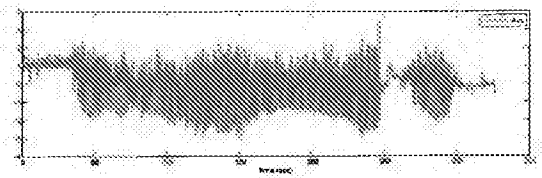


FIG. 6B

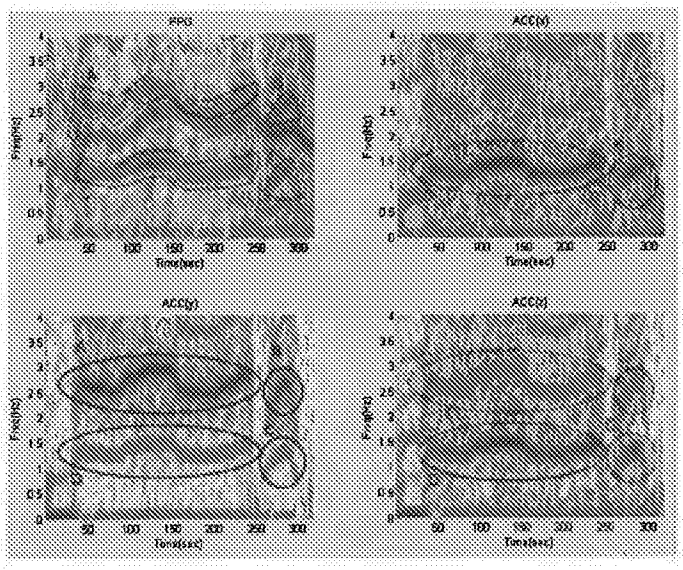


FIG. 6C

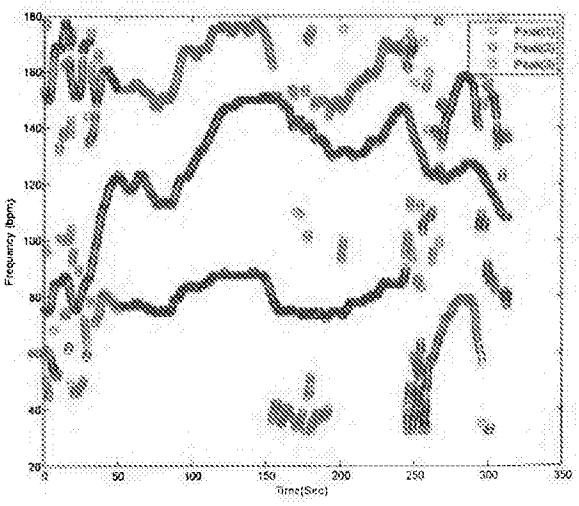

Frequency (bpm)
Time(Sec)
180
160
140
120
100
80
60
40
20
0
50
100
150
200
250
300
350

FIG. 7

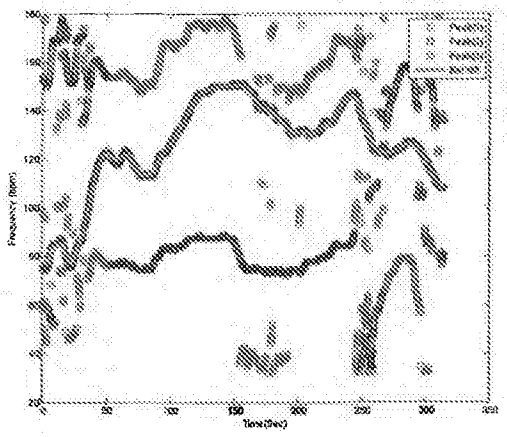


FIG. 8A

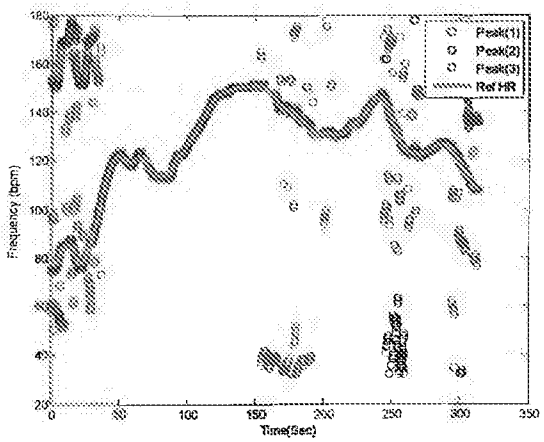


FIG. 8B

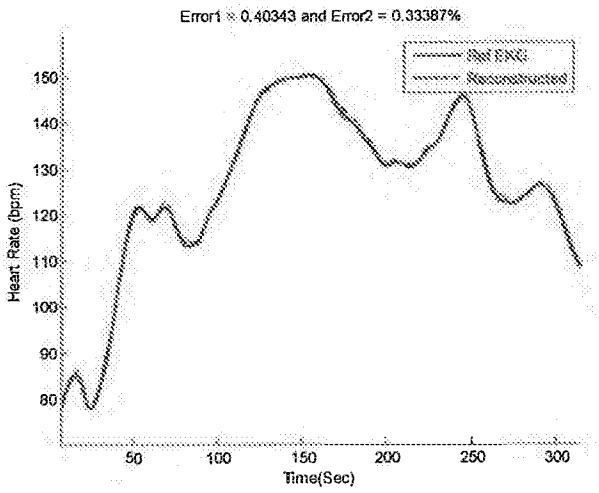

Error1 = 0.40343 and Error2 = 0.33387%
Ref EKG
Reconstructed
Heart Rate (bpm)
150
140
130
120
110
100
90
80
50
100
150
200
250
300
Time(Sec)

FIG. 9

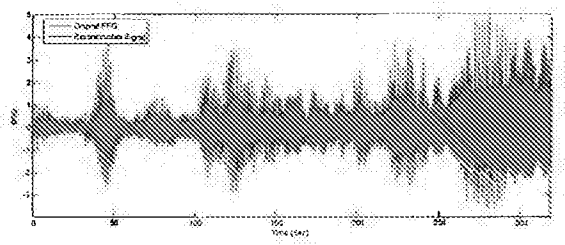


FIG. 10A

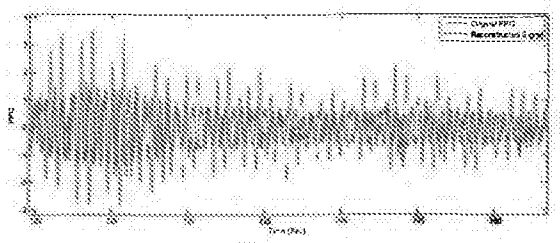


FIG. 10B

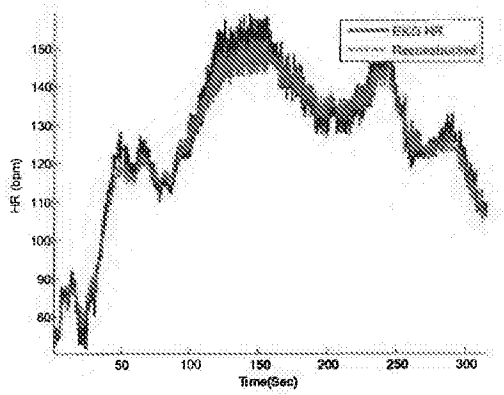


FIG. 11A

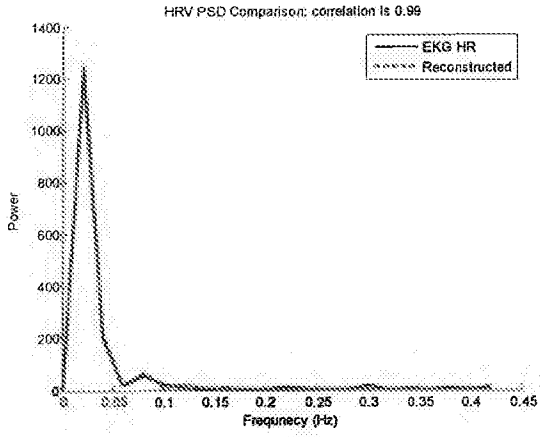


FIG. 11B

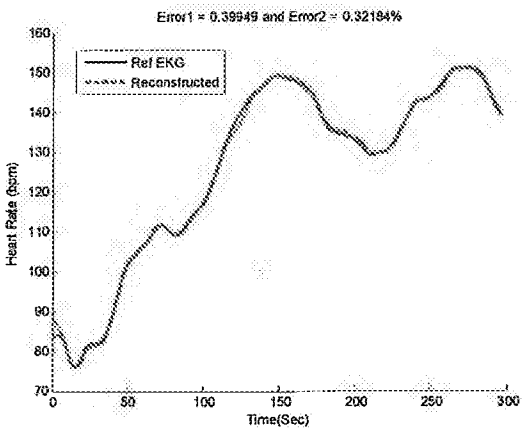


FIG. 12A

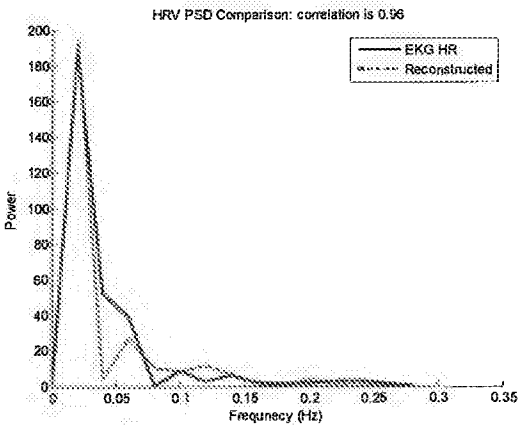


FIG. 12B

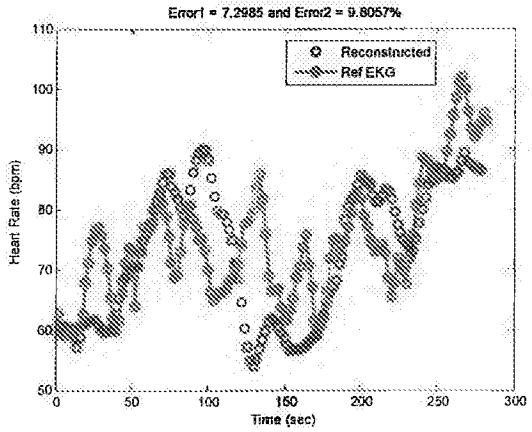


FIG. 13A

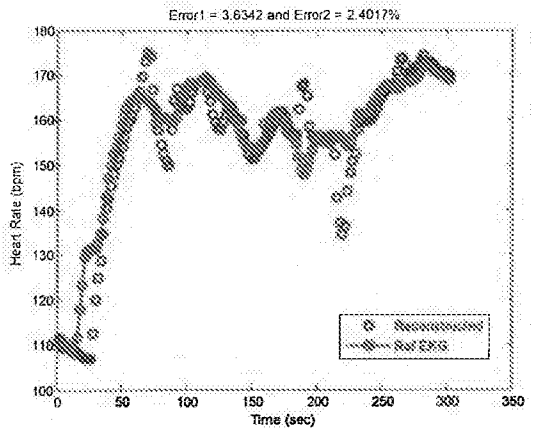


FIG. 13B

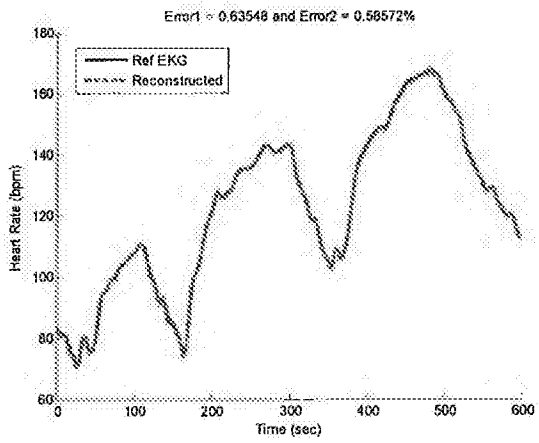


FIG. 14A

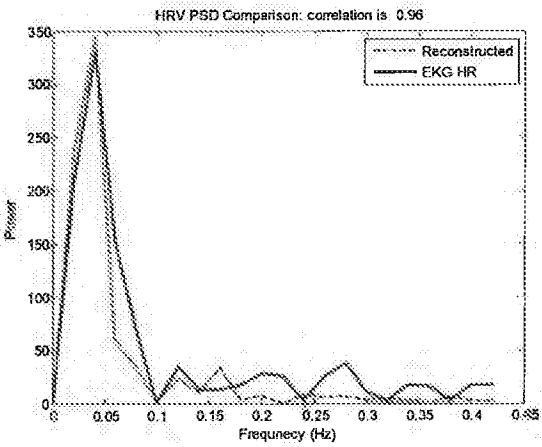


FIG. 14B

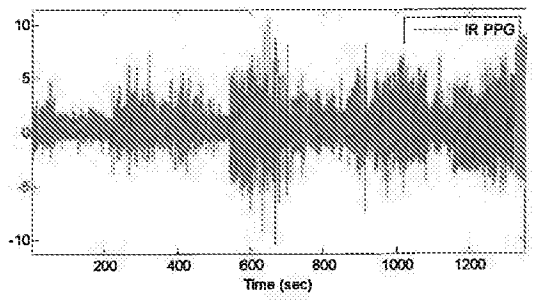


FIG. 15A

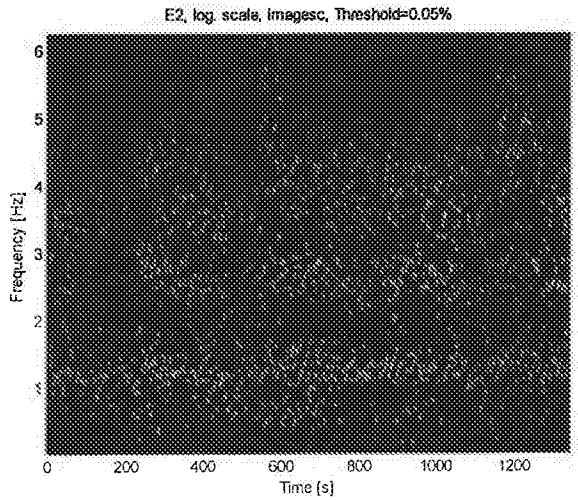


FIG. 15B

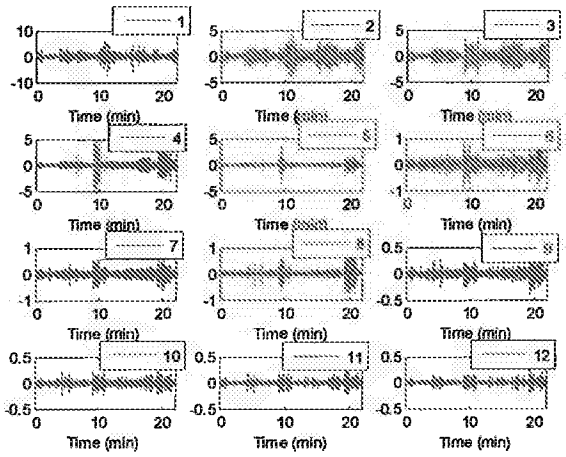


FIG. 16

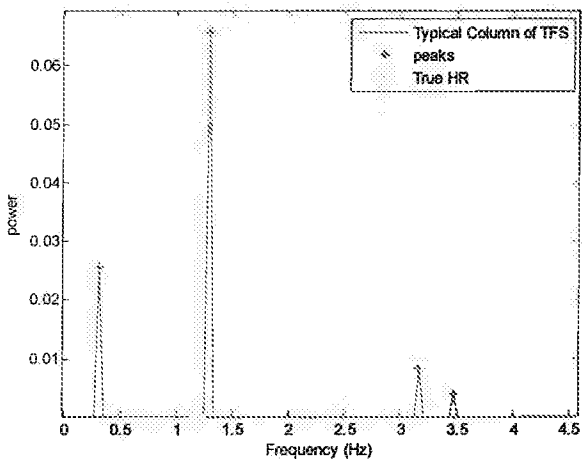


FIG. 17A

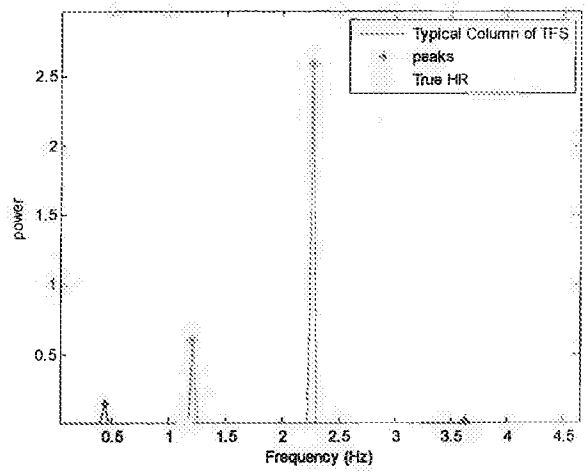


FIG. 17B

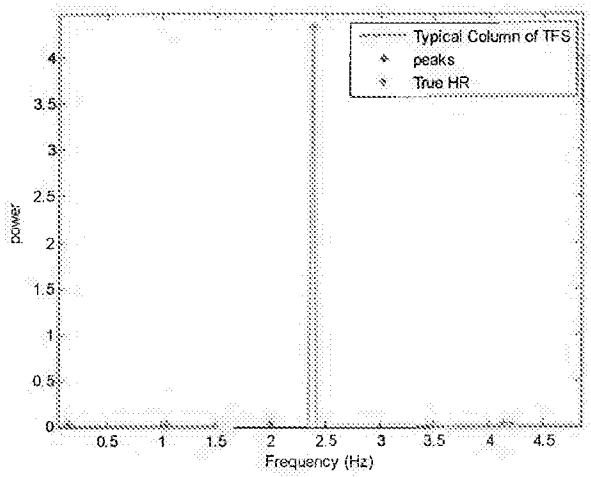


FIG. 17C

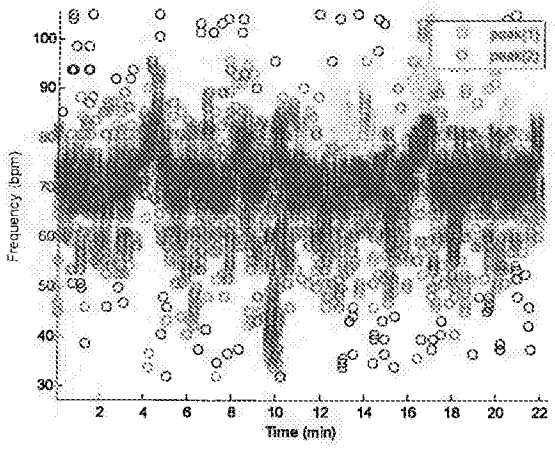


FIG. 18A

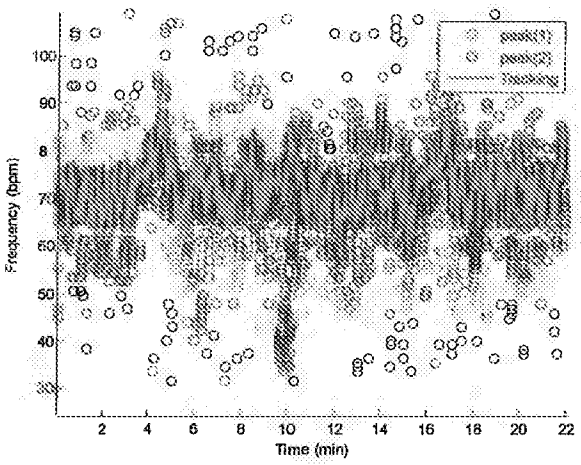


FIG. 18B

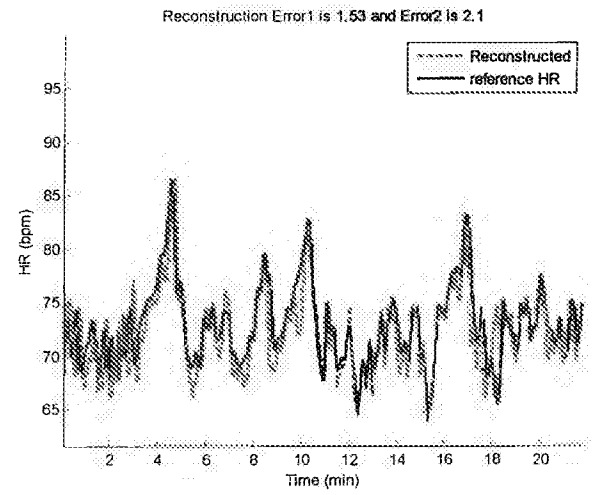


FIG. 19A

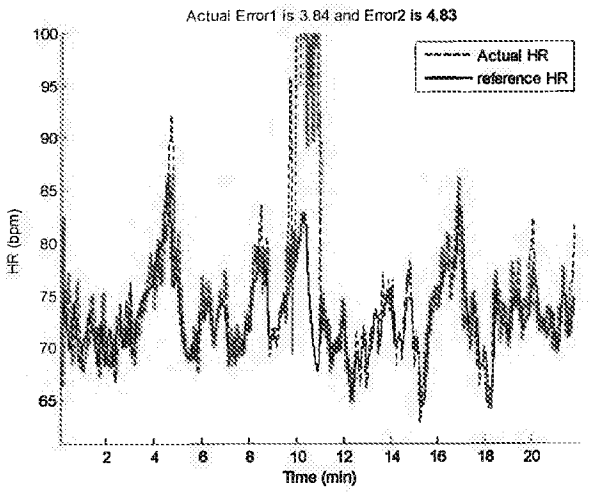


FIG. 19B

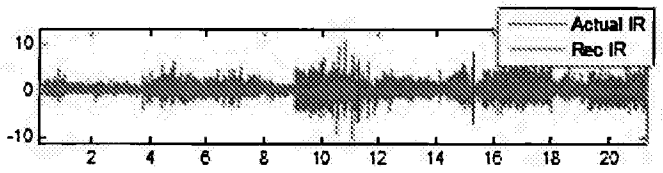


FIG. 20A

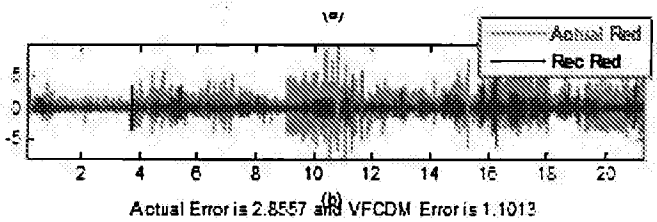


FIG. 20B

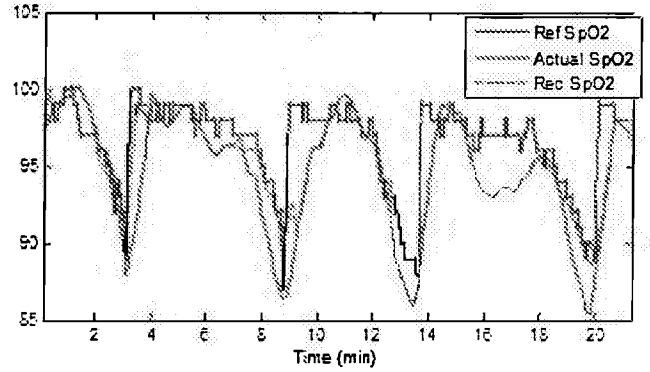


FIG. 20C

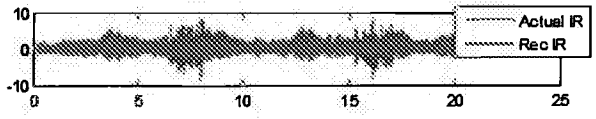


FIG. 21A

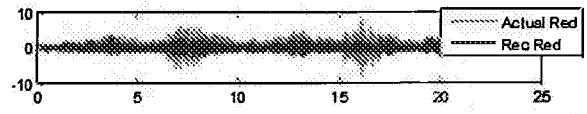


FIG. 21B

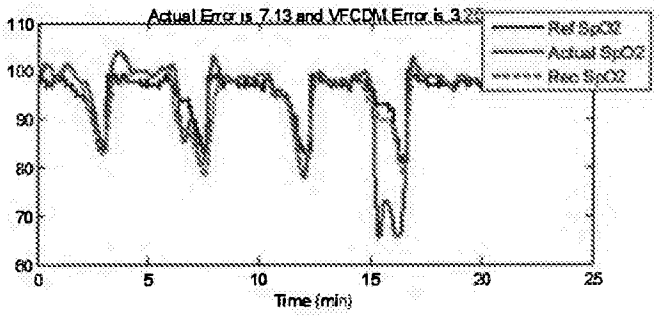


FIG. 21C

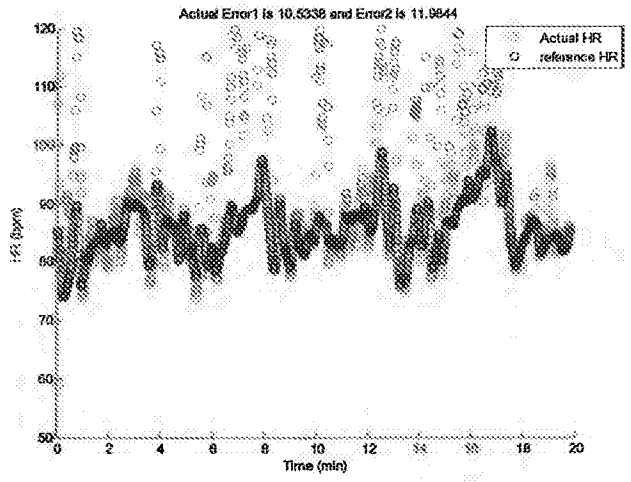


FIG. 22A

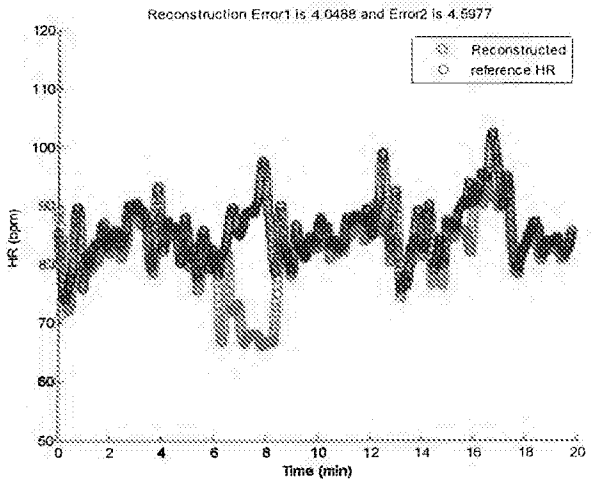


FIG.22B

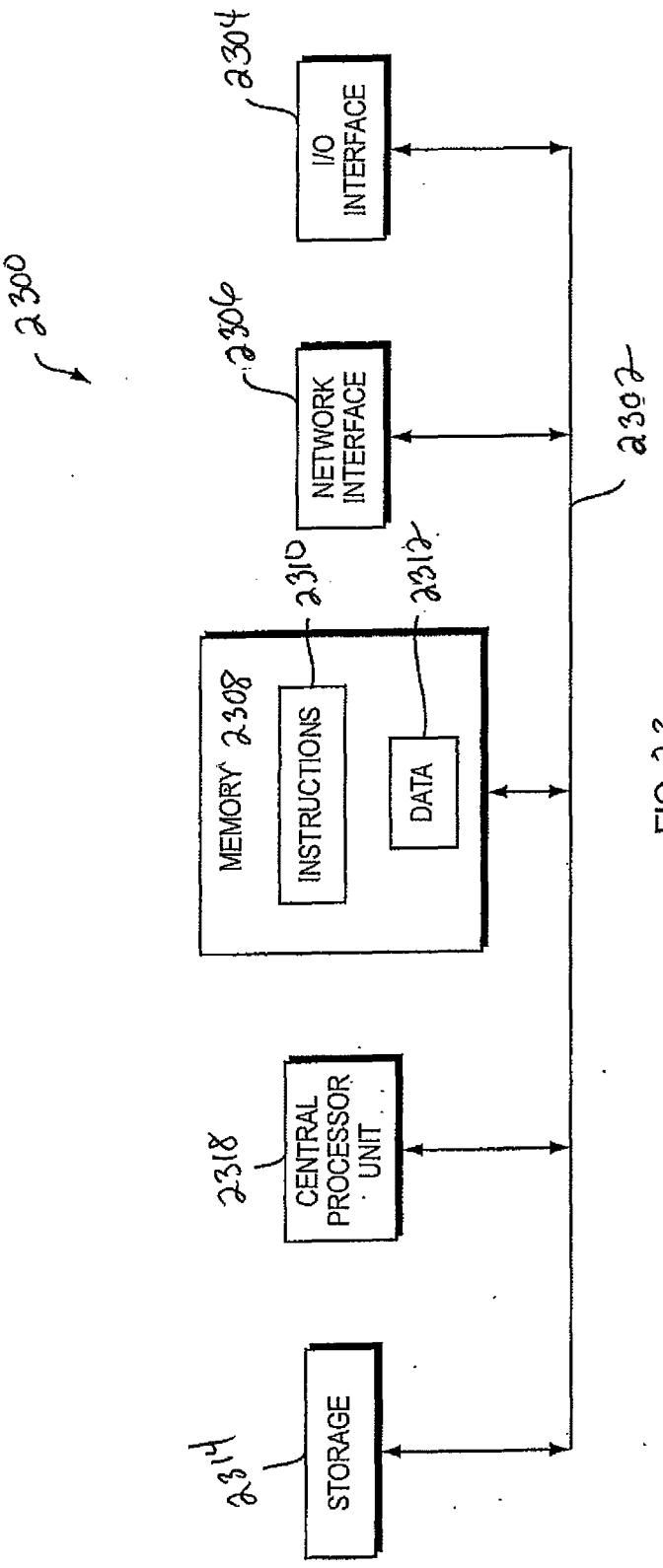

2300
2304
I/O INTERFACE
2306
NETWORK INTERFACE
2302
2310
2312
MEMORY 2308
INSTRUCTIONS
DATA
2318
CENTRAL PROCESSOR UNIT
2314
STORAGE

FIG. 23

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh

For: Method And Apparatus For Removing Motion Artifacts From Biomedical Signals

Date: _____

EXPRESS MAIL LABEL NO. _____

PETITION TO ACCEPT COLOR DRAWINGS/PHOTOGRAPHS
UNDER 37 CFR § 1.84

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

Commissioner:

Pursuant to 37 CFR § 1.84, Applicant hereby petitions for acceptance of color drawings/photographs of Figures 6A-22B, consisting of 17 sheets.

One (1) set of color drawings/photographs of Figures 6A-22B is attached as required. Please charge the Petition fee under 37 CFR § 1.17(h) in the amount of $70 to Deposit Account No. 08-0380.

REMARKS

Color drawings are the only practical medium by which to disclose the subject matter of the Figures.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By /Mark B. Solomon, Reg. No. 44348/
Mark B. Solomon
Registration No.: 44,348
Telephone: (978) 341-0036
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Concord, MA 01742-9133
Date: 6/9/2016

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4147.1020-002 (15-089)
	Application Number	
Title of Invention	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Seyed	M. A.	Salehizadeh	

Residence Information (Select One) ● US Residency ○ Non US Residency ○ Active US Military Service

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Address 2	

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Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
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Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Mailing Address of Inventor:

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Address 2	

City	State/Province	Postal Code	Country
Mansfield Center	CT	06250	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Yeonsik		Noh	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Title of Invention	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS	

City	Willington	State/Province	CT	Country of Residence	US

Mailing Address of Inventor:

Address 1	380 Daleville Road		
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City	Willington	**State/Province**	CT
Postal Code	06279	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	021005		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS		
Attorney Docket Number	4147.1020-002 (15-089)	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	25	**Suggested Figure for Publication (if any)**	1

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Petitioner Ex-1004, 0030

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Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	021005		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62299944	2016-02-25
Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Claims benefit of provisional	62172862	2015-06-09

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	4147.1020-002 (15-089)
	Application Number	
Title of Invention	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	University of Connecticut		
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Address 1	400 Farmington Avenue		
Address 2	MC 6400		
City	Farmington	**State/Province**	CT
Country	US	Postal Code	06032
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

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Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Mark B. Solomon, Reg. No. 44348/			Date (YYYY-MM-DD)	2016-06-09
First Name	Mark B.	Last Name	Solomon	Registration Number	44348

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	Application Number	
Title of Invention	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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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 CooperationTreaty.

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.

Date:_____Express Mail Label No._____

Inventors: Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh

Attorney's Docket No.: 4147.1020-002 (15-089)

METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/172,862 filed June 9, 2015 and U.S. Provisional Application No. 62/299,944 filed February 25, 2016. The entire teachings of the above applications are incorporated herein by reference.

GOVERNMENT SUPPORT

[0002] This invention was made with government support under Grant No. W81XWH-12-1-0541 from the US Army Medical Research and Material Command (USAMRMC). The government has certain rights in the invention.

BACKGROUND

[0003] Heart rate monitors have become widely-used training aids for a variety of sports. Some heart rate monitors use sensors based on photoplethysmography (PPG) technology. The PPG sensors include infrared light-emitting diodes (LEDs) and photodetectors, and offer a simple, reliable, low-cost means of monitoring pulse rate noninvasively, both at rest and during exercise.

SUMMARY

[0004] During exercise and other activities, PPG and other sensors may experience movement, such as shifting position or rotating, relative to a sensing location (*e.g.*, wrist or finger). The movement typically results in an introduction of a motion artifact in an electrical

signal produced by the sensor. The motion artifact may be interpreted by a processor as a heart-related signal if not addressed in advance of or as part of the processing in the processor. By properly addressing the motion artifact, an embodiment disclosed herein has improved accuracy in reconstructing the heart-related signal, thereby enabling processes that use the heart-related signal to have better performance.

[0005] Accordingly, a method for reconstructing a heart-related signal output by a biomedical sensor may comprise reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal. The reconstructing may be based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and the classification of the movement may be based on (ii) a classification of the movement. The method may further comprise outputting the reconstructed representation of the heart-related signal.

[0006] The motion artifacts may be suppressed in the reconstructed representation of the heart-related signal.

[0007] The time-varying spectral analysis may include pre-processing the heart-related signal to produce a pre-processed heart-related signal. In an event the classification indicates that the movement does not rise to a level causing the motion artifacts, the reconstructed representation may be based on an average value of peak-to-peak intervals in the pre-processed heart-related signal.

[0008] The pre-processing may include filtering the heart-related signal to produce a filtered heart-related signal.

[0009] The pre-processing may further include down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

[0010] The time-varying spectral analysis may include computing a first time-frequency spectrum (TFS) of the heart-related signal and computing a second TFS of the motion signal.

[0011] The first TFS computed and the second TFS computed may be 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

[0012] The first TFS computed may be a first time-varying power spectral density (PSD) and the second TFS computed may be a second time-varying PSD.

[0013] The reconstructed representation may be a current reconstructed representation. Based on the classification indicating that the movement does rise to a level causing the motion artifacts and is a pseudo-periodic movement or a periodic movement, the reconstructing may include determining whether at least one spectral peak is present having a corresponding frequency within a given frequency range at a point in time in the first TFS computed, the current reconstructed representation being reconstructed for the point in time. Based on a determination that the at least one spectral peak is not present, the current reconstructed representation may be based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed. The given frequency range may be 0.5 Hz to 3 Hz.

[0014] The reconstructing may include retaining up to a pre-determined number of candidate spectral peaks located at a first point in time in the first TFS computed. The candidate spectral peaks retained may be based on having corresponding frequencies within a given frequency range and highest amplitude or power values relative to other spectral peaks located at the first point in time, the other spectral peaks having respective frequencies within the given frequency range. The reconstructing may further include discarding each of the candidate spectral peaks retained that is associated with a same frequency as a dominant spectral peak located at a second point in time in the second TFS computed. The first point in time and the second point time may have same time values. The given frequency range may be 0.5 Hz to 3 Hz.

[0015] The representation may be a current representation and the reconstructed representation may be a current reconstructed representation. In an event the discarding discards each of the candidate spectral peaks retained, reconstructing the current representation may be based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

[0016] The discarding may be a first discarding, the representation may be a current representation and, in an event the first discarding results in at least one remaining candidate spectral peak retained, reconstructing the current representation may further include second

discarding. The second discarding may discard remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced by at least a frequency difference threshold from a prior reconstructed representation's frequency. The prior reconstructed representation associated with a previous point in time in the first TFS computed. The previous point in time may be an earlier point in time with respect to the first point in time.

[0017] Based on each of the at least one remaining candidate spectral peak retained having been discarded by the second discarding, reconstructing the current representation may be based on the prior reconstructed representation. Based on at least one last candidate spectral peak remaining, the at least one last candidate spectral peak remaining not discarded by the second discarding, reconstructing the current representation may be based on a selected candidate spectral peak. The selected candidate spectral peak may be selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining.

[0018] The dominant spectral peak may have a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS.

[0019] The retaining and the discarding may be based on the classification indicating that the movement is a pseudo-periodic movement or a periodic movement, and determining that at least one spectral peak with a corresponding frequency in the given frequency range is present at the first point in time.

[0020] The time-varying spectral analysis may further include pre-processing the heart-related signal and the motion signal for the computing of the first TFS and the second TFS.

[0021] The pre-processing may include filtering the heart-related signal and the motion signal to produce a filtered heart-related signal and a filtered motion signal, respectively. The pre-processing may further include down-sampling both the filtered heart-related signal and the filtered motion signal, the down-sampling being at a sampling rate less than an original sampling rate.

[0022] The method may further include classifying the classification of the movement by comparing an amount of amplitude modulation in the second TFS computed to an amplitude

modulation threshold. The amplitude modulation threshold may be dependent on a type of the motion detector sensor. The classification may indicate whether the movement rises to a level causing the motion artifacts based on a result of the comparing. In an event the result indicates that the movement does rise to the level causing the motion artifacts, classifying the classification of the movement may further include determining whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement.

[0023] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS. The first, second, and third peaks may have largest power or amplitude values relative to other peaks in the second TFS at the point in time. The first spectral peak may be a largest spectral peak amongst the first, second, and third spectral peaks.

[0024] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include computing a first ratio of the second frequency identified to the first frequency identified. The method may determine a first comparison result by comparing the first ratio computed to a first ratio value. The method may compute a second ratio of the third frequency identified to the first frequency identified. The method may determine a second comparison result by comparing the second ratio computed to a second ratio value. The classification may further indicate the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result. The first ratio value may be 2 and the second ratio value may be 3.

[0025] The time-varying signal analysis may include pre-processing the heart-related signal to produce a pre-processed heart-related signal and, in an event the classification of the movement indicates the random movement, the reconstructing may include computing an average value of a number of prior reconstructed representations outputted prior to the reconstructing. The number may be based on a duration of consecutive motion artifacts, detected prior to the reconstructing. The time-varying signal analysis may further include computing a bandpass filter cutoff frequency based on the average value computed, and filtering the pre-

processed heart-rate signal by applying the band pass filter computed to produce a filtered, pre-processed heart-related signal. The reconstructed representation may be based on an average peak-to-peak interval value of the filtered, pre-processed heart-rate signal.

[0026] The heart-related signal and the motion signal may be produced, concurrently.

[0027] The method may comprise segmenting the heart-related signal into a plurality of windowed heart-related signal data segments and segmenting the motion signal into a corresponding plurality of windowed motion signal data segments. The method may comprise repeating the reconstructing and the outputting for each windowed heart-related signal data segment and each corresponding motion signal data segment. The time window may be a value in a range from 2 to 32 seconds.

[0028] The biomedical sensor may be at least one of: a photoplethysmogram (PPG) sensor, piezoelectric sensor, Light Emitting Diode (LED) based sensor, camera sensor, and pulse oximeter sensor, and the motion sensor may be an accelerometer.

[0029] The biomedical sensor and the motion sensor may be co-located.

[0030] The method may further comprise employing the reconstructed representation to determine a heart rate estimate.

[0031] The method may further comprise employing the reconstructed representation to determine an arterial oxygen saturation (SpO2) estimate.

[0032] The method may further comprise employing the reconstructed representation to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0033] The reconstructing and the outputting may be performed in real-time with respect to production of the heart-related signal and the motion signal.

[0034] The reconstructing and the outputting may be performed in non-real-time with respect to production of the heart-related signal and the motion signal.

[0035] According to another embodiment, an apparatus for reconstructing a heart-related signal output by a biomedical sensor may comprise a reconstruction unit. The reconstruction unit may be configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on (i) a time-

varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of the movement. The apparatus may further comprise an output unit configured to output the reconstructed representation of the heart-related signal.

[0036] Yet another example embodiment may include a non-transitory computer-readable medium having stored thereon a sequence of instructions which, when loaded and executed by a processor, causes the processor to complete methods disclosed herein.

[0037] It should be understood that embodiments disclosed herein can be implemented in the form of a method, apparatus, system, or computer readable medium with program codes embodied thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0039] The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

[0040] FIG. 1 is a block diagram of an example application for which embodiments disclosed herein may be applied.

[0041] FIG. 2 is a flow diagram of an example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0042] FIGS. 3A-C are flow diagrams of example embodiments of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0043] FIG. 4 is a block diagram of an example embodiment of a system.

[0044] FIG. 5 is a block diagram of an example embodiment of an apparatus for reconstructing a heart-related signal output by a biomedical sensor.

[0045] FIGS. 6A-6C show Time-Frequency spectra of a recording from a dataset.

[0046] FIG. 7 is a filtered time-frequency spectral plot of a photoplethysmogram (PPG) signal.

[0047] FIGS. 8A-8B show motion artifact detection in a PPG spectrum according to embodiments disclosed herein.

[0048] FIG. 9 shows a comparison of reconstructed heart rate (HR) obtained, according to embodiments disclosed herein, to reference HR obtained from simultaneous electrocardiogram (ECG) recordings.

[0049] FIG. 10A is an example embodiment of PPG signal reconstruction according to embodiments disclosed herein.

[0050] FIG. 10B is a zoomed-in version of FIG. 10A.

[0051] FIGS. 11A-B show comparisons of heart rate variability (HRV) spectra between a reference and a reconstructed HRV time series (*e.g.*, as shown in FIGS. 10A-B) from a motion artifact-contaminated PPG signal for a given dataset.

[0052] FIGS. 12A, 12B, 13A, 13B, 14A, and 14B show the reconstructed HR and corresponding power spectral density (PSD) of a sample-sample windowed HR, according to embodiments disclosed herein, in comparison to a reference HR from an ECG.

[0053] FIGS. 15A-B show an example resultant variable frequency complex demodulation (VFCDM) time-frequency spectrum of recordings from a given subject.

[0054] FIG. 16 shows twelve components corresponding to the Infrared (IR) and Red signal for the given subject.

[0055] FIGS. 17A-C are example spectra plots corresponding to three scenarios.

[0056] FIG. 18A shows a representative filtered time-frequency spectral plot of PPG recording from subject #5.

[0057] FIG. 18B shows tracking of HR based on embodiments disclosed herein.

[0058] FIGS. 19A-B represent comparisons of an estimated 8 second moving average HR from a spectral approach for filtering motion artifacts for oxygen saturation estimation (OxiMA) method to a reference HR, and an HR calculated from a motion-corrupted PPG signal compared to a reference HR from an ECG, respectively.

[0059] FIGS. 20A-C are example plots of data showing less motion-corrupted data that can be used for oxygen saturation estimation.

[0060] FIGS. 21A-C and FIGS. 22A-B show reconstructed arterial oxygen saturation (SpO2) and HR in comparison to the reference HR from ECG recordings for the given subject.

[0061] FIG. 23 is a block diagram of an example internal structure of a computer optionally within an embodiment disclosed herein.

DETAILED DESCRIPTION

[0062] A description of example embodiments of the invention follows.

[0063] Accurate estimation of a heart rate (HR) and changing arterial oxygen saturation (SpO2) from a heart-related signal, such as a photoplethysmogram (PPG) signal, during intense physical activity is a very challenging problem. This is because strenuous and high intensity exercise can result in severe motion artifacts (MAs) in the heart-related signal, making accurate HR and SpO2 estimation difficult.

[0064] HR monitoring using PPG signals has many advantages compared to using traditional ECG sensors, such as simpler hardware implementation, lower cost, and no need for daily application of electrodes (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Fluctuations of the PPG signal are caused by changes in arterial blood volume associated with each heartbeat, where the magnitude of the fluctuations depends on the amount of blood rushing into the peripheral vascular bed, the optical absorption of the blood, skin, and tissue, and the wavelength used to illuminate the blood. The pulse oximeter signal contains not only the blood oxygen saturation and heart rate (HR) data, but also other vital physiological information (Chon, K.H., S. Dash, and J. Kihwan, Estimation of Respiratory Rate From Photoplethysmogram Data Using Time–Frequency Spectral Estimation. Biomedical Engineering, IEEE Transactions on, 2009. 56(8): p. 2054-2063; Lee, J. and K.H. Chon, Respiratory Rate Extraction Via an Autoregressive Model Using the Optimal Parameter Search Criterion. Annals of Biomedical Engineering, 2010. 38(10): p. 3218-3225; Dash, S., et al., Estimation of Respiratory Rate From ECG, Photoplethysmogram, and Piezoelectric Pulse Transducer Signals: A

Comparative Study of Time–Frequency Methods. Biomedical Engineering, IEEE Transactions on, 2010. 57(5): p. 1099-1107; Jinseok, L. and K.H. Chon, Time-Varying Autoregressive Model-Based Multiple Modes Particle Filtering Algorithm for Respiratory Rate Extraction From Pulse Oximeter. Biomedical Engineering, IEEE Transactions on, 2011. 58(3): p. 790-794. The fluctuations of PPG signals contain the influences of arterial, venous, autonomic and respiratory systems on the peripheral circulation. Utilizing a pulse oximeter as a multi-purpose vital sign monitor has clinical appeal, since it is familiar to the clinician and comfortable for the patient (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Even simple knowledge of HR patterns would provide more useful clinical information than just HR and blood oxygenation, especially in situations in which a pulse oximeter is the sole monitor available. One major example of such benefits can be seen in a study by Chong et al. which shows that accurate detection of atrial fibrillation can be obtained from PPG data (Jo Woon, C., et al., Arrhythmia Discrimination Using a Smart Phone. Biomedical and Health Informatics, IEEE Journal of, 2015. 19(3): p. 815-824). In addition to the acquisition of HR in response to exercise, research has recently focused on obtaining HRV information from wearable sensors including devices that use PPGs (Achten, J. and A.E. Jeukendrup, Heart rate monitoring: applications and limitations. Sports medicine (Auckland, N.Z.), 2003. 33(7): p. 517-538). Increased HRV has been associated with lower mortality rates and is affected by both age and sex (Achten, J. and A.E. Jeukendrup, Heart rate monitoring: applications and limitations. Sports medicine (Auckland, N.Z.), 2003. 33(7): p. 517-538). During graded exercise, the majority of studies show that HRV decreases progressively up to moderate intensities, after which it stabilizes (Laughlin, M.H., Cardiovascular response to exercise. Am J Physiol, 1999. 277(6 Pt 2): p. S244-59). Although there are many promising and attractive features of using pulse oximeters for vital sign monitoring, currently they are mainly used on stationary patients. This is because motion artifacts (MAs) result in unreliable HR and SpO_2 estimation (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Clinicians have cited motion artifacts in

pulse oximetry as the most common cause of false alarms, loss of signal, and inaccurate readings (Jubran, A., Pulse oximetry. Crit Care, 1999. 3(2): p. R11-r17). During physical activities, MA contamination in PPG signals seriously interferes with HR estimation. The MAs are mainly caused by ambient light leaking into the gap between the PPG sensor surface and skin surface. Besides, the change in blood flow due to movements is another MA source (Maeda, Y., M. Sekine, and T. Tamura, Relationship between measurement site and motion artifacts in wearable reflected photoplethysmography. J Med Syst, 2011. 35(5): p. 969-76). In practice, MAs are difficult to remove because they do not have a predefined narrow frequency band and their spectrum often overlaps that of the desired signal (Thakor, N.V. and Y.S. Zhu, Applications of adaptive filtering to ECG analysis: noise cancellation and arrhythmia detection. IEEE Trans Biomed Eng, 1991. 38(8): p. 785-94). Consequently, development of methods capable of reconstructing the corrupted signal and removing artifacts is challenging. There are a number of general techniques used for artifact detection and removal. One of the methods used to remove motion artifacts is adaptive filtering (Diniz, P., Adaptive filtering: algorithms and practical implementation. 2008: . Springer Science, Business Media L.L.C., Kalman, R.E., A New Approach to Linear Filtering and Prediction Problems Transactions of the ASME – Journal of Basic Engineering, 1960. Series D(82); Morbidi, F., et al., Application of Kalman Filter to Remove TMS-Induced Artifacts from EEG Recordings. Control Systems Technology, IEEE Transactions on, 2008. 16(6): p. 1360-1366; Seyedtabaii, S.S.a.L., Kalman filter based adaptive reduction of motion artifact from photoplethysmographic signal. World Academy of Science, Engineering and Technology, 2008. 37). An adaptive filter is easy to implement and it also can be used in real-time applications, though the requirement of additional sensors to provide reference inputs is the major drawback of such methods. There are many motion and noise artifact reduction techniques based on the concept of blind source separation (BSS). The aim of BSS is to estimate a set of uncorrupted signals from a set of mixed signals which is assumed to contain both the clean and noisy sources (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Some of the popular BSS techniques are independent component analysis (ICA) (Comon, P., Independent component analysis, A new concept? Signal Processing, 1994. 36(3): p. 287-

314), canonical correlation analysis (CCA) (Thompson, B., Canonical Correlation Analysis: Uses and Interpretation. 1984: SAGE Publications), principle component analysis (PCA) (Jolliffe, I.T., Principal Component Analysis. 2 ed. Springer Series in Statistics. 2002: Springer-Verlag New York. 488), and singular spectrum analysis (SSA) (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263; Elsner, J.B. and A.A. Tsonis, Singular Spectrum Analysis: A New Tool in Time Series Analysis. 1996: Springer). Kim and Yoo (Kim, B.S. and S.K. Yoo, Motion artifact reduction in photoplethysmography using independent component analysis. IEEE Trans Biomed Eng, 2006. 53(3): p. 566-8) suggested using a basic ICA method and block interleaving to remove MA. Krishnan et al. (Krishnan, R., B. Natarajan, and S. Warren, Two-Stage Approach for Detection and Reduction of Motion Artifacts in Photoplethysmographic Data. Biomedical Engineering, IEEE Transactions on, 2010. 57(8): p. 1867-1876) later proposed using frequency-domain-based ICA. However, the key assumption in ICA, namely statistical independence or uncorrelation, does not hold in PPG signals contaminated by MA (Yao, J. and S. Warren, A short study to assess the potential of independent component analysis for motion artifact separation in wearable pulse oximeter signals. Conf Proc IEEE Eng Med Biol Soc, 2005. 4: p. 3585-8). Salehizadeh et al. (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263) proposed a motion artifact removal method using SSA. In Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263, SSA is used to decompose the corrupted segment adjacent to the clean segment and the SSA components are chosen in the corrupted segment that have a similar frequency range to that of the adjunct clean components. Although Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263 reports good performance, the method cannot be applied in scenarios where the HR and SpO_2 are varying

rapidly due to corruption and movement. Acceleration data are also shown to be helpful to remove MA. For example, Fukushima et al. (Fukushima, H., et al., Estimating heart rate using wrist-type Photoplethysmography and acceleration sensor while running. Conf Proc IEEE Eng Med Biol Soc, 2012. 2012: p. 2901-4) suggested a spectral subtraction technique to remove the spectrum of acceleration data from that of a PPG signal. Acceleration data can be also used to reconstruct the observation model for Kalman filtering (Boreom Lee, J.H., Hyun Jae Baek, Jae Hyuk Shin, Kwang Suk Park and Won Jin Yi, Improved elimination of motion artifacts from a photoplethysmographic signal using a Kalman smoother with simultaneous accelerometry. Physiological Measurement, 2010. 31(12): p. 1585) to remove MA.

[0065] Two noteworthy methods are TROIKA and JOSS (Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1) in which sparsity-based spectrum estimation and spectral peak tracking with verification, are used to estimate and monitor heart rate during intensive physical activity, respectively. Both approaches make use of PPG and accelerometer information to obtain an accurate estimation of heart rate while running on a treadmill. TROIKA has two extra stages of signal decomposition and reconstruction using singular spectrum analysis (SSA) and then applies temporal difference operations on the SSA-reconstructed PPG. SSA components are compared to the accelerometer signals and those components with close frequencies to the accelerometer signals are discarded and the rest are used to reconstruct the signal. In JOSS and TROIKA, spectral peak tracking with verification aims to select the spectral peaks corresponding to HR. JOSS, which has been shown to estimate HR more accurately than TROIKA, is based on the idea that the spectra of PPG signals and simultaneous acceleration signals have some common spectrum structures, and, thus, formulates the spectrum estimation of these signals into a joint sparse signal recovery model using the multiple measurement vector (MMV) model. MMV is used for joint spectrum estimation based on PPG and accelerometer data, which is in contrast to the single measurement vector (SMV) model that was used in TROIKA and was based on only a single PPG signal. Although JOSS

has been shown to be much more accurate than previous methods for reconstruction of heart rate from MA-contaminated PPG signals, the main disadvantage of the method is it can merely provide smoothed HR reconstruction estimations. Neither time-domain PPG signal reconstruction nor heart rate variability analysis can be done using JOSS or TROIKA. Temko proposed an approach to HR estimation based on Wiener Filtering and the Phase Vocoder (WFPV) (Temko, A. Estimation of Heart Rate from Photoplethysmography during Physical Exercise using Wiener Filtering and the Phase Vocoder. in IEEE EMBS International Conference on Engineering in Medicine and Biology. 2015. Milan, Italy: IEEE). This work showed that WFPV on average can perform better than JOSS. The main idea of WFPV is to estimate motion artifacts from accelerometer signals and then use a Weiner filter to attenuate the motion components in the PPG signal. Phase vocoder is also applied to overcome the limited resolution of the Fourier transform and to refine the initial dominant frequency estimation.

[0066] According to embodiments disclosed herein, a motion-corrupted heart-related signal, such as a PPG signal, may be reconstructed by employing a method that is based on a time-varying spectral analysis. A method for reconstructing a heart-related signal based on the time-varying spectral analysis for HR estimation may be referred to interchangeably herein as a spectral approach for filtering motion artifacts (SpaMA) method or SpaMA. A method for reconstructing the heart-related signal based on the time-varying spectral analysis for SpO2 estimation may be referred to interchangeably herein as a spectral approach for filtering motion artifacts for oxygen saturation estimation (OxiMA) method or OxiMA.

[0067] FIG. 1 is a block diagram 100 of an example application for which embodiments disclosed herein may be applied. In FIG. 1, a subject 102 is running on a treadmill 104. The subject 102 is wearing a wrist band 106 that includes a biomedical sensor 108 that produces a heart-related signal 110. The heart-related signal 110 that is produced by the biomedical sensor 108 includes motion artifacts that are signal artifacts produced by movement of the biomedical sensor 108 relative to a sensing location (not shown). The wrist band 106 may be any suitable type of wrist band, for example, the wrist band 106 may be a smart watch.

[0068] The biomedical sensor 108 may be a PPG sensor, or any other suitable biomedical sensor, and the heart-related signal 110 may be a PPG signal, or any other suitable heart-related signal. The sensing location may a skin surface of an area on the subject's wrist where the wrist

band 106 is worn, or any other suitable sensing location at which the biomedical sensor 108 senses the heart-related signal 110. For example, the sensing location may be a skin surface on the subject's forehead, and a head band including the biomedical sensor 108 or maintain the biomedical sensor 108 at the sensing location may be used instead of the wrist band 106.

[0069] Physical activity of the subject 102 may cause movement of the wrist band 106, and, thus, movement of the biomedical sensor 108, resulting in a gap between the PPG sensor and the sensing location. Ambient light may leak into the gap inducing spectrum corruption in the PPG signal. This is because the power of the PPG signal is dependent on a depth and reflection of the PPG light from the PPG sensor to the subject's skin. As such, strenuous and high intensity exercise of the subject 102, such as running or any other suitable activity, may result in movement that rises to a level causing motion artifacts in the heart-related signal 110. According to embodiments disclosed herein, the heart-related signal 110 may be reconstructed 112, producing a reconstructed heart-related signal with the motion artifacts suppressed 114. The reconstructed heart-related signal with the motion artifacts suppressed 114 may be used to accurately estimate HR, SpO2, or any other suitable heart-related estimate. As such, the reconstructed heart-related signal may be employed to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0070] It should be understood that the PPG sensor is one example of a biomedical sensor, the PPG signal is one example of a heart-related signal, and that any suitable type of biomedical sensor may be employed to produce any suitable type of a heart-related signal. Further, movement of the biomedical sensor 108 relative to the sensing location may be caused by any suitable source of the movement that causes movement of the biomedical sensor 108 relative to the sensing location. It should also be understood that a subject referred to herein may be any living being, such as a person or an animal, and may be referred to interchangeably herein as a user.

[0071] FIG. 2 is a flow diagram 200 of an example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor. The example embodiment of the method of FIG. 2 may be applied to either SpaMA or OxiMA and may be applied to other applications that produce a heart-related estimate. The method may start (202) and reconstruct a

representation of the heart-related signal to produce a reconstructed representation of the heart-related signal. The reconstructing may be based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of movement (204). The method may output the reconstructed representation of the heart-related signal (206), and the method thereafter ends (208) in the example embodiment.

[0072] The method may comprise segmenting the heart-related signal into a plurality of windowed heart-related signal data segments and the motion signal into a corresponding plurality of windowed motion signal data segments and repeating the reconstructing and the outputting for each windowed heart-related signal data segment and each corresponding motion signal data segment. The time window may be a value in a range from 2 to 32 seconds. For example, the *window[k]* of raw PPG data of FIG. 3A, element 304, disclosed below, and the *window[k]* of raw accelerometer data shown in FIG. 3A, element 310, disclosed below, may each include data from the respective PPG and accelerometer signals that may be collected over a time window from 2 to 32 seconds. According to one embodiment, the time window may be 8 seconds.

[0073] The method may employ the reconstructed representation to determine a heart rate estimate. The method may employ the reconstructed representation to determine an arterial oxygen saturation (SpO2) estimate. The method may employ the reconstructed representation to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0074] The heart-related signal and the motion signal may be produced, concurrently.

[0075] According to some embodiments, the biomedical sensor may be at least one of: a photoplethysmogram (PPG) sensor, piezoelectric sensor, Light Emitting Diode (LED) based sensor, camera sensor, and pulse oximeter sensor. The motion sensor may be an accelerometer, or any other suitable device that produces a motion signal. If an accelerometer, the accelerometer may be a 3-axial type accelerometer, or any other suitable type of accelerometer. The biomedical sensor and the motion sensor may be co-located. For example, the wrist band 106 of FIG. 1, disclosed above, may be a smartwatch and the biomedical sensor and motion

sensor may be a PPG sensor and an accelerometer, respectively, that are both disposed in the smartwatch or other suitable wearable device.

[0076] FIGS. 3A-C are flow diagrams of example embodiments of a method for reconstructing a heart-related signal output by a biomedical sensor based on embodiments disclosed in Tables 1-3, disclosed below. The method may be either a SpaMA or OxiMA method.

Table 1. Stages 1 and 2

Stage 1. Time-Varying Spectral analysis (*see* FIG. 3A)

1.1. Filter the PPG and Accelerometer signal with cutoff frequency [1, 50]/Fs/2 Hz.
1.2. Down sample the PPG and Accelerometer signal to ¼ of original sampling rate (Fs).
1.3. Compute the time frequency spectrum of both PPG and Accelerometers [0-10 Hz].

Stage 2. Movement Classification (*see* FIG. 3A)

2.1. Check each accelerometer (X, Y or Z) amplitude modulation at each window and compare to a pre-defined motion amplitude threshold. (The threshold varies depending on the type of accelerometer sensor).

Signal is clean if $AM[Acc_{x\ or\ y\ or\ z}(k)] < Motion\_Threshold$ and the signal is corrupted by motion otherwise. If the signal is clean calculate the Heart Rate from peak-to-peak intervals, otherwise go to step 2.2.

2.2. If the signal is corrupted check if the movement is pseudo-periodic (e.g. during walk, jog, run) or non-periodic (e.g. any random movements)

The assumption is when movement is pseudo-periodic the accelerometer data should comprised of a fundamental frequency component and harmonics of the fundamental frequency at its double and third frequency band. This means the ratio of the first harmonic to the fundamental frequency should be almost 2 and the second harmonic to the fundamental should be around 3.

2.2.1. Extract the fundamental frequency component, the 1st and 2nd harmonics from (*e.g.*,VFCDM) time-frequency spectrum of accelerometers. The first three highest peaks in spectral array should represent the fundamental, 1st and 2nd harmonics as long as the movement is pseudo-periodic.
2.2.2. Calculate the ratio of the extracted 1st and 2nd fundamental frequency to the extracted fundamental frequency. If the ratios are close to 2 and 3, this indicates that the movement is most likely pseudo-periodic otherwise it is non-periodic.
2.2.3. If the movement is pseudo-periodic do the Stages 3-5 (*See* Table 2 and FIG. 3B), otherwise go to Stage 6 (*See* Table 3 and FIG. 3C).

Table 2. Stages 3-5

Stage 3. Spectral Filtering (*see* FIG. 3B)

3.1. Assume HR to be in the frequency range of [0.5Hz – 3Hz], this accounts for both low and high heart rates.
3.2. The first highest three peaks and their corresponding frequencies in the PPG filtered spectrum are assumed to have HR information.
3.3. Only the largest frequency peak (that represents the fundamental frequency of movement) of the accelerometers' spectra is used for motion artifact detection in Stage 4.

Stage 4. Motion Artifact Detection (*see* FIG. 3B)

4.1. Compare the frequencies of the three peaks in the PPG spectrum with the frequency of the largest peak in the accelerometers' spectra. If the first or second largest peaks in the PPG spectrum are similar to that of the accelerometers' peaks, then motion artifact is present in the PPG.
4.2. If motion artifact is detected from 3.1, then the corresponding frequency peak (usually the first or second largest peak) in the PPG spectrum should be discarded.

Stage 5. Heart Rate Tracking and Extraction from PPG Spectrum (*see* FIG. 3B)

Case (1): From 3.1- if the spectrum is corrupted by movement and only the first largest peak is corrupted, then the HR frequency should be the frequency of the second peak in the spectrum.
Case (2): From 3.1- if the spectrum is corrupted by movement and both the first and second largest peaks have similar frequencies to those of the accelerometers' peaks, then the HR frequency should be the frequency of the third peak in the spectrum.
Case (3): Due to a gap between the pulse oximeter and a subject's skin, the HR frequency cannot be extracted from the spectrum and in this case the previous HR frequency is used or for offline implementation a cubic spline interpolation can be applied to fill in the missing HR information.

Table 3. Stage 6

Stage 6. Adaptive Bandpass Filtering (non-periodic movements) (*see* FIG. 3C)

When the movement is random and non-periodic it is difficult or not possible to identify HR trace from time-frequency spectrum (for example if stage 5 is not applicable). In this case which may happen more often, a new procedure is adopted that is called adaptive bandpass filtering. The assumption here is that HR does not deviate more than 10 bpm from the average

of previous m HR values within 2 seconds.

6.1. Set averaging window length to m (e.g. m=5) and calculate the average of recent m estimated HR values.

$$HR_{mavg} = \frac{1}{m}\sum_{j=1}^{m} HR(k-j)$$

Where k is the current window. The window length m=5 should only be used for up to 10 seconds of consecutive motion artifact corrupted datapoints. If motion corrupted data last more than 10 seconds, m should be increased to more than 5.

6.2. Take the most recent estimated HR value and calculate bandpass filter cutoff frequency.

$$F_{CutOff} = [HR_{mavg} - 10, HR_{mavg} + 10\,]/60/Fs/2$$

Design a bandpass filter of order 4 with cutoff frequency (F_{CutOff}). Apply the filter on the PPG segment.

6.3. Calculate HR from peak-to-peak intervals of the filtered data segment obtained from 6.2. Take the average of the instantaneous HR as estimated HR value at window k.

[0077] FIG. 3A is a flow diagram (300) of an example embodiment of a method for a time-varying spectral analysis and movement classification, as disclosed in Stage 1 (time-varying spectral analysis) and Stage 2 (movement classification), respectively, in Table 1, for reconstructing the representation. The method may start (302) and the time-varying spectral analysis may be employed on a first windowed segment *window[k]* of raw PPG data (304) and a second windowed segment *window [k]* of raw accelerometer (ACC) data (310). The raw PPG data (304) and the raw ACC data (310) may be extracted from a heart-related signal that is a PPG signal and a motion signal that is an accelerometer signal, respectively.

[0078] As disclosed in Stage 1 of Table 1, the time-varying spectral analysis of FIG. 3A may include pre-processing the heart-related signal (306) to produce a pre-processed heart-related signal. The pre-processing (306) may include filtering the heart-related signal to produce a filtered heart-related signal. The pre-processing (306) may further include down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate, to produce a down-sampled, filtered heart-rate signal. The time-varying spectral analysis may further include pre-processing the motion signal (312) to produce a pre-processed motion signal. The pre-processing (312) may include filtering the motion signal to produce a filtered motion signal. The pre-processing (312) may further include down-sampling the filtered

motion signal, the down-sampling being at a sampling rate less than an original sampling rate, to produce a down-sampled, filtered motion signal.

[0079] As further disclosed in Stage 1 of Table 1, the time-varying spectral analysis of FIG. 3A may include computing a first time-frequency spectrum (TFS) to produce a first TFS (308) of the down-sampled, filtered heart-related signal and computing a second TFS to produce a second TFS (314) of the down-sampled, filtered motion signal. According to some embodiments, filtering and down-sampling of the heart-related signal and motion signal for computing the first TFS (308) and the second TFS (314), respectively, may be optional. The first TFS (308) (also referred to interchangeably herein as the first TFS computed) and the second TFS (314) (also referred to interchangeably herein as the second TFS computed) may be 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

[0080] For example, the first TFS computed may be a first time-varying power spectral density (PSD) and the second TFS computed may be a second time-varying PSD. A time-frequency technique, such as a variable frequency complex demodulation (VFCDM), disclosed in U.S. Patent No. 8,388,543 B2, incorporated herein in its entirety by reference, may be used for computing the first TFS (308), that is, a TFS of the PPG signal, and the second TFS (314), that is, a TFS of the accelerometer signal. However, it should be understood that any suitable time-frequency technique may be used, such as a smoothed pseudo wigner-ville method, or a wavelet based method.

[0081] As disclosed in Stage 2 of Table 1, classifying the classification of the movement (316) in FIG. 3A may include comparing an amount of amplitude modulation in the second TFS (314) computed to an amplitude modulation threshold. The amplitude modulation threshold may be dependent on a type of the motion detector sensor, such as a type of the accelerometer. The classification of the movement may indicate whether the movement rises to a level causing motion artifacts in the heart-related signal, that is, the PPG signal, based on a result of the comparing, as disclosed in Stage 2 of Table 1.

[0082] In an event the movement classification (316) of FIG. 3A indicates that the movement does not rise to a level causing the motion artifacts (322), a peak-peak interval (PP) of the filtered heart-related signal, or alternatively, the filtered, down-sampled heart-rate signal, may be

computed (318) and the reconstructed representation *HR(k)* may be based on an average value of peak-to-peak intervals (320) in the pre-processed heart-related signal, and the method thereafter ends (325) in the example embodiment.

[0083] In an event the movement classification (316) indicates that the movement does rise to the level causing the motion artifacts (323), classifying the classification of the movement may further include determining (324) whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement, as disclosed in Stage 2 of Table 1.

[0084] With reference to Stage 2 of Table 1, in determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS. The first, second, and third peaks may have largest power or amplitude values relative to other peaks in the second TFS at the point in time. The first spectral peak may be a largest spectral peak amongst the first, second, and third spectral peaks.

[0085] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may compute a first ratio of the second frequency identified to the first frequency identified. The method may determine a first comparison result by comparing the first ratio computed to a first ratio value. The method may compute a second ratio of the third frequency identified to the first frequency identified and determine a second comparison result by comparing the second ratio computed to a second ratio value. The classification may further indicate the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result. The first ratio value may be 2 and the second ratio value may be 3. The classification of the movement may be periodic if the first ratio and the second ratio are exactly 2 and 3, respectively, while the classification of the movement may be pseudo-periodic if the first ratio and the second ratio are approximately 2 and 3, respectively, within a pre-determined level of accuracy.

[0086] In an event the classification of the movement is periodic or pseudo-periodic, the method of FIG. 3A may continue with the method of FIG. 3B, disclosed below. In an event the

classification of the movement is random, the method of FIG. 3A continues to the method of FIG. 3C, disclosed below.

[0087] FIG. 3B is a flow diagram (330) of an example embodiment of a method for spectral filtering, motion artifact detection, and heart rate tracking and extraction, as disclosed in Stages 3, 4, and 5, respectively, of Table 2, for reconstructing the representation. The reconstructed representation may be referred to herein as a current reconstructed representation or *HR(k)*. As disclosed above with regard to FIG. 3A, in an event the classification of the movement (316) is periodic or pseudo-periodic, the method of FIG. 3A may continue with the method of FIG. 3B.

[0088] The method of FIG. 3B may start (331) and retain (332) up to a pre-determined number *N* of candidate spectral peaks located at a first point in time in the first TFS, that is, the first TFS from FIG. 3A. It should be understood that the method of FIG. 3B may be performed for each point in time of the first TFS and the second TFS. According to one embodiment, the pre-determined number *N* may be 3. The candidate spectral peaks retained may be based on having corresponding frequencies within a given frequency range. The candidate spectral peaks may be *N* peaks in the given frequency range that have highest amplitude or power values relative to other spectral peaks, that is, the first *N* highest peaks. It should be understood that the other spectral peaks have respective frequencies also within the given frequency range and are peaks located at the first point in time in the first TFS. The given frequency range may be 0.5 Hz to 3 Hz. As such, the *N* first highest peak in the range 0.5 Hz to 3 Hz in the first TFS may be retained at the first time point. Since no peaks in the given frequency range may be present at the first time point, the method may determine (336) whether at least one spectral peak is present.

[0089] Based on the determination (336) that no peak is present, the current reconstructed representation *HR(k)* may be based on a prior reconstructed representation *HR(k-1)* (340), the prior reconstructed representation *HR(k-1)* associated with a previous point in time, such as the previous window *k-1*, in the first TFS computed, and the method thereafter ends (354) in the example embodiment.

[0090] Based on a determination (336) that the at least one spectral peak is present, the method may discard (338) each of the candidate spectral peaks retained, that is, each peak of the *N* first highest peaks determined at (332), if the peak is associated with a same frequency as a

dominant spectral peak located at a second point in time in the second TFS (314) computed as disclosed above with regard to FIG. 3A. The first point in time and the second point time may have same time values. The dominant spectral peak may have a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS. The method may determine (342) whether any peaks are retained after the discarding (338). The discarding (338) may be referred to herein as a first discarding.

[0091] In an event the discarding (338) discards each of the candidate spectral peaks retained, reconstructing the current representation *HR(k)* may be based on the prior reconstructed representation, *HR(k-1)* (340), and the method thereafter ends (354) in the example embodiment.

[0092] In an event the first discarding (338) results in at least one remaining candidate spectral peak retained, reconstructing the current representation may further include second discarding (348). The second discarding (348) may discard remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced (346) by at least a frequency difference threshold, such as 10bpm, from a prior reconstructed representation's frequency, that is, a frequency associated with, for example, *HR(k-1)*.

[0093] Based on each at least one remaining candidate spectral peak retained having been discarded by the second discarding (348), reconstructing the current representation may be based on the prior reconstructed representation *HR(k-1)* (350), and the method thereafter ends (354) in the example embodiment.

[0094] Based on at least one last candidate spectral peak remaining from the second discarding (348), reconstructing the current representation may be based on a selected candidate spectral peak (352). The selected candidate spectral peak may be selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining, and the method thereafter ends (354) in the example embodiment.

[0095] As disclosed above with regard to FIG. 3A, in an event the classification of the movement (316) is random, the method of FIG. 3A may continue with the method of FIG. 3C.

[0096] FIG. 3C is a flow diagram (330) of an example embodiment of a method for adaptive bandpass filtering of non-periodic movements, that is, random movements, for reconstructing the representation, as disclosed in Stage 6 of Table 3. The method of FIG. 3C may start (362) and compute an average value of a number *m* of prior reconstructed representations outputted prior to the reconstructing (362). The number *m* may be based on a duration of consecutive motion artifacts, detected prior to the reconstructing of the representation *HR*(*k*). For example, if motion artifacts were detected for windows *k-1*, *k-2*, and *k-3*, *m* may be understood to be 3.

[0097] The method may compute a bandpass filter cutoff frequency (366). The cutoff frequency F_c may be based on the average value computed HR_{mavg}. The method may filter the pre-processed heart-rate signal (306), disclosed in FIG. 3A, above, by applying the band pass filter computed (368) to produce a filtered, pre-processed heart-related signal. The reconstructed representation *HR(k)* may be based on an average peak-to-peak interval value (372) of the filtered, pre-processed heart-rate signal, and the method thereafter ends (374) in the example embodiment.

[0098] FIG. 4 is a block diagram of an example embodiment of a system (400). The system includes an apparatus 420 for reconstructing a heart-related signal 410c output by a biomedical sensor (not shown). The apparatus 420 includes a reconstruction unit 416 and an output unit 418. The reconstruction unit 416 may be configured to produce a reconstructed representation of the heart-related signal 414c. The reconstructing may be based on (i) a time-varying spectral analysis of the heart-related signal 410c and a motion signal 411c, the motion signal 411c output by a motion sensor (not shown) and representative of motion artifacts in the heart-related signal 410c, the motion artifacts being signal artifacts produced by movement of the biomedical sensor (not shown) relative to a sensing location (not shown), and (ii) a classification of the movement. The output unit 418 may be configured to output the reconstructed representation of heart-related signal 414c.

[0099] The apparatus 420 may be communicatively coupled to a network 401 to receive the heart related signal 410c and the motion signal 411c. The network may be a wireless network or any other suitable network. The reconstructing and the outputting may be performed in near real-time with respect to production of the heart-related signal 410c and the motion signal 411c. Alternatively, the apparatus may be coupled to a database (not shown) storing representations of

the heart related signal 410c and the motion signal 411c, and the reconstructing and the outputting may be performed in non-real-time with respect to production of the heart-related signal 410c and the motion signal 414c.

[00100] The heart-related signal 410c may include raw heart-related signal data that includes the raw heart-related signal data 410a and the raw heart-related signal data 410b produced by biometric sensors (not shown) that sense the heart-related signal data 410a and the raw heart-related signal data 410b from sensing locations (not shown) on a first user 406a and a second user 406b, respectively. The motion signal 411c may include raw motion signal data that includes the raw motion signal data 411a and the raw motion signal data 411b from motion sensors (not shown). The raw motion signal data 411a and the raw motion signal data 411b may represent motion artifacts in the heart-related signal data 410a and the raw heart-related signal data 410b, respectively.

[00101] It should be understood that the raw heart-related signal data 410a-b and the raw motion signal data 411a-b may be sent to the apparatus 420 in any suitable way. For example, the raw heart-related signal data 410a and the raw motion signal data 411a may be sent in a payload of a packet; alternatively the raw heart-related signal data 410a and the raw motion signal data 411a may be sent in payloads of different packets. Similarly, the raw heart-related signal data 410b and the raw motion signal data 411b may be sent in a payload of a packet; alternatively, the raw heart-related signal data 410b and the raw motion signal data 411b may be sent in payloads of different packets.

[00102] The user 406a may be at a gym where the user 406a is exercising, and such physical activity by the user 406a may cause motion artifacts in the raw heart-related signal data 410a. The user 406b may be in a different location, such as a hospital. The user 406b may perform movements out of boredom, such wrist shaking, causing motion artifacts in the raw heart-related signal data 410b. As such, the corresponding motion artifacts may be suppressed in the reconstructed representations 414a and 414b of the heart-related signals 414a and 414b, respectively, according to embodiments disclosed herein. The reconstructed representations 414a and 414b, or information derived therefrom, may sent to biometric devices or other devices communicatively coupled to the network 401 the user 406a and 406 may have access to such device, respectively. Alternatively, the reconstructed representations 414a and 414b, or

information derived therefrom, may sent in any suitable manner to another device communicatively coupled to the network 401 such that the reconstructed representations 414a and 414b, or information derived therefrom, may be accessible to a third party, such as doctor, or any other suitable party.

[00103] FIG. 5 is a block diagram 500 of an example embodiment of an apparatus (520) for reconstructing a heart-related signal 510 output by a biomedical sensor 508. The apparatus 520 includes a reconstruction unit 516 and an output unit 518. The reconstruction unit 516 may be configured to produce a reconstructed representation of the heart-related signal 514. The reconstructing based on (i) a time-varying spectral analysis of the heart-related signal 510 and a motion signal 511, the motion signal 511 output by a motion sensor 509 and representative of motion artifacts in the heart-related signal 510. The motion artifacts may be signal artifacts produced by movement of the biomedical sensor 508 relative to a sensing location (not shown), and (ii) a classification of the movement.

[00104] The output unit 518 may be configured to output the reconstructed representation of the heart-related signal 514. The apparatus 520 may include the biomedical sensor 508 and the motion sensor 509. The reconstructing and the outputting may be performed in real-time with respect to production of the heart-related signal 510 and the motion signal 511.

[00105] The apparatus 520 may be a wearable device, such as a smartwatch, or any other suitable device, such as a wearable personal biometric monitoring device. The apparatus 520 may have a user interface (not shown) to present the reconstructed representation of the heart-related signal 514 or information derived therefrom, such as a characteristic, notification, alarm, or any other suitable information. The reconstructed representation of heart-related signal 514 or the information derived therefrom may be presented to a user via a user interface that may be a visual or audio based user interface.

[00106] According to one embodiment, the apparatus 520 may include a heart rate unit (not shown) configured to employ the reconstructed representation of the heart-related signal 514 to determine a heart rate estimate. According to another embodiment, the apparatus 520 may include an arterial oxygen saturation (SpO2) unit (not shown) configured to employ the reconstructed representation of the heart-related signal 514 to determine a SpO2 estimate. According to yet another embodiment, the apparatus may include an ailment unit (not shown)

configured to employ the reconstructed representation of the heart-related signal 514 to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, an atrial fibrillation condition, a congestive heart failure condition, and a tachycardia condition. It should be understand that any combination of the heart rate unit, SpO2 unit, and ailment unit may be included in the apparatus 520 in combination with any other units disclosed herein.

[00107] SpaMA Results

[00108] According to embodiments disclosed herein, HR reconstruction and PPG signal reconstruction may be based on a time-varying spectral analysis. As disclosed above with reference to FIGS. 3A-F, embodiments disclosed herein may be based on power spectral densities (PSDs) of both PPG and accelerometer signals for each time shift of a corresponding windowed data segment of the respective signal. According to embodiments disclosed herein, by comparing time-varying spectra of the PPG and accelerometer data, those frequency peaks resulting from motion artifacts may be suppressed from the PPG spectrum.

[00109] According to some embodiments, the method may be comprised of six stages, such as the six stages disclosed above in reference to FIGS. 3A-F. According to another embodiment the method may have five distinct stages: (1) time-varying power spectral density (PSD) calculation, (2) spectral filtering, (3) motion artifact detection, (4) HR reconstruction and (5) signal reconstruction. According to embodiments disclosed herein, the method may include computing a window-segmented power spectral density of both PPG and accelerometer signals in real-time to scale each estimate of the PSD by the equivalent noise bandwidth of the window (Stoica, P. and R.L. Moses, Introduction to Spectral Analysis. 1997: Prentice Hall).

[00110] The simplest way to approach the PSD calculation may be to employ a periodogram. However, a periodogram has drawbacks in that it is an inconsistent spectrum estimator, has high variance, and has leakage effects (Stoica, P. and R.L. Moses, Introduction to Spectral Analysis. 1997: Prentice Hall). Thus, a dominant spectral peak can lead to an estimated spectrum that contains power in frequency bands where there should be no power. However, both problems can be solved by down-sampling the raw signal, as disclosed above with reference to FIGS. 3A-F, and then using a sufficiently small frequency step by setting a large number of frequency points. Thus, embodiments disclosed herein may resample the signal from the original sampling

frequency to, for example 1/4 of it, that is, down-sample the signal, and then apply a periodogram method with frequency resolution of 0.001.

[00111] Embodiments disclosed herein may limit the spectrum to the heart rate frequency range of [0.5Hz – 3 Hz], as disclosed above with reference to FIGS. 3A-F, and take the frequency and power information of the first three peaks in the PSD at each window and signal segment. Embodiments disclosed herein may be based on an understanding that the heart rate component in a typical clean (motion free) PPG signal is always the dominant frequency component in the time-varying power spectrum, thus, the highest peak of the spectrum corresponds to the HR frequency. Thus, when movement happens the dominant component can be replaced by movement components which shift the HR to the second or third peak in the spectrum. As such, embodiments disclosed herein may compare the first N peaks, such as 3 peaks, disclosed above, and corresponding frequencies of the PPG spectrum to the first peak and frequency of the accelerometers' spectra at each window and choose the frequency components (out of three) that are different from the accelerometers' frequency.

[00112] Embodiments disclosed herein may be further based on an understanding that there is coherence between a spectral peak in the PPG and the accelerometers' spectra that signifies a motion noise artifact in the PPG signal and that peak should be discarded in the HR reconstruction. After discarding these movement peaks in the spectrum, the next highest peak that is closest to the estimated HR of the previous window may be chosen at each window. By reconstructing the HR frequency at each window, simultaneously, the PPG signal may be reconstructed by using the power, frequency and phase of the signal that corresponds to the HR frequency. That is, the time-domain signals may be reconstructed from the time-frequency domain.

[00113] The SpaMA method was applied to three different datasets and 4 types of activities. The three different datasets included: 1) training datasets from the 2015 IEEE Signal Processing Cup Database recorded from 12 subjects while performing treadmill exercise from 1 km/h to 15 km/h; 2) test datasets from the 2015 IEEE Signal Processing Cup Database recorded from 11 subjects while performing forearm and upper arm exercise; and 3) Chon Lab dataset including 10 min recordings from 10 subjects during treadmill exercise.

[00114] Electrocardiogram (ECG) signals from all three datasets provided the reference HRs which were used to determine the accuracy of the SpaMA method. The performance of the SpaMA method was calculated by computing the mean absolute error between the estimated HR from the PPG and the reference HR from the ECG. The average estimation errors using the SpaMA method on the first, second and third datasets are 0.89, 1.93 and 1.38 beats/min respectively, while the overall error on all 33 subjects is 1.86 beats/min and the performance on only treadmill experiment datasets (22 subjects) is 1.11 beats/min. Moreover, it was found that dynamics of heart rate variability (HRV) can be accurately captured using the SpaMA method where the mean Pearson's correlation coefficient was found to be 0.98 between the power spectral densities of the reference and the reconstructed heart rate time series. These results show that the SpaMA method has a potential for PPG-based HR monitoring in wearable devices for fitness tracking and health monitoring during intense physical activities.

[00115] Embodiments disclosed herein not only provide PPG signal and HR reconstruction but also the potential to do heart rate variability analysis on the results. As disclosed below, embodiments disclosed herein can outperform the JOSS technique in heart rate estimation by providing less error to the reference, which yields higher accuracy.

[00116] Embodiments disclosed herein were evaluated on three different datasets. The first two datasets were provided for the IEEE Signal Processing Cup and are publically available. The three datasets are: 1.) 12 PPG training datasets (running on treadmill) from an IEEE signal processing competition (Available from: http://www.signalprocessingsociety.org/spcup2015/index.html) which was initially used in (Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1, 2.) 11 PPG test datasets (e.g., arm exercise) from the IEEE signal processing competition and 3.) 10 PPG recordings from the Chon lab (running on treadmill).

[00117] (1) IEEE Signal Processing Competition Training Dataset: A single-channel PPG signal, a three-axis acceleration signal, and an ECG signal simultaneously recorded from 12

Asian male subjects ranging in age from 18 to 35. For each subject, the PPG signal was recorded from their wrist using a pulse oximeter (PO) with green LED (wavelength: 609 nm). The acceleration signal was also recorded from each subject's wrist using a three-axis accelerometer. Both the PO and the accelerometer were embedded in a wristband, which was comfortably worn. The ECG signal was recorded from the chest and it is used as the reference heart rate. All signals were sampled at 125 Hz.

[00118] (2) IEEE Signal Processing Competition Test Dataset: The dataset consists of 11 five minute recordings which were collected from 19 to 58 year old subjects performing intensive arm movements (e.g. boxing). For each subject, PPG signals were recorded with a sensing location at the wrist using a pulse oximeter with green LEDs (wavelength: 515nm). The acceleration signal was also recorded from at the sensing location at the wrist using a three-axis accelerometer. Both the PO and the accelerometer were embedded in a wristband. An ECG signal was recorded simultaneously from each subject's chest using wet ECG sensors. All signals were sampled at 125 Hz and sent to a nearby computer via Bluetooth.

[00119] (3) Chon Lab Dataset: This dataset was recorded in the Chon Lab from 10 healthy subjects (9 male/1 female), with ages ranging from 26 to 55. For each subject, the PPG signal was recorded from their forehead using a PO with red and infrared LED (wavelength: 660 and 940 nm). The acceleration signal was also recorded from each subject's forehead using a three-axis accelerometer. Both the pulse oximeter and the accelerometer were embedded in a headband and the signals were sampled at 80 Hz. The ECG signal was recorded as a reference from the chest using ECG sensors, sampled at 400Hz. During data recording, the subjects walked, jogged and ran on a treadmill with speeds of 3, 5 and 7 mph, respectively, for 9 min. At the end, all experimental subjects were asked to perform random arbitrary movements for 1 min.

[00120] For all three datasets, the data was down-sampled to 20 Hz since the estimation of heart rate is carried out in the frequency domain and this sampling rate is sufficiently high to obtain even heart rates that are as high as 240 beats/min or 4 Hz. Moreover, this down-sampling enables a focus on heart rates in the lower frequencies rather than in the physiologically irrelevant higher frequency ranges. Further details of this study's databases are given in Table 4, below. Four types of activities were involved:

- Type (1): activity involved walking or running on a treadmill for intervals of 0.5 min-1 min-1 min-1 min-1 min-0.5 min with speeds of 1-2 km/h, 6-8 km/h, 12-15 km/h, 6-8 km/h, 12-15 km/h, 1-2 km/h, respectively. The subjects were asked to purposely move the hand with the wristband to generate motion artifacts.
- Type (2): activity included various forearm and upper arm exercise which are common arm motions (*e.g.*, shaking hands, stretching, pushing objects, running, jumping, and push-ups).
- Type (3): activity consisted of intensive forearm and upper arm movements (*e.g.*, boxing).
- Type (4): activity involved 1 min rest, 1 min walking (3 mph), 1 min rest, 2 min jogging (5 mph), 1 min rest, 2 min running (7 mph), 1 min rest, 1 min arbitrary movement. The ECG-based reference HR was recorded in order to assess the performance of the methods under test.

[00121] In summary, the first dataset includes only Type (1) activities, the second dataset includes both Type (1) and (2) activities, and the third dataset includes only Type (4) activities.

Table 4. PPG Datasets and Experiments Settings

<table>
<tr><th>Subject</th><th>Dataset</th><th>Activity Type</th><th>Pulse Oximeter Type</th><th>Subject's Age/Sex</th></tr>
<tr><td>1</td><td rowspan="12">1 (IEEE Cup)</td><td rowspan="12">Type (1)</td><td rowspan="12">Wrist: green LED (wavelength: 609nm)</td><td rowspan="12">18-38 y (All Male)</td></tr>
<tr><td>2</td></tr>
<tr><td>3</td></tr>
<tr><td>4</td></tr>
<tr><td>5</td></tr>
<tr><td>6</td></tr>
<tr><td>7</td></tr>
<tr><td>8</td></tr>
<tr><td>9</td></tr>
<tr><td>10</td></tr>
<tr><td>11</td></tr>
<tr><td>12</td></tr>
<tr><td>13</td><td rowspan="5">2 (IEEE Cup)</td><td rowspan="3">Type (2)</td><td rowspan="5">Wrist: green LED (wavelength: 515nm)</td><td rowspan="5">19-58 y (9 Male, 1 Female)</td></tr>
<tr><td>14</td></tr>
<tr><td>15</td></tr>
<tr><td>16</td><td rowspan="2">Type (3)</td></tr>
<tr><td>17</td></tr>
</table>

18				
19				
20		Type (2)		
21		Type (3)		
22				
23		Type (2)		
24	3 (Chon Lab)	Type (4)	Forehead: Red and Infrared LED (wavelength: 660 nm, 940nm)	26-55 y (9 Male, 1 Female)
25				
26				
27				
28				
29				
30				
31				
32				
33				

[00122] An example embodiment for reconstructing a heart-related signal during intensive movements is disclose by the HR monitoring method presented below in Table 5. Details of each stage are described in subsections *i* to *v*.

Table 5. HR and PPG signal reconstruction method

Stage 1. Time-Varying Spectral analysis

1.1. Down sample the PPG and Accelerometer signal to 20 Hz.
1.2. Compute the power spectral density of both PPG and Accelerometers [0-10 Hz].

Stage 2. Spectral Filtering

2.1. Assume HR to be in the frequency range of [0.5Hz – 3Hz], this accounts for both low and high heart rates.
2.2. The first highest three peaks and their corresponding frequencies in the PPG filtered spectrum are assumed to have HR information.
2.3. Only the largest frequency peak of the accelerometers' spectra is used for MA detection in stage 3.

Stage 3. Motion Artifact Detection

3.1. Compare the frequencies of the three peaks in the PPG spectrum with the frequency of the largest peak in the accelerometers' spectra. If the first or second largest peaks in the PPG spectrum are similar to that of the accelerometers' peaks, then motion artifact is present in the

PPG.
3.2. If motion artifact is detected from 3.1, then the corresponding frequency peak (usually the first or second largest peak) in the PPG spectrum should be discarded.

Stage 4. Heart Rate Tracking and Extraction from PPG Spectrum

Case (1): From 3.1- if the spectrum is corrupted by movement and only the first largest peak is corrupted, then the HR frequency should be the frequency of the second peak in the spectrum.
Case (2): From 3.1- if the spectrum is corrupted by movement and both the first and second largest peaks have similar frequencies to those of the accelerometers' peaks, then the HR frequency should be the frequency of the third peak in the spectrum.
Case (3): Due to a gap between the pulse oximeter and a subject's skin, the HR frequency cannot be extracted from the spectrum and in this case the previous HR frequency is used or for offline implementation a cubic spline interpolation can be applied to fill in the missing HR information.

Stage 5. PPG Signal Reconstruction

5.1. The PPG signal is reconstructed by using the amplitude, frequency and phase information corresponding to the HR components (extracted in stage 4) that are calculated from the spectrum at each window.

❖ Heart Rate Variability Analysis

By using a sample-by-sample windowing strategy, HR can be extracted, from which dynamics of heart rate variability analysis can be obtained on the motion artifact-removed reconstructed HR time series.

[00123] i. Time-Varying Spectral Analysis of PPG and Accelerometer Data

[00124] Embodiments disclosed herein may produce a time-varying spectrum by taking a T-sec window of the signal and computing the power spectral density (PSD) of the segment and then sliding the window through the whole dataset which yields a time-frequency matrix in which each array represents the power of the signal corresponding to a specific frequency and sliding time-step (shift) of S-sec. The sliding process and frequency step specify the resolution and dimension of the time-frequency matrix. According to embodiments disclosed herein, two different sliding window approaches may be used, depending on the application. For estimating either heart rates or heart rate variability, data may be shifted sample-by-sample with no overlap for the entire dataset. Such an approach enables capturing beat-to-beat dynamics of HRV which

requires sample-to-sample estimation of PSD. Since some data is down-sampled data to 20 Hz in some of the database, as disclosed above, each data point may be shifted by 0.05 seconds. For estimating only the heart rates, the shift may be a data segment-by-segment shift rather than a sample-by-sample shift. This coarse-grain windowing approach has less computational cost and it can provide good tracking of heart rates, but does not apply well to HRV.

[00125] As such, according to some embodiments, a window segment length T may be set to 8 seconds and shifted by 2 seconds. The 8 second data segment and a shift of 2 seconds was chosen to compare results according to embodiments disclosed herein to other methods (TROIKA, JOSS and WFPV) which have used this chosen data segment length and time shift (Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1). Moreover, the assumption of 8 second data length largely stems from the fact that heart rates do not change instantaneously, hence, an 8 second duration is a reasonable choice.

[00126] As a representative example, the resultant frequency components in the time-frequency matrix of recordings from subject #8 from the competition training dataset, for a window length of 8 seconds that is shifted by every 2 seconds, is shown in FIG. 6A, disclosed below.

[00127] FIGS. 6A-6C show Time-Frequency spectra of recording #8 from dataset (1).

[00128] FIG. 6A shows the PPG signal.

[00129] FIG. 6B shows the simultaneous Accelerometer-Z signal.

[00130] FIG. 6C (Top-Left) shows the TF spectrum of the PPG signal. FIG. 6C (Top-Right) shows the TF spectrum of ACC(x). FIG. 6C (Bottom-Left) shows the TF spectrum of ACC(y),. FIG. 6C (Bottom-Right) shows the TF spectrum of ACC(z); all computed from stage (1) of Table 5. The blue circles and letters represent movement elements in all four spectra.

[00131] The panels of FIG. 6A and FIG. 6B show a PPG time series and the z-axis accelerometer data, respectively. From the upper left panel of FIG. 6C, which represents the time-frequency plot of the PPG signal, it is observed that there are three dominant frequency

components - one of them represents HR and the other two are similar to those of the accelerometers' spectra shown in the upper right and lower left and right panels of FIG. 6C. FIG. 6C illustrates 4 motion artifact elements (A, B, C, D) that are present in exactly the same areas among all spectra. By comparing the time-frequency (TF) spectrum of PPG to those of the accelerometers' spectra, the marked dynamics (A, B, C and D) in the PPG spectrum can be detected as sharing the same frequency dynamics as those of the accelerometer spectra marked in circles. Hence, both the top and bottom marked lines in the PPG spectrum most likely represent the motion artifacts, and the unmarked frequency represents the HR. The next section details how these motion artifact frequency dynamics may be detected and filtered according to embodiments disclosed herein.

[00132] ii. Spectral Filtering

[00133] After obtaining the power spectral density at each window, as disclosed above, embodiments disclosed herein may confine the HR frequency to the range [0.5 Hz – 3 Hz], which takes into account both at rest and high HR due to either tachycardia or exercise scenarios. Hence, for HR estimation, the strategy is to eliminate frequencies that are outside of this HR frequency range as they are most likely due to motion artifacts or harmonics of the HR frequency.

[00134] In general, HR frequency in the power spectral density of PPG at each window can have three different scenarios: (1) PPG is devoid of MA and there is no spatial gap between the sensor and the subject's skin during recording, (2) PPG is corrupted by MA and there is no spatial gap between the sensor and the subject's skin during recording and (3) There is a spatial gap between the sensor and the subject's skin during recording. For the ideal case (1), HR can be extracted and it is most likely represented as the highest peak in the PPG spectrum. For case (2), MA dynamics can result in predominately either one or two dominant peaks depending on the severity of repetitive motions, and the HR peak may be relegated to either the second or third highest peak. Non-repetitive motion artifacts will show up as a broadband spectrum without a dominant peak if they are not severe (Marmarelis, V.Z., et al., Nonlinear analysis of renal autoregulation under broadband forcing conditions. Ann Biomed Eng, 1993. 21(6): p. 591-603). The only scenario that makes it difficult to extract HR from the spectrum is scenario (3) when there is a spatial gap between the PPG sensor and the subject's skin during recording. In this

scenario, assuming that the motion artifacts are short lasting, the missing HR values can be interpolated using a cubic spline approach.

[00135] FIG. 7 is an example embodiment of spectral filtering. FIG. 7 shows a representative filtered time-frequency spectral plot of a PPG signal. As disclosed above, embodiments disclosed herein may retain only the three largest frequency peaks at each time point within the defined HR range (30-180 bpm) and such retained frequency peaks are represented as blue, green and red colors, respectively. Retaining only the three largest frequency peaks at each time point may be reasonable for the first two cases, as outlined above. In the PPG time-frequency spectrum of FIG. 7, the Blue, Green and Red circles correspond to the first three highest peaks in the defined HR frequency range of (30-180 bpm), respectively, at each sliding window.

[00136] iii. Motion Artifact Detection

[00137] FIGS. 8A-8B show motion artifact detection in the PPG spectrum according to embodiments disclosed herein.

[00138] FIG. 8A shows a filtered PPG spectrum with movement and HR components. FIG. 8A is an example embodiment of a PPG spectrum which is identical to FIG. 7, but it also identifies the frequencies associated with accelerometers, as marked by the shaded areas and the letters A-D, in the top left and two bottom panels of FIG. 6C, disclosed above. The shaded yellow elements (A, B, C, D) of FIG. 8A represent motion frequency components in the PPG spectrum, and the light blue line is the reference HR from a clean reference ECG signal. By removing the accelerometers' related frequencies in FIG. 8A, the remaining frequency dynamics which should represent HR frequency and its harmonics are shown in FIG 8B.

[00139] FIG. 8B shows a filtered PPG spectrum after removing motion artifact frequency components.

[00140] iv. Heart Rate Tracking & Extraction

[00141] A flow diagram for heart rate tracking and extraction is disclosed above, with reference to FIG. 3B. Embodiments disclosed herein may identify HR frequencies with time, such as HR frequencies from FIG. 8B. Note that in FIG. 8B, there are three peaks at each time instance (also referred to interchangeably herein as a time point). Embodiments disclosed herein may identify which of the three peaks represents the HR at each time point. For the initial time window of 8 seconds, a clean data segment may be used so that true HR can be determined. This

scenario is case (1), disclosed above, in the spectral filtering section, and the detection of HR is simply the highest peak in the spectrum. Embodiments disclosed herein may estimate HR for each sliding window of data. Embodiments disclosed herein may choose a HR peak in the PPG spectrum with the knowledge of estimated HR values in previous time windows. Two main scenarios may present: (1) no peak exists in the spectrum that can represent HR, and (2) there is a spectral peak among the first three highest peaks of spectrum that belongs to the HR component.

[00142] In case (1), where HR is not detectable in the window (*e.g.*, due to spatial gap between the PO sensor and skin), in real-time implementation embodiments disclosed herein may take a previous window's HR value as the current HR (or simply use a moving average of several past HR beats or some other variant). In post-processing, or offline processing, a cubic spline interpolation may be used to fill in the missing HR information. In the more general case (2), where the HR peak is among the first three highest peaks in the spectrum, three possible scenarios can occur: (2-A) the windowed PPG signal is clean and the first highest peak in the spectrum represents the HR fundamental frequency, (2-B) the windowed PPG signal is corrupted by movement and at most two of the spectral peaks represent the accelerometers' frequency components, thus, the second or the third peak corresponds to HR, (2-C) while the HR spectral peak is detectable, the difference between its value and that of the previous HR is more than 10 bpm, as such, embodiments disclosed herein may replace the HR by the most recent HR value from a previous window segment (or a moving average of several past HR beats or some other variant).

[00143] According to embodiments disclosed herein, criterion may be set that the HR value cannot change more than 10 BPM from a previous time window. In FIG. 8B, these cases are illustrated. For example, in most cases, the blue circle which represents the largest spectral peak is chosen but in other cases, either green or red circles are chosen for certain time points. For the HR peaks associated with either the green or red circles, embodiments disclosed herein may choose those peaks because either the first two highest peaks are related to accelerometers or the highest magnitude peak deviates more than 10 BPM from the previous HR value.

[00144] FIG. 9 shows a comparison of reconstructed HR obtained, according to embodiments disclosed herein, to reference HR obtained from simultaneous ECG recordings. In FIG. 9, the

extracted HR (red color) from PPG spectra of recording#8 from the competition training dataset, according to embodiments disclosed herein, is shown in red color and the reference ECG-derived HR is shown in black color. In order to calculate the performance of HR reconstruction according to embodiments disclosed herein, the error value in each time window was calculated from the estimated HR to the reference ECG-derived HR. Two measurement indices of absolute error similar to the indices in (Krishnan, R., B. Natarajan, and S. Warren, Two-Stage Approach for Detection and Reduction of Motion Artifacts in Photoplethysmographic Data. Biomedical Engineering, IEEE Transactions on, 2010. 57(8): p. 1867-1876) were used.

$$Error(1) = \frac{1}{W}\sum_{k=1}^{w}\left|HR_{SpaMA}(k) - HR_{ref}(k)\right| \quad (1)$$

$$Error(2) = \frac{1}{W}\sum_{k=1}^{w}\frac{\left|HR_{SpaMA}(k) - HR_{ref}(k)\right|}{HR_{ref}(k)} \times 100\% \quad (2)$$

where W is the total number of windows.

[00145] v. PPG Signal Reconstruction for HRV analysis

[00146] For an HRV analysis application, the above-disclosed embodiments are identical except that the beat-by-beat shift is of data rather than the 8 second data segment shift or its variant. According to embodiments disclosed herein, the PPG signal may be reconstructed using heart rate frequency, amplitude and phase changes, window-by-window using the sample-by-sample windowing process:

$$Rec_{Signal}(k) = A_{HR}(k) \times \sin\left(2\pi t(k) f_{HR}(k) + \varphi_{HR}(k)\right) \quad (3)$$

where $k = 1, \ldots, N$ and N is number of signal samples and total number of windows. $A_{HR}(k)$ and $\varphi_{HR}(k)$ are calculated according to the power of the signal for HR frequencies in the PSD and phase angles of complex elements in a Fast Fourier Transform (FFT) matrix that correspond to HR frequencies.

[00147] FIG. 10A is an example embodiment of PPG signal reconstruction according to embodiments disclosed herein. FIG. 10A shows a comparison between reconstructed PPG and original recording #8 from IEEE competition training dataset. The left and right panels of FIGS. 10A-B show the reconstructed PPG versus the original PPG and their HRV time series, respectively.

[00148] FIG. 10B is a zoomed-in version of FIG. 10A.

[00149] Given that embodiments disclosed herein estimate quite accurate heart rates, it is not surprising to observe similar frequency dynamics between the reference and reconstructed HRV time series, as shown in FIGS. 11A-B.

[00150] FIGS. 11A-B show comparisons of HRV spectra between the reference and the reconstructed HRV time series (*e.g.*, as shown in FIGS. 10A-B) from the MA-contaminated PPG signal for dataset #8. Note that for computing HRV, matching the amplitude of the reference HR is not a concern, as the focus is only in the dynamics of the fluctuations in the heart rates.

[00151] FIG. 11A shows a time-domain comparison of a reconstructed HR and a reference HR.

[00152] FIG. 11B shows a spectral comparison of heart rate variability between reconstructed HR and reference HR calculated from the reference ECG using Pan & Tompkins peak detection approach (Pan J, T.W., A real-time QRS detection algorithm. IEEE Trans Biomed Eng, 1985. 32(3): p. 230-236).

[00153] Results

[00154] Table 6 represents the average absolute error (E1) and the average absolute error percentage (E2) of embodiments disclosed herein as applied to all 3 datasets, respectively. Embodiments disclosed herein are compared to three methods: TROIKA, JOSS and WFPV. The results in Table 6 show that better performance from embodiments disclosed herein as comparted to JOSS and TROIKA for all 12 subjects in the first datasets. In comparison to WFPV, embodiments disclosed herein outperform WFPV on average across all 23 subjects in both datasets (1) and (2). The total average of E1 for embodiments disclosed herein is less than 2 beats per minutes for all 33 subjects. The average of E1 across the treadmill experiment recordings (activity Type 1- IEEE dataset and Type 4- Chon Lab dataset) is around 1 beat per minute for all 22 subjects.

Table 6. SpaMA Method Performance Comparison

Subject	Dataset	Activity Type	TROIKA		JOSS		WFPV		SpaMA	
			E1	E2%	E1	E2%	E1	E2%	E1	E2%
1	1 (IEEE Cup)	Type (1)	2.87	2.18	1.33	1.19	1.23	-	**1.23**	**1.14**
2			2.75	2.37	1.75	1.66	1.26	-	1.59	1.30
3			1.91	1.50	1.47	1.27	0.72	-	**0.57**	**0.45**
4			2.25	2.00	1.48	1.41	0.98	-	**0.44**	**0.31**
5			1.69	1.22	0.69	0.51	0.75	-	**0.47**	**0.31**
6			3.16	2.51	1.32	1.09	0.91	-	**0.61**	**0.45**
7			1.72	1.27	0.71	0.54	0.67	-	**0.54**	**0.40**
8			1.83	1.47	0.56	0.47	0.91	-	**0.40**	**0.33**
9			1.58	1.28	0.49	0.41	0.54	-	**0.40**	**0.32**
10			4.00	2.49	3.81	2.43	2.61	-	2.63	1.59
11			1.96	1.29	0.78	0.51	0.94	-	**0.64**	**0.42**
12			3.33	2.30	1.04	0.81	0.98	-	1.20	0.86
mean±std			2.42±0.8	1.82±0.5	1.28±0.9	1.02±0.6	1.04±0.5	-	**0.89±0. 6**	**0.65±0.4**
13	2 (IEEE Cup)	Type (2)					3.58	-	**3.41**	**4.25**
14							9.66	-	**7.29**	**9.80**
15							2.31	-	2.73	2.21
16		Type (3)					4.93	-	**3.18**	**2.11**
17							3.07	-	**3.01**	**2.52**
18							2.67	-	4.46	3.23
19							3.11	-	3.58	3.98
20		Type (2)					2.10	-	**1.94**	**1.66**
21		Type (3)					3.22	-	**2.56**	**2.02**
22							4.35	-	**3.12**	**3.28**
23		Type (2)					0.75	-	1.72	1.97
mean±std							3.61±2.2	-	**3.36±1.5**	**3.33±2.2**
Type (1,2) mean±std							2.27±2.0	-	**1.93±2.0**	**2.07±1.7**
24	3 (Chon Lab)	Type (4)							**0.88**	**0.91**
25									**1.03**	**0.83**
26									**1.10**	**0.90**
27									**1.64**	**1.54**
28									**1.41**	**1.12**
29									**0.82**	**0.70**
30									**0.63**	**0.58**
31									**4.78**	**3.87**
32									**0.95**	**0.79**
33									**0.62**	**0.52**
mean±std									**1.38±1.2**	**1.17±1.0**

Total: mean±std		**1.86±1.6**	**1.70±1.8**

[00155] FIGS. 12A, 12B, 13A, 13B, 14A, and 14B show the reconstructed HR and corresponding PSD of a sample-sample windowed HR, according to embodiments disclosed herein, in comparison to a reference HR from an ECG. The results for recording #9 from the first dataset (IEEE Competition Training dataset) and activity Type 1 (*e.g.*, running on treadmill) are shown in FIGS. 13A-B. As shown, E1 for this particular subject is as low as 0.4 bpm and the correlation between the PSD of reconstructed HR and reference HR is as high as 96%.

[00156] FIG. 12A shows a reconstructed HR vs. reference HR. FIG. 12B shows a spectral comparison of reconstructed HR and reference HR (estimated from reference ECG).

[00157] FIG. 13A illustrates the comparison between the reconstructed HR and the reference HR for Subject #14 (IEEE Competition Test Dataset) which has the highest errors. Subject #14 belongs to the second dataset (IEEE Competition Test dataset) and Type 2 activities (e.g. jumping). It can be seen that the largest error is obtained when both the physiological HR and the motion artifacts change rapidly so that the true HR cannot be reliably estimated.

[00158] FIG. 13B shows a reconstructed HR vs. reference HR for Subject 16 (IEEE Competition Test Dataset). FIG. 13B shows the comparison results of reconstructed HR and reference HR for recording #16 of the second dataset (IEEE Competition Test dataset) which has the Type 3 activities (*e.g.*, arm exercise).

[00159] FIG. 14A shows a reconstructed HR vs. reference HR for Subject #30 (Chon Lab Dataset). FIG. 14B shows a spectral comparison of reconstructed HR and reference HR (estimated from reference ECG). The results for recording #30 from the third datasets (Chon Lab datasets) and activity Type 4 (*e.g.*, running on treadmill) are shown in FIGS. 14A-B. It can be seen that the E1 for this subject is around 0.6 bpm and the correlation between the PSD of reconstructed HR and reference HR is as high as 99% for LF and 0.96 for HF frequency range. All subjects' results are provided in Table 7, disclosed below.

[00160] Table 7 represents the correlation and statistical difference using the student's t-test between PSD of estimated and reference HRV in both LF (0.04-0.15 Hz) and HF (0.15-0.4 Hz) frequency ranges. The correlation values in the table are calculated based on Pearson's linear

correlation coefficient. As shown in Table 7, there was no difference between the reference and the derived HRV for LF, according to embodiments disclosed herein, and a difference was seen in only 4 out of 10 subjects for HF.

Table 7. Frequency Domain HRV analysis Comparison: PSD of SpaMA Method vs. reference

Subjects	**Correlation**	
	LF (LF is [0.04-0.15] Hz and HF is [0.15-0.4] Hz)	**HF**
1	0.99	0.98
2	0.99	0.96
3	0.99	0.95* (*) indicates significantly different (P-value>0.05)
4	1.00	0.99
5	1.00	0.99
6	0.99	0.96*
7	0.98	0.92*
8	0.97	0.90*
9	1.00	0.99
10	1.00	0.99
mean	0.99	0.96

[00161] Table 8 shows some of the widely-reported time-domain HRV parameters such as the mean HR, standard-deviation (SDNN) of the normal-to-normal (NN) interval, root-mean-square of successive difference (RMSSD) of the NN interval, and the number of interval differences of successive NN intervals greater than 50 ms divided by the total number of NN intervals (pNN50) estimated from embodiments disclosed herein in comparison to the reference ECG NN interval. None of these parameters were found to be significantly different between those derived according to embodiments disclosed herein and the reference HRV.

Table 8. Time Domain HRV analysis Comparison: SpaMA Method vs. reference HRV

Subjects	**SDNN**		**meanNN**		**RMSSD**		**pNN50**	
	SpaMA	Reference	SpaMA	Reference	SpaMA	Reference	SpaMA	Reference
1	2620.75	2566.47	10481.89	10480.72	33.24	18.05	0.001	0.020
2	2115.44	2079.58	9908.00	10020.00	25.93	16.32	0.011	0.019
3	3173.73	3177.68	10764.20	10829.06	89.70	56.15	0.019	0.207
4	2517.78	2533.20	10376.95	10426.26	13.54	19.58	0.001	0.030
5	2654.42	2670.32	10846.04	10990.08	11.88	18.59	0.003	0.018
6	2012.53	1974.65	9737.35	9827.63	39.64	21.17	0.004	0.025
7	3056.36	2925.19	12519.74	13134.05	27.66	30.61	0.015	0.071
8	3133.76	2756.66	10504.00	10530.00	32.57	36.38	0.002	0.003

9	2195.08	2142.53	10499.81	10470.06	8.23	13.01	0.002	0.004
10	2454.57	2406.96	12936.62	12981.21	41.52	20.28	0.006	0.024
p-value	> 0.05		> 0.05		> 0.05		> 0.05	

[00162] As such, the SpaMA method, according to embodiments disclosed herein, that may be based on time-varying spectral analysis of the PPG signal addresses Heart Rate monitoring in the real world with challenges ranging from a subject who makes sudden movements but is otherwise sedate, to intensive physical activities. Embodiments disclosed herein compare spectral changes in PPG and accelerometer signals. As disclosed above, three different datasets have been used to verify the SpaMA performance. Each dataset reflects different types of activities and movements. In all of the experiments, the reference HR was calculated from an ECG signal that was collected simultaneously with the PPG signal. The estimated HR was calculated from the spectrum of PPG in 8 second time windows. Based on the results, disclosed above, the SpaMA method may be used for tracking HR changes during severe motion artifacts with an average error of just 1.86 bpm compared to that of the reference ECG; these results are superior to three other methods tested: TROIKA, JOSS and WFPV (Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1).

[00163] Out of 33 recordings, 23 are from a wrist pulse oximeter, and the rest of the data were recorded by a forehead pulse oximeter. The results from Table 8, disclosed above, show that the SpaMA method can be applied to monitor HR from both wrist and forehead pulse oximeters. By comparing the performance of the method for treadmill experiments (dataset 1 and dataset 3), the error is lower by almost 1 beat using a wrist pulse oximeter. However, it should be noted that from this result a conclusion that the wrist PPG provides less error than the forehead should not be drawn, as the experiments used different subjects and were two separate studies. The prior methods (TROIKA, JOSS and WFPV) were tested using only on the wrist-based PPG signals as the implementers of those methods did not have access to forehead PPG sensors. The SpaMA

method, according to embodiment disclosed herein, was tested on data from both PPG sensor locations, and proved to be effective regardless of the location of the PPG sensor.

[00164] Several observations were made while analyzing the data, disclosed above. The tracking ability of the SpaMA method decreased as the frequency changes during recordings increased. This phenomenon mostly was observed while dealing with the second set of datasets from the IEEE competition, which involved Type (2) and Type (3) activities. These types of exercises involved more abrupt movements which consequently made it more difficult to track the HR-related frequencies in the spectrum. In the three datasets that have been analyzed, recordings #10 and 14 are examples of this phenomenon.

[00165] A strength of the PPG's LED is one of the most important factors determining the SpaMA method performance. Movement induces much less spectrum corruption (shift) in the PPG if the LED is sufficiently strong. A reduction in the strength of the PPG signal can also be caused by ambient light leaking into the gap between a PPG sensor and the skin surface (Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1). This is because the power of the signal is dependent on the depth and reflection of the light from the pulse oximeter to the subject's skin. This gap between skin and the planar substrate where the LEDs and PD are mounted may be the result of movement during physical activities or the shape of tissue that the sensors touch. Among the three datasets, low performance for recordings #16 and 31 is the result of a weak PPG signal most likely due to a gap between the sensor and skin caused by motion artifacts.

[00166] By using the sample-by-sample windowing process, SpaMA, according to embodiments disclosed herein, can be utilized for both Heart Rate monitoring and HRV analysis in both frequency- and time-domains. From the results, disclosed above, it can be observed that embodiments disclosed here are able to replicate both the low frequency (0.04-0.15Hz) and the high frequency (0.15-0.4) dynamics well, albeit better the former than the latter, when compared to a reference HRV. For time-domain HRV measures, the mean HR, SDNN, RMSSD, and pNN50 based on embodiments disclosed herein were all found to be not significantly different than the reference HRV. It has long been shown that during dynamic exercise, heart rate increases due to both a parasympathetic withdrawal and an augmented sympathetic activity

(Iellamo, F., Neural mechanisms of cardiovascular regulation during exercise. Auton Neurosci, 2001. 90(1-2): p. 66-75; Bernardi, L. and M.F. Piepoli, [Autonomic nervous system adaptation during physical exercise]. Ital Heart J Suppl, 2001. 2(8): p. 831-9). The relative role of the two drives depends on the exercise intensity (Perini, R., et al., The influence of exercise intensity on the power spectrum of heart rate variability. Eur J Appl Physiol Occup Physiol, 1990. 61(1-2): p. 143-8; Sarmiento, S., et al., Heart rate variability during high-intensity exercise. Journal of Systems Science and Complexity, 2013. 26(1): p. 104-116; Roure, R., et al., Autonomic nervous system responses correlate with mental rehearsal in volleyball training. Eur J Appl Physiol Occup Physiol, 1998. 78(2): p. 99-108). Analysis of HRV permits insight into this control mechanism (Aubert, A.E., B. Seps, and F. Beckers, Heart rate variability in athletes. Sports Med, 2003. 33(12): p. 889-919). Also, being able to do HRV analysis from PPG even during movement and physical activities would be an advantage for detecting and diagnosing many cardiovascular diseases using only PPG recordings.

[00167] The SpaMA method, according to embodiments disclosed herein, can be potentially implemented in real time. The method written in Matlab®, version R2014 and CPU 3.4 GHz takes only 110 msec per 8 second segments. Therefore, given the high accuracy of the method in estimating HR despite severe motion artifacts, the SpaMA method, according to embodiments disclosed herein, has the potential to be applicable for implementation on wearable devices such as smart watches and PPG-based fitness sensors.

[00168] As disclosed above, accurate estimation of changing arterial oxygen saturation (SpO2) from photoplethysmogram (PPG) signals during movement is a very challenging problem. This is because strenuous and high intensity movements can result in severe motion artifacts (MA), making accurate SpO2 estimation from PPG signals difficult. As such, embodiment disclosed herein may applied the methods for reconstructing a PPG signal, as disclosed above, and include an additional stage of SpO2 estimation.

[00169] According to one embodiment, OxiMA may be comprised of the 6 stages disclosed above, with reference to FIGS. 3A-F, and include Stage 7, that is SpO2 Estimation.

[00170] According to another embodiment, OxiMA may be comprised of 6 stages: (1) Time-frequency Spectral Analysis, (2) Signal Decomposition, (3) Spectral Filtering, (4) Heart Rate (HR) extraction and tracking, (5) Signal Reconstruction, (6) SpO2 Estimation.

[00171] OxiMA

[00172] According to some embodiments, OxiMA may decompose the PPG signal into its frequency components by using a complex demodulation-based technique and may choose the components with frequencies close to the HR frequency for reconstructing the clean PPG signal. Next, SpO2 may be estimated from the reconstructed PPG signal. Such a method is applied to 22 minute datasets recorded from 10 subjects. A Nellcor OxiMax transmission sensor was used to collect analog PPG signals, while reference SpO2 and HR were collected simultaneously from the FDA approved Masimo SET Radical RDS-1 pulse oximeter. The performance of the OxiMA method according to embodiments disclosed herein, was determined by computing the mean absolute error between the estimated HR/SpO2 from the PPG and reference HR [Masimo]/SpO2[Masimo] oximeter. The results show the average estimation error using OxiMA are only 2.4 beats/minute for HR and 1.8% for SpO2, respectively. As such, the OxiMA method has great potential for MA reduction for both SpO2 and HR monitoring.

[00173] Vital signs and clinical symptoms have been shown to be poor predictors of hypoxia, and in order to rationalize oxygen therapy, measurement of arterial oxygen saturation by pulse oximetry is being increasingly recommended (Laman, M., et al., Can clinical signs predict hypoxaemia in Papua New Guinean children with moderate and severe pneumonia? Ann Trop Paediatr, 2005. 25(1): p. 23-7) Arterial oxygen saturation (SpO2) reflects the relative amount of oxyhemoglobin in the arterial blood. The most common method to measure SpO2 is based on pulse oximetry, whereby oxidized hemoglobin and reduced hemoglobin have significantly different optical spectra.

[00174] Specifically, at a red wavelength of about 660 nm, there is a significant difference in light absorbance between reduced (Hb) and oxidized hemoglobin (HbO2). A measurement of the percent oxygen saturation of blood is defined as the ratio of oxyhemoglobin to the total concentration of hemoglobin present in the blood. Pulse oximetry assumes that the fluctuations of the PPG signal are caused by changes in arterial blood volume associated with each heartbeat, where the magnitude of the fluctuations depends on the amount of arterial blood rushing into the peripheral vascular bed, the optical absorption of the blood, skin and tissue, and the wavelengths used to illuminate the blood. The photoplethysmogram (PPG) can be used to derive not only the SpO2 and heart rate (HR) data, but also other vital physiological information (Laman, M., et al.,

Can clinical signs predict hypoxaemia in Papua New Guinean children with moderate and severe pneumonia? Ann Trop Paediatr, 2005. 25(1): p. 23-7; Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263; Tamisier, R., et al., A new model of chronic intermittent hypoxia in humans: effect on ventilation, sleep, and blood pressure. J Appl Physiol (1985), 2009. 107(1): p. 17-24; Jubran, A., Pulse oximetry. Crit Care, 1999. 3(2): p. R11-r17). As disclosed above, utilizing a pulse oximeter as a multi-purpose vital sign monitor has clinical appeal, since it is familiar to clinicians and comfortable for the patient (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263).

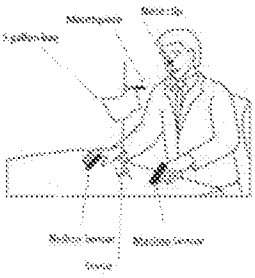
[00175] In healthy persons, SpO2 is typically near 98%. A lower reading indicates a level of hypoxia. SpO2 readings below 95% are usually a cause for concern, indicating the need for supplemental oxygen therapy. In certain individuals, such as those with chronic respiratory or cardiac diseases, SpO2 readings below 95% may be considered normal. However, in general, SpO2 readings between 90%-95% represent mild hypoxia, while 85%-90% indicates serious hypoxia, and readings below 85% are considered critical hypoxia (Tamisier, R., et al., A new model of chronic intermittent hypoxia in humans: effect on ventilation, sleep, and blood pressure. J Appl Physiol (1985), 2009. 107(1): p. 17-24).

[00176] As disclosed below, the OxiMA method according to embodiments disclosed herein, provides HR reconstruction with accurate SpO2 estimation even during movement. The most recent methods as noted above (e.g., TROIKA and JOSS) do not show their ability to obtain SpO2 estimates as they were mainly designed for HR calculations in the presence of intense motion artifacts.

[00177] The OxiMA method was evaluated on a lab controlled dataset that was recorded during voluntary induced hypoxia. In an IRB approved study which recruited 10 subjects, one set of data was collected from each subject for a duration of 22 min. Reference arterial SpO2 and HR were collected from the FDA approved Masimo SET Radical RDS-1 pulse oximeter

(mounted on the left hand), while a Nellcor OxiMax sensor (mounted on the right hand) was used to collect analog PPG signals, simultaneously (Table 9).

TABLE 9
PPG DATASETS AND EXPERIMENTS SETTINGS

Scenario	Sensor Type	Age/Sex Ethnicity
Oxygen Saturation Variations 	[Actual PPG] Finger Pulse Oximeter Nellcor [Ref SpO_2] Finger Pulse Oximeter [Ref HR] SilverRest ECG Electrode	23-58 yr (10 Males) 3 Asian 2 Hispanic 3 American 2 White

[00178] Each subject sat in a chair and was asked to re-breathe into a 1-gallon bag four times for approximately two minutes each time. During the first and third time the subject rebreathed into the bag, subjects were asked to remain still. During the second and fourth time the subject rebreathed into the bag, subjects were asked to introduce motion artifacts into the measurement by shaking their right hand. Each subject wore a disposable nose clip to prevent accidental breathing of room air. The Masimo reference sensor placed in the left hand remained motionless for the entire duration of the study. Subjects had at least two minutes of rest between successive breathing maneuvers, with more time if requested. The protocol for this experiment is presented in Table 10. Worcester Polytechnic Institute IRB approved the study protocol and informed consent was required by all subjects prior to data recording.

[00179] This sequence of data recording allowed us to test the efficacy of the OxiMA method while a subject experienced different levels of short lasting hypoxia during motion artifacts. For reference, other clinical studies showed that SpO2 levels in patients suffering from mild to moderate sleep apnea can drop to about 80% for short periods of time until the patient is awakened without irreversible physiological effects (Maeda, Y., M. Sekine, and T. Tamura,

Relationship between measurement site and motion artifacts in wearable reflected photoplethysmography. J Med Syst, 2011. 35(5): p. 969-76).

[00180] Methodology

[00181] The protocol for testing performance of the OxiMA method is presented in Table 10.

TABLE 10
EXPERIMENT PROTOCOL

End Time (min)	Event
2	Rest (baseline)
4	Bag breathing (motion)
5	Rest (oxygen recovery)
7	Rest
9	Bag breathing (motion)
10	Rest (oxygen recovery)
12	Rest
14	Bag breathing (no motion)
15	Rest (oxygen recovery)
17	Rest
19	Bag breathing (motion)
20	Rest (oxygen recovery)
22	Rest

[00182] Details of each stage of the OxiMA method as applied in the experiment are disclosed below.

[00183] Time-Varying Spectral Analysis of PPG and Accelerometer Data

[00184] To compute the time-frequency spectrum, a variable frequency complex demodulation technique was employed. Table 11, disclosed below, presents the OxiMA method, according to one embodiment.

[00185] The time-varying spectrum is estimated by taking a T-sec window of the PPG signal and computing the VFCDM time-frequency of the segment and then sliding the window through the whole dataset. There is no overlapping between the sliding time windows. The window segment length T was set to 8 seconds and was shifted by 8 seconds. The assumption of 8 second data length largely stems from the fact that SpO2 and heart rates do not change instantaneously; hence, an 8 second duration is a reasonable choice.

TABLE 11
OXIMA METHOD: HR AND SPO2 RECONSTRUCTION

Stage 1. VFCDM Time-Frequency Spectrum
1.1. Downsample the PPG signal to ¼ of the original sampling frequency.
1.2. Compute the VFCDM based time-frequency spectrum (TFS)

Stage 2. Signal Decomposition
2.1. Decompose the PPG signal into its frequency components according to frequency bands in the TFS

Stage 3. Spectral Filtering
3.1. Assume HR to be in the frequency range of [0.5Hz – 3Hz], to account for both low and high HR values.
3.2. The first highest two peaks and their corresponding frequencies in the PPG filtered spectrum are assumed to have HR information.

Stage 4. Heart Rate Tracking and Extraction from PPG Spectrum
Case (1): From 3.1- if the spectrum is corrupted by movement and only the first largest peak is corrupted, then the HR frequency should be the frequency of the second peak in the spectrum.
Case (2): Due to the sensor-skin interface interruption, which could be a result of gap between the pulse oximeter and a subject's skin or slight sensor alignment variations relative to skin, the HR frequency cannot be extracted from the spectrum and in this case the previous HR frequency is used or for offline implementation a cubic spline interpolation can be applied to fill in the missing HR information.

Stage 5. PPG Signal Reconstruction
5.1. The PPG signal is reconstructed by using the summation of VFCDM components with frequency close to the HR frequency at each window.

Stage 6. Oxygen Saturation Estimation
6.1. Calculate the SpO2 estimations from reconstructed infrared and red PPG signals using the following empirical calibration equation [2]

$$SpO_2(\%) = (110 - 25R)$$

where,

$$R = \frac{AC_{Red}/DC_{Red}}{AC_{IR}/DC_{IR}}$$

[00186] FIGS. 15A-B show the resultant VFCDM time-frequency spectrum of recordings from subject #5, as a representative example.

[00187] The panels in FIGS. 15A-B show infrared PPG time series data. FIG. 15B represents the time-frequency plot of the infrared PPG signal. The next section details how the PPG data is decomposed into its frequency components using VFCDM.

[00188] Signal Decomposition

[00189] The original PPG signal was decomposed into sinusoidal modulations using a VFCDM method, as disclosed in Table 12 below.

$$x(t) = \sum_{i=1}^{N} Component\{i\} = \sum_{i=1}^{N} dc_i(t)A_i(t)cos\big(2\pi f_i(t) + \phi_i(t)\big) \quad (4)$$

[00190] By assuming N=12 fixed frequency bands each with a distinct central frequency, the PPG and accelerometer signals may be decomposed using the VFCDM method of Table 12 which yields 12 components.

TABLE 12
VFCDM METHOD

Consider a sinusoidal signal $x(t)$ to be a narrow band oscillation with a time-varying center frequency $f(\tau)$, instantaneous amplitude $A(t)$, phase $\phi(t)$, and the direct current component $dc(t)$:

$$\boldsymbol{x(t) = dc(t) + A(t)\cos\left(\int_0^t 2\pi f(\tau)d\tau + \phi(t)\right)}$$

Step (1) For a given center frequency, we can extract the instantaneous amplitude information $A(t)$ and phase information $\phi(t)$ by multiplying (1) by $e^{-j\int_0^t 2\pi f(\tau)d\tau}$ which results in the following:

$$z(t) = x(t)e^{-j\int_0^t 2\pi f(\tau)d\tau} = dc(t)e^{-j\int_0^t 2\pi f(\tau)d\tau} + \frac{A(t)}{2}e^{j\phi(t)} + \frac{A(t)}{2}e^{-j\left(\int_0^t 4\pi f(\tau)d\tau + \phi(t)\right)}$$

Step (2) From (2), if $z(t)$ is filtered with an ideal low-pass filter (LPF) with a cutoff frequency $f_c < f_0$, where f_0 is the center frequency of interest. Then the filtered signal $z_{lp}(t)$ will contain only the component of interest $z_{lp}(t) = \frac{A(t)}{2}e^{j\phi(t)}$.

Step (3) By changing the center frequency followed by using the variable frequency approach as well as the LPF, the signal, $x(t)$, will be decomposed into the sinusoid modulations, d_i, by the CDM technique as follows:

$$\boldsymbol{x(t) = \sum_i d_i = dc(t) + \sum_i A_i(t)\cos\left(\int_0^t 2\pi f_i(\tau)d\tau + \phi_i(t)\right)}$$

Step (4) The instantaneous frequency and amplitude of d_i can be calculated using the Hilbert transform

$$A(t) = 2|z_{lp}(t)| = [X^2(t) + Y^2(t)]^{1/2}$$
$$X(t) = real(z_{lp}(t))$$
$$Y(t) = imag\left(z_{lp}(t)\right) = H[X(t)] = \frac{1}{\pi}\int \frac{X(t')}{t - t'}dt'$$
$$\phi(t) = \arctan\left(\frac{imag\left(z_{lp}(t)\right)}{real\left(z_{lp}(t)\right)}\right) = \arctan\left(\frac{Y(t)}{X(t)}\right) \qquad f(t) = f_0 + \frac{1}{2\pi}\frac{d\phi(t)}{dt}$$

[00191] FIG. 16 shows the twelve components corresponding to the IR and Red signal for subject #5. Among the twelve frequency bands, bands 1 to 5 correspond to frequency range of [0.5 Hz to 3 Hz], which is typically the HR frequency range accounting for both normal and elevated heart rates. Embodiments disclosed herein select a component of these 5 components to reconstruct the signal that preserves the HR and is less corrupted by the motion artifacts. For the selection, an accurate HR may be estimated by selecting the components that match closest to the actual HR frequency in order to reconstruct a less noisy PPG signal than the original motion corrupted data.

[00192] Spectral Filtering

[00193] After obtaining the power spectral density at each window, HR frequency may be assumed to be confined in the range [0.5 Hz – 3 Hz], which takes into account both at rest and high HR values due to either tachycardia or exercise scenarios. Next, for HR estimation, the strategy is to keep only frequencies that correspond to the first and second peak at each column of time-frequency matrix, as disclosed above, with reference to FIG. 3B.

[00194] In general, HR frequency in the VFCDM based power spectral density of the PPG at each window can have three different scenarios: (1) PPG is devoid of MA and there is no sensor-skin interface problems like a spatial gap between the sensor and the subject's skin during recording, (2) PPG is corrupted by MA and there is no spatial gap between the sensor and the subject's skin during recording and (3) There is a spatial gap between the sensor and the subject's skin during recording. For the ideal case (1), HR can be extracted and it is most likely represented as the highest peak in the PPG spectrum. For case (2), MA dynamics can result in the dominant peak and HR frequency peak's magnitude become smaller than the MA frequency peak in the spectrum. The only scenario that makes it difficult to extract HR from the spectrum is scenario (3) when there is a spatial gap between the PPG sensor and the subject's skin during recording. In this scenario, assuming that the motion artifacts are short lasting, the missing HR values can be interpolated using the cubic spline approach.

[00195] FIGS. 17A-C are plots of the above three scenarios. In FIG. 17A and FIG. 17B, the true HR frequency is close to the first and second peak respectively, while in FIG. 17C, the true HR frequency is far from the dominant peaks in the spectrum. As long as the PPG data is clean, an assumption may be made that the HR frequency belongs to the frequency component with the

highest power (peak) at the each column of the TFS matrix. On the other hand, when the data becomes corrupted by MA, it might shift the HR frequency to the next highest peak in the spectrum or might lose the dominant HR frequency.

[00196] Embodiments disclosed herein employ a TFS filtering step to search for N first highest spectral peaks and their associated frequencies in each column of the TFS. Hence, the original TFS of FIG. 15B can be filtered to select only N, for example, 2, in the example embodiments, highest spectral peaks.

[00197] FIG. 18A shows a representative filtered time-frequency spectral plot of PPG recording from subject #5. This portion of the OxiMA method involves retaining only the two largest frequency peaks at each time point within the defined HR range (30-180 bpm) and they are represented as blue and green traces, respectively.

[00198] Heart Rate Tracking and Extraction

[00199] After filtering the TFS, the HR may be extracted. The HR tracking method may be summarized as: Assume there is only knowledge of the initial HR, the HR at each window is extracted by comparing the peaks to the previous HR value.

[00200] As disclosed above with reference to FIG. 3B, if the largest peak is within the 10 bpm range from the previous value of HR, it is chosen; if not, the second largest peak is checked for compliance of this scenario. If the HR value deviates by more than 10 bpm, the HR from the previous window may be adopted by the method.

[00201] FIG. 18B illustrates the tracking of HR based on OxiMA method, disclosed above.

[00202] FIGS. 19A and 19B represent comparisons, of the estimated 8 second moving averaged HR from the OxiMA method, to the reference HR, and the HR calculated from the motion-corrupted PPG signal, compared to the reference HR from the ECG, respectively. In order to calculate the performance of the OxiMA method for HR reconstruction, the error value in each time window was calculated from the estimated HR to the reference ECG-derived HR. Two measurement indices of absolute and normalized errors similar to the indices in (Wang, H., et al., A high resolution approach to estimating time-frequency spectra and their amplitudes. Ann Biomed Eng, 2006. 34(2): p. 326-3) were used.

$$Error(1) = \frac{1}{W}\sum_{k=1}^{W}\left|HR_{OxiMA}(k) - HR_{ref}(k)\right| \quad (5)$$

$$Error(2) = \frac{1}{W}\sum_{k=1}^{w}\frac{\left|HR_{OxiMA}(k) - HR_{ref}(k)\right|}{HR_{OxiMA}(k)} \times 100\% \quad (6)$$

where, W is the total number of windows.

[00203] PPG signal reconstruction

[00204] Now that HR values at each time window are estimated from the time-frequency spectrum, the signal reconstruction phase of the OxiMA method may be performed. An assumption may be made that the signal components corresponding to the HR frequency are more robust against motion and, thus, a less corrupted signal can be reconstructed using the summation of these components.

[00205] By calculating the components from the Signal Decomposition, using Eq (4) and the time-frequency spectrum of the PPG, at each 8-sec window a signal component may be chosen that has a frequency close to estimated HR frequency and that component may be employed to reconstruct infrared and red PPG data at each window. This yields a less motion-corrupted data that can be used for oxygen saturation estimation, as disclosed in FIG. 20A and FIG. 20B.

[00206] Oxygen Saturation Estimation

[00207] In order to calculate SpO2 from PPG signals, red and infrared PPG signals with clearly separable DC and AC components are required. Let the pulsatile components of the red and infrared PPG signals be denoted as AC_{Red} and AC_{IR}, respectively, then the "ratio-of-ratio" R is estimated (Thakor, N.V. and Y.S. Zhu, Applications of adaptive filtering to ECG analysis: noise cancellation and arrhythmia detection. IEEE Trans Biomed Eng, 1991. 38(8): p. 785-94; Diniz, P., Adaptive filtering: algorithms and practical implementation. 2008: . Springer Science, Business Media L.L.C) as

$$\boldsymbol{R = \frac{AC_{Red}/DC_{Red}}{AC_{IR}/DC_{IR}}} \quad (7)$$

[00208] Accordingly, SpO2 may be computed by substituting the R value in an empirical linear approximated relation given by $SpO_2(\%) = (110 - 25R)$.

[00209] FIG. 20C represents the reconstructed SpO2 values obtained from OxiMA in comparison to the reference SpO2 values and the estimated values before reconstruction.

[00210] OxiMA Results

[00211] Table 13 represents the average absolute error (E1) and the average absolute error percentage (E2) of HR and SpO2 estimations of the OxiMA method on the varying hypoxia level dataset.

TABLE 13
OXIMA METHOD PERFORMANCE COMPARISON (HR ESTIMATIONS)

Subject	Actual HR estimation error		OxiMA HR estimation error	
	E1	E2%	E1	E2%
1	3.84	4.83	**1.53**	**2.10**
2	6.84	9.57	**2.72**	**3.97**
3	8.15	9.59	**1.69**	**2.29**
4	4.55	5.39	**2.61**	**3.18**
5	10.53	11.96	**4.04**	**4.60**
6	4.46	5.52	**2.04**	**2.66**
7	12.41	19.65	**2.81**	**4.37**
8	3.84	4.35	**2.10**	**2.46**
9	3.80	4.13	**2.57**	**2.83**
10	3.65	4.20	**1.85**	**2.41**
mean±std	6.20±3.2	7.91±5.0	2.40±0.73	3.09±0.90

[00212] The OxiMA method is compared to the HR and SpO2 estimations prior to the reconstruction method, where both pre- and post-reconstruction estimations are compared to the reference HR and reference SpO2 values obtained from the Masimo pulse oximeter.

[00213] The results presented in Table 13 show that OxiMA on average improves the HR and SpO2 estimations by 100% and 105%, respectively when compared to those estimations without the reconstruction method. Improvement rates are calculated as follow:

$$\boldsymbol{ImRate1}(\%) = \frac{\mathbf{1}}{\boldsymbol{W}}\sum_{\boldsymbol{k=1}}^{\boldsymbol{W}}\frac{|\boldsymbol{Error1_{OxiMA}(k)} - \boldsymbol{Error1_{Act}(k)}|}{\boldsymbol{Error1_{OxiMA}(k)}} \times \mathbf{100}\% \qquad (\mathbf{8})$$

$$ImRate2(\%) = \frac{1}{W}\sum_{k=1}^{w}\frac{|Error2_{OxiMA}(k) - Error2_{Act}(k)|}{Error2_{OxiMA}(k)} \times 100\% \quad (9)$$

[00214] FIGS. 21A-C and FIGS. 22A-B show the reconstructed SpO2 and HR in comparison to the reference HR from ECG recordings for subject #5. The largest error among all recordings was found to be from this recording, as shown in Tables 13 and 14. The larger error could be due to rapid movements or skin-sensor gap during the recordings.

TABLE 14
OXIMA METHOD PERFORMANCE COMPARISON (SpO_2 ESTIMATIONS)

Subject	Actual SpO_2 estimation error		OxiMA SpO_2 estimation error	
	E1	E2%	E1	E2%
1	2.51	2.63	**0.86**	**0.90**
2	7.14	9.63	**2.45**	**3.10**
3	6.21	6.59	**1.61**	**1.67**
4	1.89	2.46	**0.95**	**1.16**
5	7.13	7.80	**3.25**	**3.47**
6	2.85	2.99	**1.10**	**1.14**
7	5.83	9.09	**2.57**	**4.52**
8	3.51	4.63	**1.73**	**2.22**
9	1.81	2.10	**1.50**	**1.61**
10	4.85	5.91	**1.93**	**2.07**
mean±std	4.37±2.1	5.38±2.8	1.79±0.8	2.19±1.2

[00215] As such, the E1 (HR) for this particular subject is as low as 4.05 bpm while the E1 (SpO2) is as low as 3.25%. It can be seen from Table 15, disclosed below, that HR and SpO2 both improved by 160% and 119%, respectively, post reconstruction method.

TABLE 15
OXIMA METHOD PERFORMANCE COMPARISON (SpO_2 ESTIMATIONS)

Subject	HR Improvement Rate		SpO_2 Improvement Rate	
	ImRate1%	ImRate2%	ImRate1%	ImRate2%
1	150.90	130.00	191.86	192.22
2	151.47	141.05	191.43	210.64
3	323.08	318.78	285.71	294.61
4	74.33	69.50	98.95	112.07
5	160.17	160.66	119.38	124.78
6	118.63	107.52	159.09	162.28
7	377.22	372.54	126.85	101.10
8	82.86	76.83	102.89	108.55
9	47.86	45.94	20.67	30.43
10	97.30	74.27	151.30	185.5
mean±std	158.38±108.2	149.71±109.9	144.81±70.5	152.2±73.2

V. Conclusions

[00216] As such, the OxiMA method that may be based on time-varying spectral analysis of the PPG signal combats motion artifacts that can degrade the accuracy of SpO2 and HR estimations. According to embodiments disclosed herein, the OxiMA method may decompose the PPG signal into many frequency bands using a VFCDM method (Chon, K.H., S. Dash, and J. Kihwan, Estimation of Respiratory Rate From Photoplethysmogram Data Using Time–Frequency Spectral Estimation. Biomedical Engineering, IEEE Transactions on, 2009. 56(8): p. 2054-2063), or any other suitable time-frequency technique, such as a wavelet analysis (Chon, K.H., S. Dash, and J. Kihwan, Estimation of Respiratory Rate From Photoplethysmogram Data Using Time–Frequency Spectral Estimation. Biomedical Engineering, IEEE Transactions on, 2009. 56(8): p. 2054-2063). According to embodiments disclosed herein, those components that are within the heart rate ranges including both extreme ranges of the low and high heart rates may be decomposed and used to reconstruct the PPG signal based on those components. As such, frequencies that are not within the prescribed HR ranges may be removed. From this reconstructed time series HR may be estimated and SpO2 may be estimated, as disclosed above.

[00217] The dataset used to verify the OxiMA method's performance was collected from 10 subjects during hypoxic experiments. The results show accurate estimation of both HR and SpO2 even during the presence of severe motion artifacts where the average error was only 2.4 bpm. More importantly, the average improvements in these estimates are astoundingly high for both HR (149%) and SpO2 (152%) when the reconstruction method applied, according to

embodiments disclosed herein. Other methods for estimates of HR during severe motion artifacts for PPG signal Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1; Salehizadeh, S., et al., A Novel Time-Varying Spectral Filtering Algorithm for Reconstruction of Motion Artifact Corrupted Heart Rate Signals During Intense Physical Activities Using a Wearable Photoplethysmogram Sensor. Sensors, 2015. 16(1): p. 10) produced good results (Kalman, R.E., A New Approach to Linear Filtering and Prediction Problems Transactions of the ASME – Journal of Basic Engineering, 1960. Series D (82)). However, these methods are only confined to HR estimation and not SpO2. Specifically, previous PPG reconstruction methods, such as (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263; Kim, B.S. and S.K. Yoo, Motion artifact reduction in photoplethysmography using independent component analysis. IEEE Trans Biomed Eng, 2006. 53(3): p. 566-8), have been tested under MA conditions but not with concomitant hypoxia. The results, disclosed abele, illustrate the efficacy of a method which provides accurate estimates of both SpO2 and HR even when there are significant MA and concomitant low oxygen saturation values.

[00218] Observations were made while analyzing the OxiMA data. The tracking ability of the OxiMA method decreased as the frequency changes during recordings increased. This is mostly likely because OxiMA tracks a dominant frequency through an 8-second window. Since each subjects' motion varied throughout each hypoxic maneuver, the dominant frequency can change within the observed window. The strength of the PPG's LED is one of the most important factors determining the performance. A reduction in the strength of the PPG signal can be caused by ambient light leaking into the gap between a PPG sensor and the skin surface (Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1). This is because the power of the signal is dependent on the depth and reflection of the light from

the pulse oximeter sensor to the subject's skin. This gap between the skin and the sensor may be the result of movement during physical activities or the shape of tissue that the sensors touch. In the datasets that have been analyzed, recordings #5 and #7 are examples of the above two scenarios.

[00219] Additionally, the local blood perfusion of the monitored region affects the signal-to-noise ratio of the PPG signal. When performing the hypoxic maneuvers, subjects' HR and breathing rate normally increase as oxygen saturation decreases. These physiologic changes cause more distinct pulsations in the digits, which increase the signal-to-noise ratio.

[00220] The OxiMA method can be easily implemented in real-time. Execution time of the method has been found to be only 180 msec on data divided into 8 second segments using Matlab® R2014a and CPU 3.6GHz. Therefore, given the high accuracy of the OxiMA method in estimating HR and SpO2 despite severe motion artifacts, this method has the potential to be applicable for implementation on wearable devices such as smart watches and PPG-based fitness sensors.

[00221] FIG. 23 is a block diagram of an example of the internal structure of a computer 2300 in which various embodiments of the present disclosure may be implemented. The computer 2300 contains a system bus 2302, where a bus is a set of hardware lines used for data transfer among the components of a computer or processing system. The system bus 2302 is essentially a shared conduit that connects different elements of a computer system (*e.g.*, processor, disk storage, memory, input/output ports, network ports, *etc.*) that enables the transfer of information between the elements. Coupled to the system bus 2302 is an I/O device interface 2404 for connecting various input and output devices (*e.g.*, keyboard, mouse, displays, printers, speakers, *etc.*) to the computer 2300. A network interface 2306 allows the computer 2300 to connect to various other devices attached to a network. Memory 2308 provides volatile storage for computer software instructions 2310 and data 2312 that may be used to implement embodiments of the present disclosure. Disk storage 2314 provides non-volatile storage for computer software instructions 2310 and data 2312 that may be used to implement embodiments of the present disclosure. A central processor unit 2318 is also coupled to the system bus 2302 and provides for the execution of computer instructions.

[00222] Further example embodiments disclosed herein may be configured using a computer program product; for example, controls may be programmed in software for implementing example embodiments. Further example embodiments may include a non-transitory computer-readable medium containing instructions that may be executed by a processor, and, when loaded and executed, cause the processor to complete methods described herein. It should be understood that elements of the block and flow diagrams, such as the reconstruction unit 416, output unit 418, reconstruction unit 516, output unit 518, heart rate unit, arterial oxygen saturation (SpO2) unit, and ailment unit, disclosed above, may be implemented in software, hardware, such as via one or more arrangements of circuitry of FIG. 23, disclosed above, or equivalents thereof, firmware, a combination thereof, or other similar implementation determined in the future. In addition, the elements of the block and flow diagrams described herein may be combined or divided in any manner in software, hardware, or firmware. If implemented in software, the software may be written in any language that can support the example embodiments disclosed herein. The software may be stored in any form of computer readable medium, such as random access memory (RAM), read only memory (ROM), compact disk read-only memory (CD-ROM), and so forth. In operation, a general purpose or application-specific processor or processing core loads and executes software in a manner well understood in the art. It should be understood further that the block and flow diagrams may include more or fewer elements, be arranged or oriented differently, or be represented differently. It should be understood that implementation may dictate the block, flow, and/or network diagrams and the number of block and flow diagrams illustrating the execution of embodiments disclosed herein.

[00223] The teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety.

[00224] While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A method for reconstructing a heart-related signal output by a biomedical sensor, the method comprising:

reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of the movement; and

outputting the reconstructed representation of the heart-related signal.

2. The method of Claim 1, wherein the motion artifacts are suppressed in the reconstructed representation of the heart-related signal.

3. The method of Claim 1, wherein:

the time-varying spectral analysis includes pre-processing the heart-related signal to produce a pre-processed heart-related signal; and

in an event the classification indicates that the movement does not rise to a level causing the motion artifacts, the reconstructed representation is based on an average value of peak-to-peak intervals in the pre-processed heart-related signal.

4. The method of Claim 3, wherein the pre-processing includes filtering the heart-related signal to produce a filtered heart-related signal.

5. The method of Claim 4, wherein the pre-processing further includes down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

6. The method of Claim 1, wherein the time-varying spectral analysis includes:

computing a first time-frequency spectrum (TFS) of the heart-related signal; and

computing a second TFS of the motion signal.

7. The method of Claim 6, wherein the first TFS computed and the second TFS computed are 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

8. The method of Claim 6, wherein the first TFS computed is a first time-varying power spectral density (PSD) and the second TFS computed is a second time-varying PSD.

9. The method of Claim 6, wherein the reconstructed representation is a current reconstructed representation and wherein, based on the classification indicating that the movement does rise to a level causing the motion artifacts and is a pseudo-periodic movement or a periodic movement, the reconstructing includes:

determining whether at least one spectral peak is present having a corresponding frequency within a given frequency range at a point in time in the first TFS computed, the current reconstructed representation being reconstructed for the point in time; and

wherein, based on a determination that the at least one spectral peak is not present, the current reconstructed representation is based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed.

10. The method of Claim 9, wherein the given frequency range is 0.5 Hz to 3 Hz.

11. The method of Claim 6, wherein the reconstructing includes:

retaining up to a pre-determined number of candidate spectral peaks located at a first point in time in the first TFS computed, the candidate spectral peaks retained based on having corresponding frequencies within a given frequency range and highest amplitude or power values relative to other spectral peaks located at the first point in time, the other spectral peaks having respective frequencies within the given frequency range; and

discarding each of the candidate spectral peaks retained that is associated with a same frequency as a dominant spectral peak located at a second point in time in the second TFS computed, the first point in time and the second point in time having same time values.

12. The method of Claim 11, wherein the given frequency range is 0.5 Hz to 3 Hz.

13. The method of Claim 11, wherein the representation is a current representation, wherein the reconstructed representation is a current reconstructed representation, and wherein, in an event the discarding discards each of the candidate spectral peaks retained, reconstructing the current representation is based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

14. The method of Claim 11, wherein the discarding is a first discarding and wherein the representation is a current representation and, wherein, in an event the first discarding results in at least one remaining candidate spectral peak retained, reconstructing the current representation further includes:

second discarding, wherein the second discarding discards remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced by at least a frequency difference threshold from a prior reconstructed representation's frequency, the prior reconstructed representation

associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

15. The method of Claim 14, wherein:

based on each of the at least one remaining candidate spectral peak retained having been discarded by the second discarding, reconstructing the current representation is based on the prior reconstructed representation; and

based on at least one last candidate spectral peak remaining, the at least one last candidate spectral peak remaining not discarded by the second discarding, reconstructing the current representation is based on a selected candidate spectral peak selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining.

16. The method of Claim 11, wherein the dominant spectral peak has a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS.

17. The method of Claim 11, wherein the retaining and the discarding are based on:

the classification indicating that the movement is a pseudo-periodic movement or a periodic movement; and

determining that at least one spectral peak with a corresponding frequency in the given frequency range is present at the first point in time.

18. The method of Claim 6, wherein the time-varying spectral analysis further includes pre-processing the heart-related signal and the motion signal for the computing of the first TFS and the second TFS.

19. The method of Claim 6, wherein the pre-processing includes filtering the heart-related signal and the motion signal to produce a filtered heart-related signal and a filtered motion signal, respectively.

20. The method of Claim 19, wherein the pre-processing further includes down-sampling both the filtered heart-related signal and the filtered motion signal, the down-sampling being at a sampling rate less than an original sampling rate.

21. The method of Claim 6, further including:

classifying the classification of the movement by comparing an amount of amplitude modulation in the second TFS computed to an amplitude modulation threshold, wherein the classification indicates whether the movement rises to a level of causing the motion artifacts based on a result of the comparing.

22. The method of Claim 21, wherein the amplitude modulation threshold is dependent on a type of the motion detector sensor.

23. The method of Claim 21, wherein, in an event the result indicates that the movement does rise to the level causing the motion artifacts, classifying the classification of the movement further includes determining whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement.

24. The method of Claim 23, wherein, in determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement includes, the method further includes:

identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS, the first, second, and third peaks having largest power or amplitude values relative

to other peaks in the second TFS at the point in time, the first spectral peak being a largest spectral peak amongst the first, second, and third spectral peaks;

computing a first ratio of the second frequency identified to the first frequency identified and determining a first comparison result by comparing the first ratio computed to a first ratio value; and

computing a second ratio of the third frequency identified to the first frequency identified and determining a second comparison result by comparing the second ratio computed to a second ratio value, wherein the classification further indicates that the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result.

25. The method of Claim 24, wherein the first ratio value is 2 and the second ratio value is 3.

26. The method of Claim 1, wherein the time-varying signal analysis includes pre-processing the heart-related signal to produce a pre-processed heart-related signal and, in an event the classification of the movement indicates random movement, the reconstructing includes:

computing an average value of a number of prior reconstructed representations outputted prior to the reconstructing, the number based on a duration of consecutive motion artifacts, detected prior to the reconstructing;

computing a bandpass filter cutoff frequency based on the average value computed;

filtering the pre-processed heart-related signal by applying the band pass filter computed to produce a filtered, pre-processed heart-related signal; and

wherein the reconstructed representation is based on an average peak-to-peak interval value of the filtered, pre-processed heart-related signal.

27. The method of Claim 1, wherein the heart-related signal and the motion signal are produced, concurrently.

28. The method of Claim 1, further comprising:

segmenting the heart-related signal into a plurality of windowed heart-related signal data segments and the motion signal into a corresponding plurality of windowed motion signal data segments; and

repeating the reconstructing and the outputting for each windowed heart-related signal data segment and each corresponding motion signal data segment.

29. The method of Claim 28, wherein the time window is a value in a range from 2 to 32 seconds.

30. The method of Claim 1, wherein the biomedical sensor is at least one of: a photoplethysmogram (PPG) sensor, piezoelectric sensor, Light Emitting Diode (LED) based sensor, camera sensor, and pulse oximeter sensor, and wherein the motion sensor is an accelerometer.

31. The method of Claim 1, wherein the biomedical sensor and the motion sensor are co-located.

32. The method of Claim 1, further comprising employing the reconstructed representation to determine a heart rate estimate.

33. The method of Claim 1, further comprising employing the reconstructed representation to determine an arterial oxygen saturation (SpO2) estimate.

34. The method of Claim 1, further comprising employing the reconstructed representation to detect or predict a heart-related ailment, the heart-related ailment including at least one of

a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

35. The method of Claim 1, wherein the reconstructing and the outputting are performed in real-time with respect to production of the heart-related signal and the motion signal.

36. The method of Claim 1, wherein the reconstructing and the outputting are performed in non-real-time with respect to production of the heart-related signal and the motion signal.

37. An apparatus for reconstructing a heart-related signal output by a biomedical sensor, the apparatus comprising:

a reconstruction unit configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of the movement; and

an output unit configured to output the reconstructed representation of the heart-related signal.

38. The apparatus of Claim 37, wherein the motion artifacts are suppressed in the reconstructed representation of the heart-related signal.

39. The apparatus of Claim 37, wherein:

the time-varying spectral analysis includes pre-processing the heart-related signal to produce a pre-processed heart-related signal; and

in an event the classification indicates that the movement does not rise to level causing the motion artifacts, the reconstructed representation is based on an average value of peak-to-peak intervals in the pre-processed heart-related signal.

40. The apparatus of Claim 39, wherein the pre-processing includes filtering the heart-related signal to produce a filtered heart-related signal.

41. The apparatus of Claim 40, wherein the pre-processing further includes down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

42. The apparatus of Claim 37, wherein the time-varying spectral analysis includes:

computing a first time-frequency spectrum (TFS) of the heart-related signal; and

computing a second TFS of the motion signal.

43. The apparatus of Claim 42, wherein the first TFS computed and the second TFS computed are 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

44. The apparatus of Claim 42, wherein the first TFS computed is a first time-varying power spectral density (PSD) and the second TFS computed is a second time-varying PSD.

45. The apparatus of Claim 42, wherein the reconstructed representation is a current reconstructed representation and wherein, based on the classification indicating that the movement does rise to a level causing the motion artifacts and is a pseudo-periodic movement or a periodic movement, to reconstruct the representation includes:

determining whether at least one spectral peak is present having a corresponding frequency within a given frequency range at a point in time in the first TFS computed, the current reconstructed representation being reconstructed for the point in time; and

wherein, based on a determination that the at least one spectral peak is not present, the reconstructed current representation is based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed.

46. The apparatus of Claim 45, wherein the given frequency range is 0.5 Hz to 3 Hz.

47. The apparatus of Claim 42, wherein to reconstruct the representation includes:

retaining up to a pre-determined number of candidate spectral peaks located at a first point in time in the first TFS computed, the candidate spectral peaks retained based on having corresponding frequencies within a given frequency range and highest amplitude or power values relative to other spectral peaks located at the first point in time, the other spectral peaks having respective frequencies within the given frequency range; and

discarding each of the candidate spectral peaks retained that is associated with a same frequency as a dominant spectral peak located at a second point in time in the second TFS computed, the first point in time and the second point in time having same time values.

48. The apparatus of Claim 47, wherein the given frequency range is 0.5 Hz to 3 Hz.

49. The apparatus of Claim 47, wherein the representation is a current representation, wherein the reconstructed representation is a current reconstructed representation, and wherein, in an event the discarding discards each of the candidate spectral peaks retained, reconstructing the current representation is based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

50. The apparatus of Claim 47, wherein the discarding is a first discarding and wherein the representation is a current representation and, wherein, in an event the first discarding results in at least one remaining candidate spectral peak retained, reconstructing the current representation further includes:

second discarding, wherein the second discarding discards remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced by at least a frequency difference threshold from a prior reconstructed representation's frequency, the prior reconstructed representation associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

51. The apparatus of Claim 50, wherein:

based on each of the at least one remaining candidate spectral peak retained having been discarded by the second discarding, reconstructing the current representation is based on the prior reconstructed representation; and

based on at least one last candidate spectral peak remaining, the at least one last candidate spectral peak remaining not discarded by the second discarding, reconstructing the current representation is based on a selected candidate spectral peak selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining.

52. The apparatus of Claim 47, wherein the dominant spectral peak has a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS.

53. The apparatus of Claim 47, wherein the retaining and the discarding are based on:

the classification of the movement indicating that the movement is a pseudo-periodic movement or a periodic movement; and

determining that at least one spectral peak with a corresponding frequency in the given frequency range is present at the first point in time.

54. The apparatus of Claim 42, wherein the time-varying spectral analysis further includes pre-processing the heart-related signal and the motion signal for the computing of the first TFS and the second TFS.

55. The apparatus of Claim 42, wherein the pre-processing includes filtering the heart-related signal and the motion signal to produce a filtered heart-related signal and a filtered motion signal, respectively.

56. The apparatus of Claim 55, wherein the pre-processing further includes down-sampling, at a sampling rate less than an original sampling rate, both the filtered heart-related signal and the filtered motion signal.

57. The apparatus of Claim 42, further including a classification unit, the classification unit configured to:

classify the classification of the movement by comparing an amount of amplitude modulation in the second TFS computed to an amplitude modulation threshold, wherein the classification indicates whether the movement rises to a level causing the motion artifacts based on a result of the comparing.

58. The apparatus of Claim 57, wherein the amplitude modulation threshold is dependent on a type of the motion detector sensor.

59. The apparatus of Claim 57, wherein, in an event the result indicates that the movement does rise to the level causing the motion artifacts, the classification unit is further

configured to classify the classification of the movement by determining whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement.

60. The apparatus of Claim 59, wherein to determine whether the movement is either the pseudo-periodic movement or the periodic movement versus a random movement includes:

identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS, the first, second, and third peaks having largest power or amplitude values relative to other peaks in the second TFS at the point in time, the first spectral peak being a largest spectral peak amongst the first, second, and third spectral peaks;

computing a first ratio of the second frequency identified to the first frequency identified and determining a first comparison result by comparing the first ratio computed to a first ratio value; and

computing a second ratio of the third frequency identified to the first frequency identified and determining a second comparison result by comparing the second ratio computed to a second ratio value, wherein the classification further indicates that the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result.

61. The apparatus of Claim 60, wherein the first ratio value is 2 and the second ratio value is 3.

62. The apparatus of Claim 59, wherein the time-varying signal analysis includes pre-processing the heart-related signal to produce a pre-processed heart-related signal and, in an event the classification of the movement indicates random movement, the reconstructing includes:

computing an average value of a number of prior reconstructed representations outputted prior to the reconstructing, the number based on a duration of consecutive motion artifacts, detected prior to the reconstructing;

computing a bandpass filter cutoff frequency based on the average value computed;

filtering the pre-processed heart-related signal by applying the band pass filter computed to produce a filtered, pre-processed heart-related signal; and

wherein the reconstructed representation is based on an average peak-to-peak interval value of the filtered, pre-processed heart-related signal.

63. The apparatus of Claim 37, wherein the heart-related signal and the motion signal are produced, concurrently.

64. The apparatus of Claim 37, further comprising segmentation unit configured to:

segment the heart-related signal into a plurality of windowed heart-related signal data segments and the motion signal into corresponding plurality of windowed motion signal data segments, wherein the reconstruction unit and the output unit reconstruct the representation and output the reconstructed representation, respectively, based on each windowed heart-related signal data segment and each corresponding motion signal data segment.

65. The apparatus of Claim 64, wherein the time window is a value in a range from 2 to 32 seconds.

66. The apparatus of Claim 37, wherein the biomedical sensor is at least one of: a photoplethysmogram (PPG) sensor, piezoelectric sensor, Light Emitting Diode (LED) based sensor, camera sensor, and pulse oximeter sensor, and wherein the motion sensor is an accelerometer.

67. The apparatus of Claim 37, wherein the apparatus includes the biomedical sensor and the motion sensor.

68. The apparatus of Claim 37, further comprising a heart rate unit configured to employ the reconstructed representation to determine a heart rate estimate.

69. The apparatus of Claim 37, further comprising an arterial oxygen saturation (SpO2) unit configured to employ the reconstructed representation to determine a SpO2 estimate.

70. The apparatus of Claim 37, further comprising an ailment unit configured to employ the reconstructed representation to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, an atrial fibrillation condition, a congestive heart failure condition, and a tachycardia condition.

71. The apparatus of Claim 37, wherein the reconstruction unit and the output unit are configured to reconstruct and to output, respectively, in real-time with respect to production of the heart-related signal and the motion signal.

72. The apparatus of Claim 37, wherein the reconstruction unit and the output unit are configured to reconstruct and to output, respectively, in non-real-time with respect to production of the heart-related signal and the motion signal.

73. A non-transitory computer-readable medium having encoded thereon a sequence of instructions which, when loaded and executed by a processor, causes the processor to reconstruct a heart-related signal output by a biomedical sensor, the processor reconstructing the heart-related signal by:

reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-

related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of the movement; and

outputting the reconstructed representation of the heart-related signal.

ABSTRACT OF THE DISCLOSURE

A method and corresponding apparatus employ a time-varying spectral analysis approach for reconstructing a heart-related signal that includes motion artifacts. The motion artifacts are produced by motion of a biomedical sensor relative to a sensing location. By comparing time-varying spectra of the heart-related signal and a motion signal, those frequency peaks resulting from the motion artifacts may be suppressed in a time-varying spectrum of the heart-related signal. The time-varying spectral analysis based approach enables the heart-related signal to be reconstructed with accuracy by suppressing the motion artifacts. Example applications for the method and corresponding apparatus include training aids (*e.g.*, runners' heart-rate monitors) and hospital patient heart-rate monitors.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Filer:	Mark B Solomon/Donna Bartolone
Attorney Docket Number:	4147.1020-002 (15-089)

Filed as Small 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:				
Petition Fee-37CFR 1.17(h) (Group II)	2464	1	70	70
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**70**

Electronic Acknowledgement Receipt

EFS ID:	26007585
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Donna Bartolone
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	09-JUN-2016
Filing Date:	
Time Stamp:	16:36:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$70
RAM confirmation Number	3385
Deposit Account	080380
Authorized User	Bartolone, Donna

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	41471020002TransmittalofApplication.pdf	122114 74cf228543787a6f3581ba5dbe23d0b9d27290f0	no	1
Warnings:					
Information:					
2	Drawings-other than black and white line drawings	41471020002Drawings.pdf	7580150 57564d1bbf8a78e847c8dc2bcbae6597765f144f	no	25
Warnings:					
Information:					
3	Petition for review by the Office of Petitions	41471020002PetitiontoAcceptColorDrawings.pdf	94084 3d7223e498eb6f320f256e35c634b38608086aa9	no	2
Warnings:					
Information:					
4	Application Data Sheet	41471020002ADS.PDF	1815744 048cc6bf7226982cc24701aad2e8e525bc43f428	no	9
Warnings:					
Information:					
5		41471020002Application.pdf	434820 23b30818e52a5bbfbb8d723398dee9d98904cca9	yes	77

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	60
Claims	61	76
Abstract	77	77

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30383 3d40e75fc72f5f9c9a737cd31bba45ba34f8c601	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	10077295

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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.

Electronic Acknowledgement Receipt

EFS ID:	26007585
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Donna Bartolone
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	09-JUN-2016
Filing Date:	
Time Stamp:	16:36:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$70
RAM confirmation Number	3385
Deposit Account	080380
Authorized User	Bartolone, Donna

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	41471020002TransmittalofApplication.pdf	122114 74cf228543787a6f3581ba5dbe23d0b9d27290f0	no	1
Warnings:					
Information:					
2	Drawings-other than black and white line drawings	41471020002Drawings.pdf	7580150 57564d1bbf8a78e847c8dc2bcbae6597765f144f	no	25
Warnings:					
Information:					
3	Petition for review by the Office of Petitions	41471020002PetitiontoAcceptColorDrawings.pdf	94084 3d7223e498eb6f320f256e35c634b38608086aa9	no	2
Warnings:					
Information:					
4	Application Data Sheet	41471020002ADS.PDF	1815744 048cc6bf7226982cc24701aad2e8e525bc43f428	no	9
Warnings:					
Information:					
5		41471020002Application.pdf	434820 23b30818e52a5bbfbb8d723398dee9d98904cca9	yes	77

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	60
Claims	61	76
Abstract	77	77

Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30383 3d40e75fc72f5f9c9a737cd31bba45ba34f8c601	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	10077295

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.

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 15178089 Document Date: 06/09/2016

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via eDAN using the Supplemental Content tab, or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: August 26, 2013

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
15/178,089	06/09/2016	Seyed M. A. Salehizadeh	4147.1020-002 (15-089)

CONFIRMATION NO. 7605

21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

FORMALITIES LETTER

OC000000084027724

Date Mailed: 06/30/2016

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of $ **2120** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **70** basic filing fee.
- $ **70** surcharge.
- $ **300** search fee.
- $ **360** examination fee.
- $ **2120** for **53** total claims over 20.

- $(**0**) previous unapplied payment amount.
- $ **2920** TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Seyed M. A. Salehizadeh
  Ki H. Chon
  Yeonsik Noh

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

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**.

/ldvan/

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/178,089	06/09/2016	3766	0.00	4147.1020-002 (15-089)	73	3

CONFIRMATION NO. 7605

FILING RECEIPT

21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

OC000000084027723

Date Mailed: 06/30/2016

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Seyed M. A. Salehizadeh, Coventry, CT;
Ki H. Chon, Mansfield Center, CT;
Yeonsik Noh, Willington, CT;

Applicant(s)

University of Connecticut, Farmington, CT;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 62/299,944 02/25/2016
and claims benefit of 62/172,862 06/09/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/28/2016

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/178,089**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/178,089

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	73 minus 20 =	* 53	x 40 =	2120	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	2850		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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 found in the appropriate box in column 1.

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 15178089 Document Date: 08/30/2016

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

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- External customers may access SCORE content via PAIR using the Supplemental Content tab.

Form Revision Date: August 26, 2013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	
Confirmation No:	7605		
For:	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals		

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:

_____ _____
Date Signature

_____
Typed or printed name of person signing certificate

PRELIMINARY AMENDMENT

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

Commissioner:

Please amend the Application as follows:

Amendments to the Drawings

FIG. 3A is being amended to add reference indicator 325 to the text box including the text “end” with input from element 320.

Attachment: Replacement Sheet
Annotated Marked-Up Drawings

REMARKS

FIG. 3A is being amended to add reference indicator 325 to the text box including the text "end" with input from element 320. Support for the amendment may be found through Applicant's Specification, as originally filed, including at least at page 20 through 21, paragraph [0082]. No new matter is being added by way of this Preliminary Amendment.

Payment of Fees

Authorization is hereby granted to charge the fees due with this submission, including any extension of time fee, to Deposit Account No. 08-0380.

CONCLUSION

Entry of the Preliminary Amendment is respectfully requested.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By /Mark B. Solomon, Reg. No. 44348/
Mark B. Solomon
Registration No. 44,348
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Date: 8/30/2016

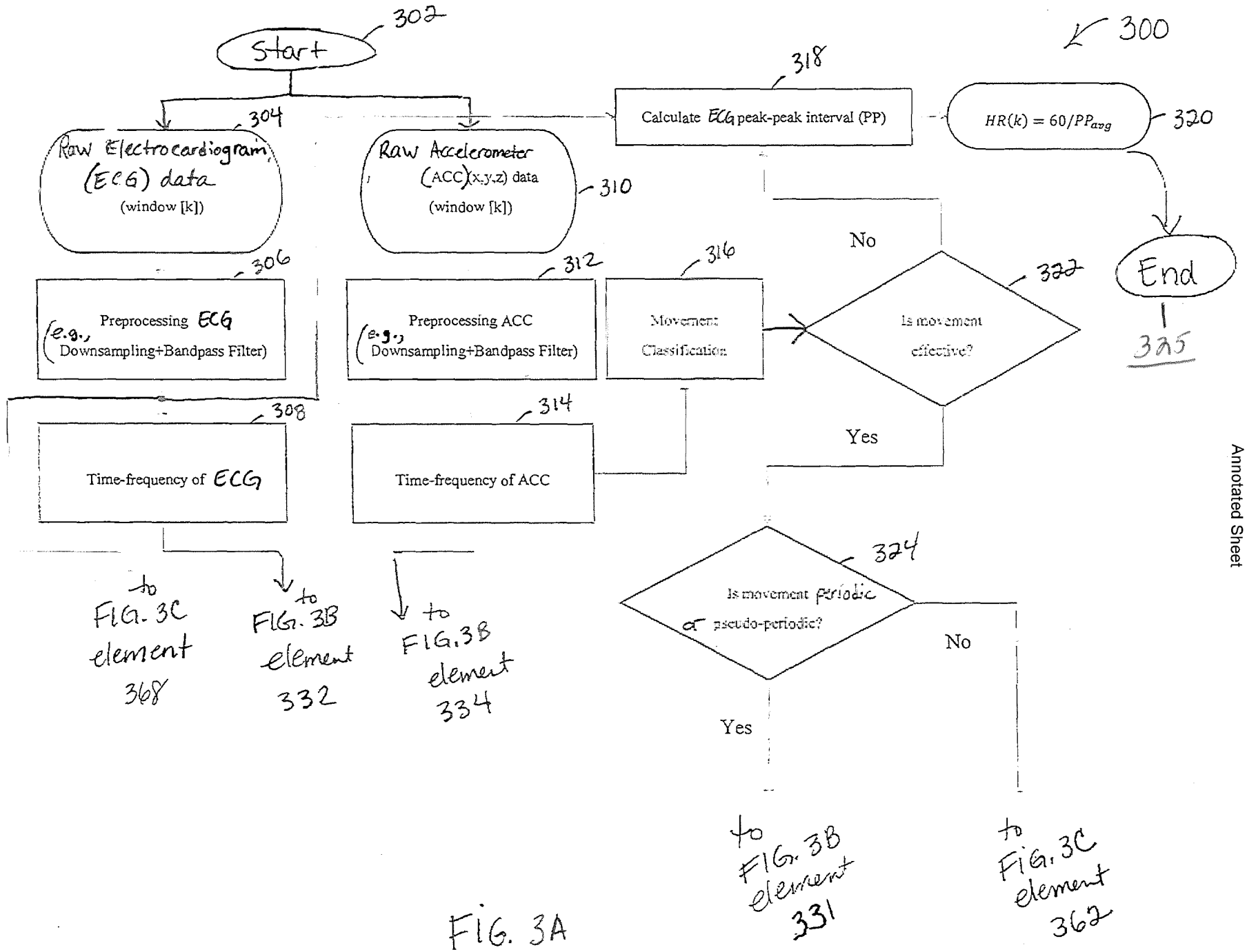


FIG. 3A

Docket No.: 4147.1020-002 (15-089)
Title: Method and Apparatus for Removing ...
Inventors: Seyed M. A. Salehizadeh, et al.
Annotated Sheet

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	
Confirmation No.:	7605		

For: Method And Apparatus For Removing Motion Artifacts From Biomedical Signals

CERTIFICATE OF MAILING OR TRANSMISSION

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Date _____ Signature _____

Typed or printed name of person signing certificate

REPLY TO NOTICE TO FILE MISSING PARTS OF APPLICATION

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

In reply to the Notice to File Missing Parts dated June 30, 2016, the following documents and fees are being submitted for filing in the captioned application.

☐ **COPY OF EXECUTED DECLARATION FOR PATENT APPLICATION**
(Separate transmittal letter and postcard not required)

☒ **POWER OF ATTORNEY DOCUMENT**
- ☐ Granted by Inventor(s)
- ☒ Granted by Assignee, including Transmittal For Power of Attorney to One or More Registered Practitioners
(Separate transmittal letter and postcard not required)

☒ **PRELIMINARY AMENDMENT**
(Separate transmittal letter and postcard not required)

☒ **FILING FEE**
Fee calculations based on:
- ☒ Claims as originally filed
  - ☐ The Notice to File Missing Parts states an erroneous number of claims.
- ☐ Claims upon entry of the Preliminary Amendment filed **[**herewith**][**with the application**]**
(Separate transmittal letter and postcard not required)

☒ **SURCHARGE - surcharge fee of $70**
(Separate transmittal letter and postcard not required)

☐ **SEQUENCE LISTING - Filed concurrently and is attached**

☐ Preliminary Amendment included in Sequence Listing Transmittal
(Separate transmittal letter and postcard required)

☒ **REPLACEMENT DRAWINGS - 26 sheets of replacement drawings consisting of Figs. 1 - 23 are enclosed** ***(Separate transmittal letter and postcard not required)***

☐ A Petition to Accept Color Drawings/Photographs (Fig(s). [ ]) is attached as required.
(Separate check for fees and postcard required)

☐ **PETITION FOR EXTENSION OF TIME**

☐ Applicant hereby petitions to extend the time to respond to the Notice to File Missing Parts dated [ ] for [ ] month(s) from [ ] to [ ]. The appropriate fee of $[ ] is included as indicated in the Method of Payment section below.

☐ A [ ] month extension of time to respond to the Notice to File Missing Parts dated [ ] was filed on [ ] with payment of a $[ ] fee

☐ Applicant hereby petitions for an additional [ ] month extension of time to respond to the Notice to File Missing Parts. The appropriate fee of $[ ] is included as indicated in the Method of Payment section below.

(Separate Petition for Extension of Time and postcard not required)

☐ **REQUEST FOR CORRECTED FILING RECEIPT - Filed concurrently and is attached**
(Separate transmittal letter and postcard required)

☐ **STATEMENT CLAIMING SMALL ENTITY STATUS**

☐ Was filed on [ ]

☐ Is enclosed herewith
(Separate transmittal letter and postcard not required)

☐ In view of the small entity status of the captioned application, we hereby request a reimbursement of 50% of the filing fees in the amount of $[ ] which were paid on [ ] to be deposited in Deposit Account No. 08-0380

☒ **OTHER** Annotated Marked-up Drawing for FIG 3A

☒ **METHOD OF PAYMENT**

☐ The fees required for filing the indicated documents are enclosed in the form of a check in the total amount of $[ ].

☒ Please charge Deposit Account 08-0380 in the amount of $2,920 for the fees required for filing the indicated documents.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By /Mark B. Solomon, Reg. No. 44348/

Mark B. Solomon
Registration No.: 44,348
Tel.: (978) 341-0036
Fax: (978) 341-0136

Concord, Massachusetts 01742-9133
Date: 8/30/2016

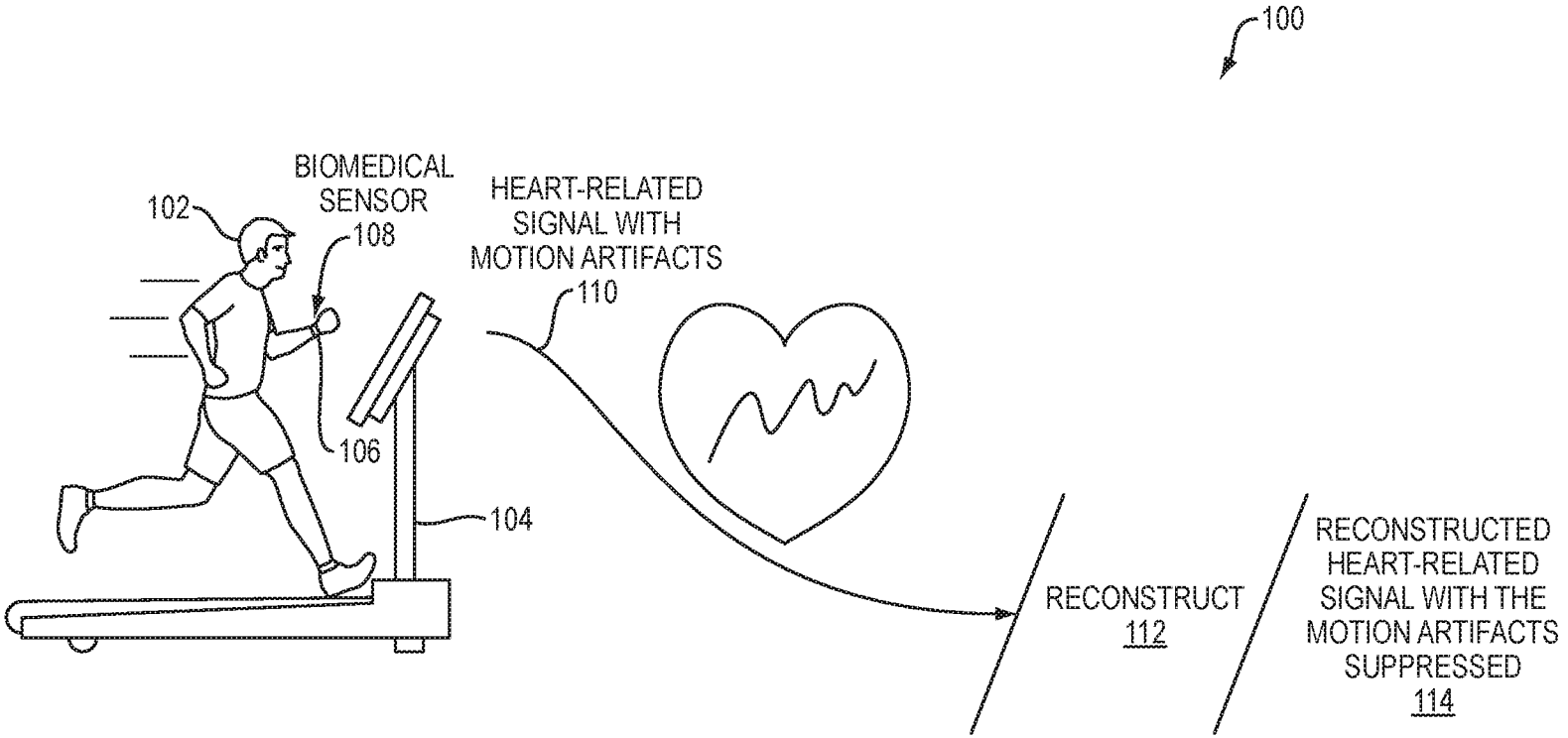

100
BIOMEDICAL SENSOR
102
108
HEART-RELATED SIGNAL WITH MOTION ARTIFACTS
110
106
104
RECONSTRUCT
112
RECONSTRUCTED HEART-RELATED SIGNAL WITH THE MOTION ARTIFACTS SUPPRESSED
114

FIG. 1

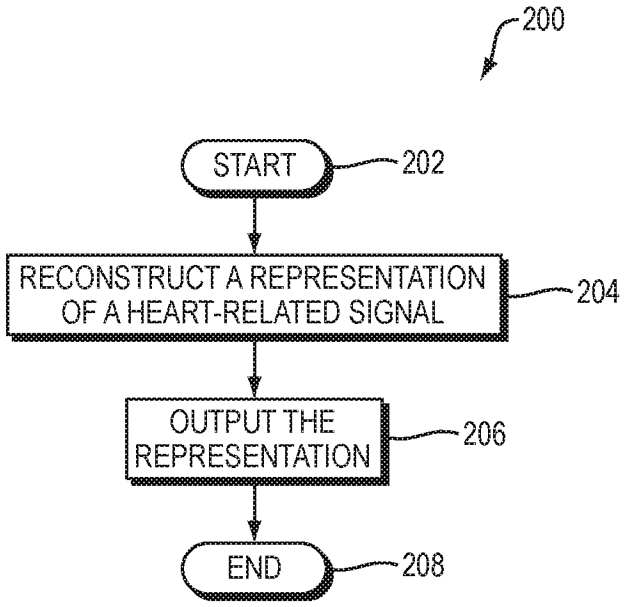

200
START
202
RECONSTRUCT A REPRESENTATION OF A HEART-RELATED SIGNAL
204
OUTPUT THE REPRESENTATION
206
END
208

FIG. 2

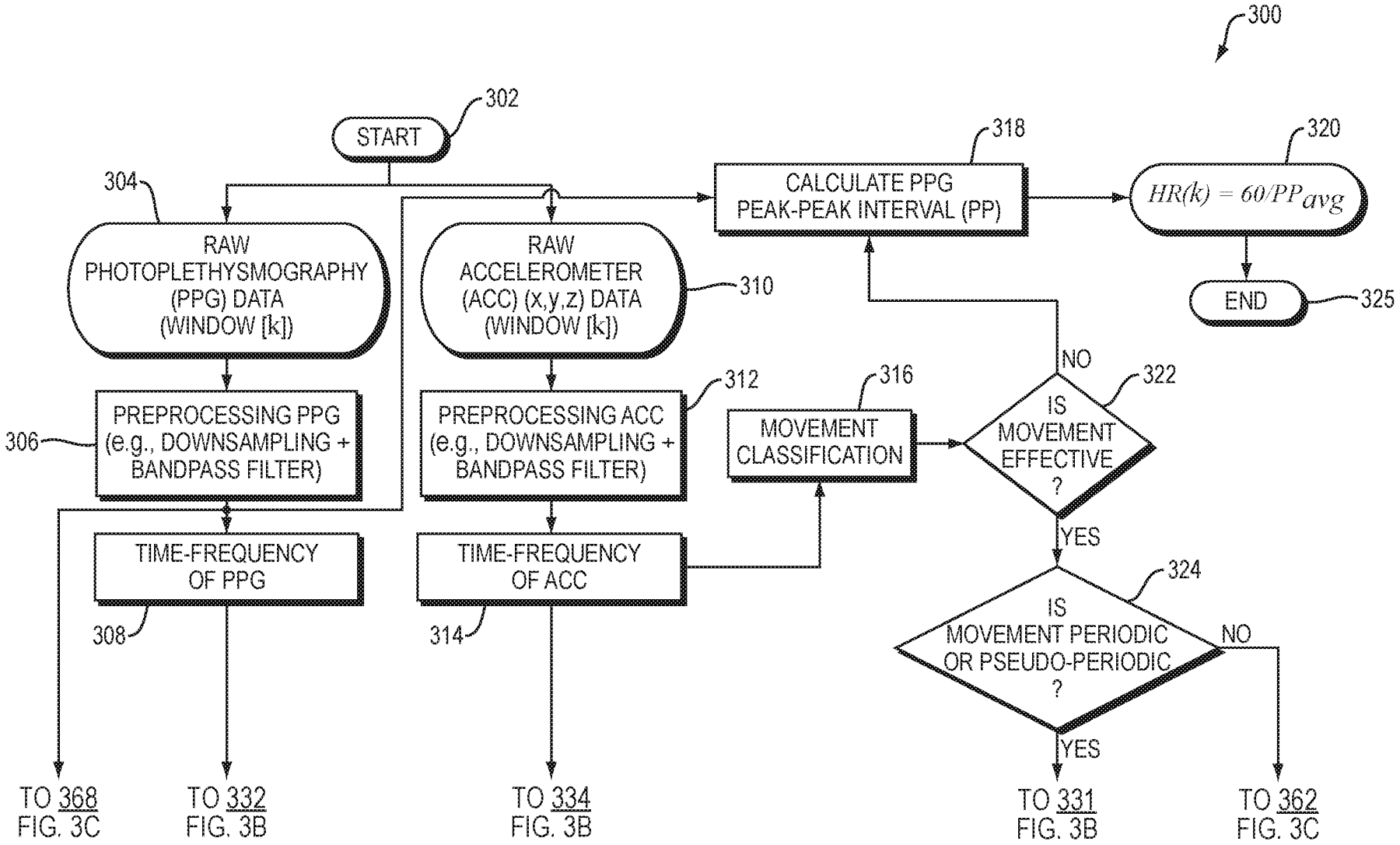

300
START
302
304
RAW PHOTOPLETHYSMOGRAPHY (PPG) DATA (WINDOW [k])
RAW ACCELEROMETER (ACC) (x,y,z) DATA (WINDOW [k])
310
CALCULATE PPG PEAK-PEAK INTERVAL (PP)
318
HR(k) = 60/PPavg
320
END
325
306
PREPROCESSING PPG (e.g., DOWNSAMPLING + BANDPASS FILTER)
312
PREPROCESSING ACC (e.g., DOWNSAMPLING + BANDPASS FILTER)
316
MOVEMENT CLASSIFICATION
322
IS MOVEMENT EFFECTIVE ?
NO
YES
TIME-FREQUENCY OF PPG
308
TIME-FREQUENCY OF ACC
314
324
IS MOVEMENT PERIODIC OR PSEUDO-PERIODIC ?
NO
YES
TO 368 FIG. 3C
TO 332 FIG. 3B
TO 334 FIG. 3B
TO 331 FIG. 3B
TO 362 FIG. 3C

FIG. 3A

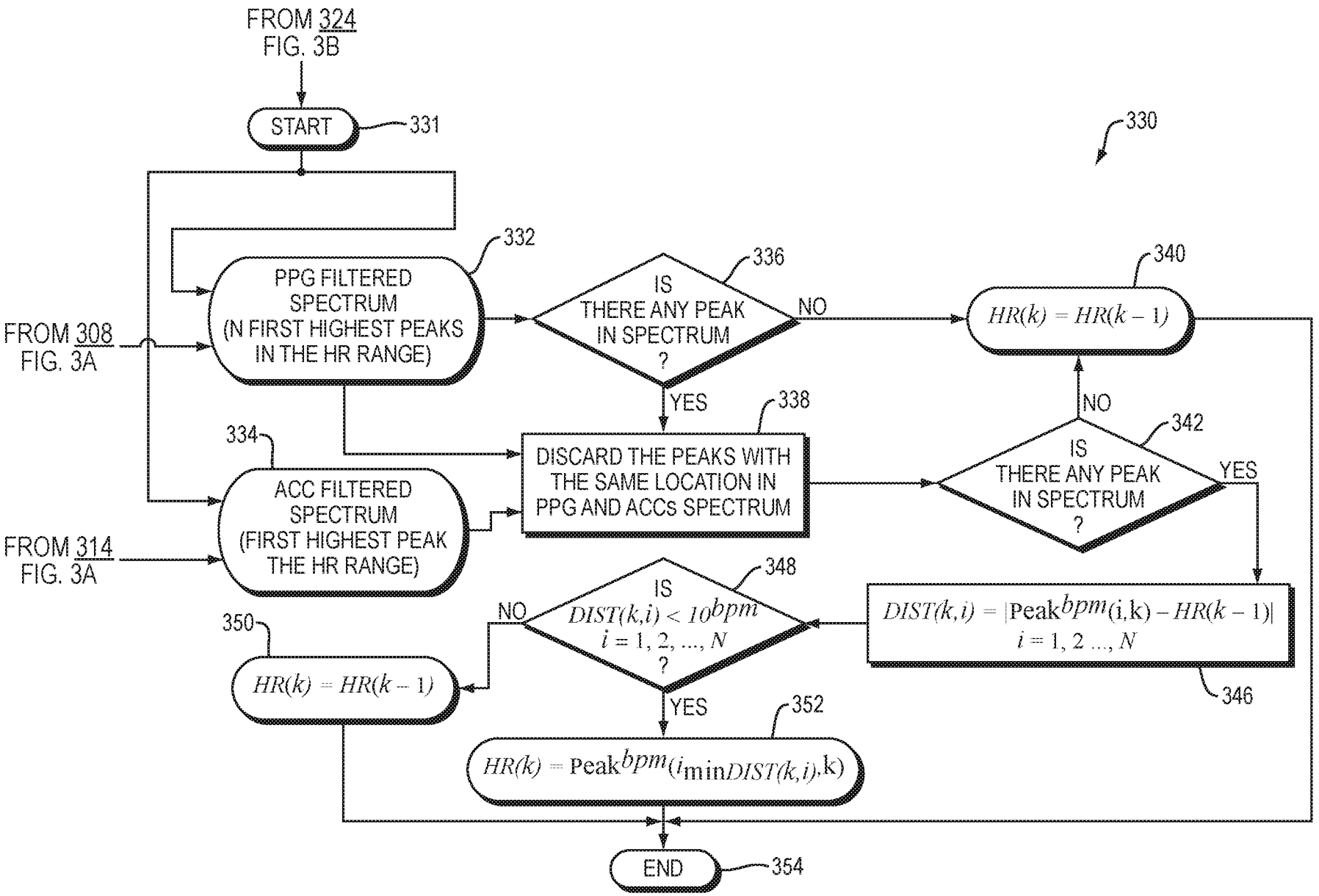

FROM 324
FIG. 3B
START
331
330
332
PPG FILTERED SPECTRUM (N FIRST HIGHEST PEAKS IN THE HR RANGE)
336
IS THERE ANY PEAK IN SPECTRUM ?
NO
340
$HR(k) = HR(k-1)$
YES
338
DISCARD THE PEAKS WITH THE SAME LOCATION IN PPG AND ACCs SPECTRUM
NO
342
IS THERE ANY PEAK IN SPECTRUM ?
YES
FROM 308
FIG. 3A
334
ACC FILTERED SPECTRUM (FIRST HIGHEST PEAK THE HR RANGE)
FROM 314
FIG. 3A
348
IS $DIST(k,i) < 10^{bpm}$ $i = 1, 2, ..., N$?
NO
$DIST(k,i) = |\text{Peak}^{bpm}(i,k) - HR(k-1)|$ $i = 1, 2 ..., N$
346
350
$HR(k) = HR(k-1)$
YES
352
$HR(k) = \text{Peak}^{bpm}(i_{\min DIST(k,i)},k)$
END
354

FIG. 3B

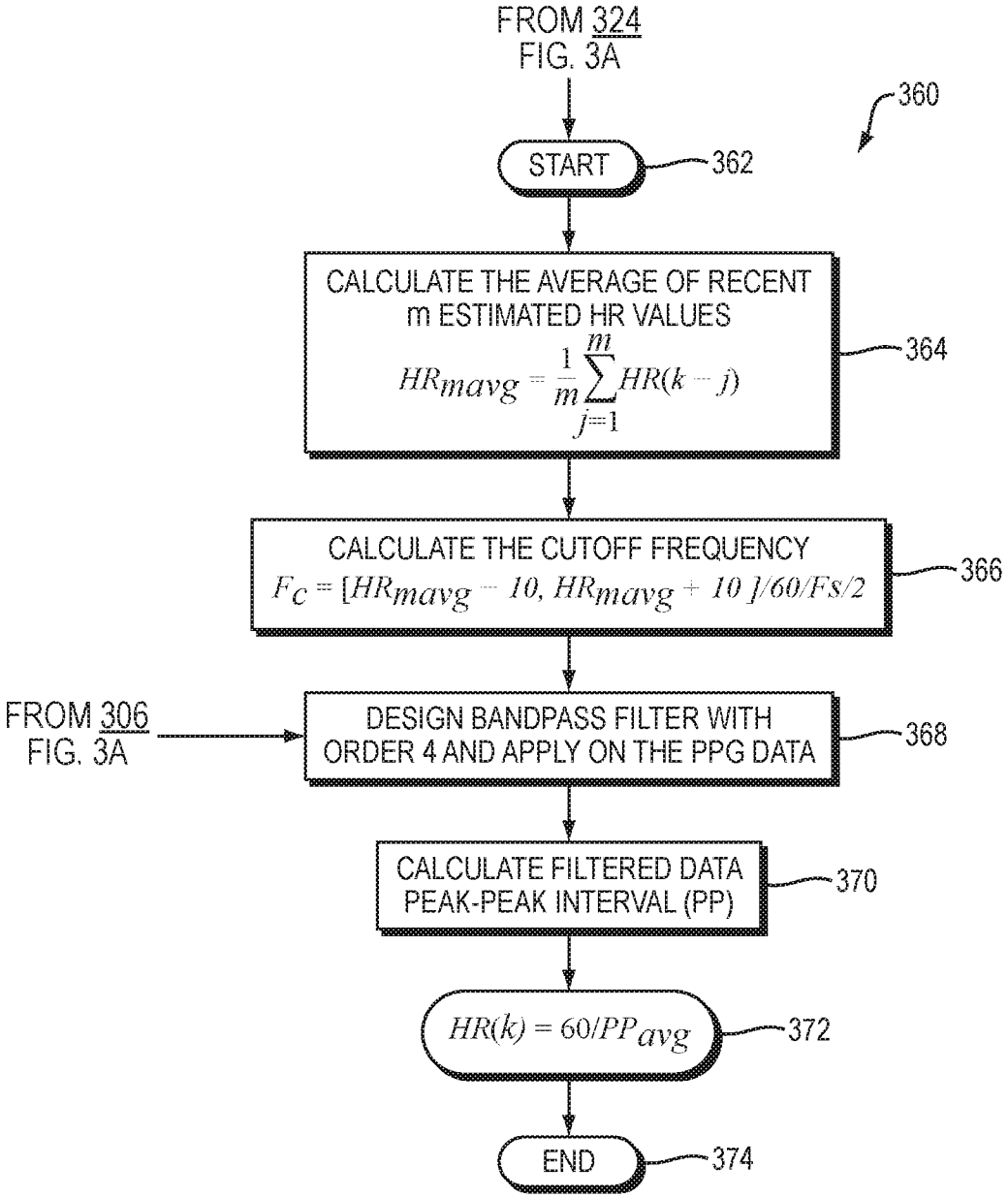

FROM 324
FIG. 3A
360
START
362
CALCULATE THE AVERAGE OF RECENT m ESTIMATED HR VALUES
$HR_{mavg} = \frac{1}{m}\sum_{j=1}^{m} HR(k-j)$
364
CALCULATE THE CUTOFF FREQUENCY
$F_C = [HR_{mavg} - 10, HR_{mavg} + 10\ ]/60/Fs/2$
366
FROM 306
FIG. 3A
DESIGN BANDPASS FILTER WITH ORDER 4 AND APPLY ON THE PPG DATA
368
CALCULATE FILTERED DATA PEAK-PEAK INTERVAL (PP)
370
$HR(k) = 60/PP_{avg}$
372
END
374

FIG. 3C

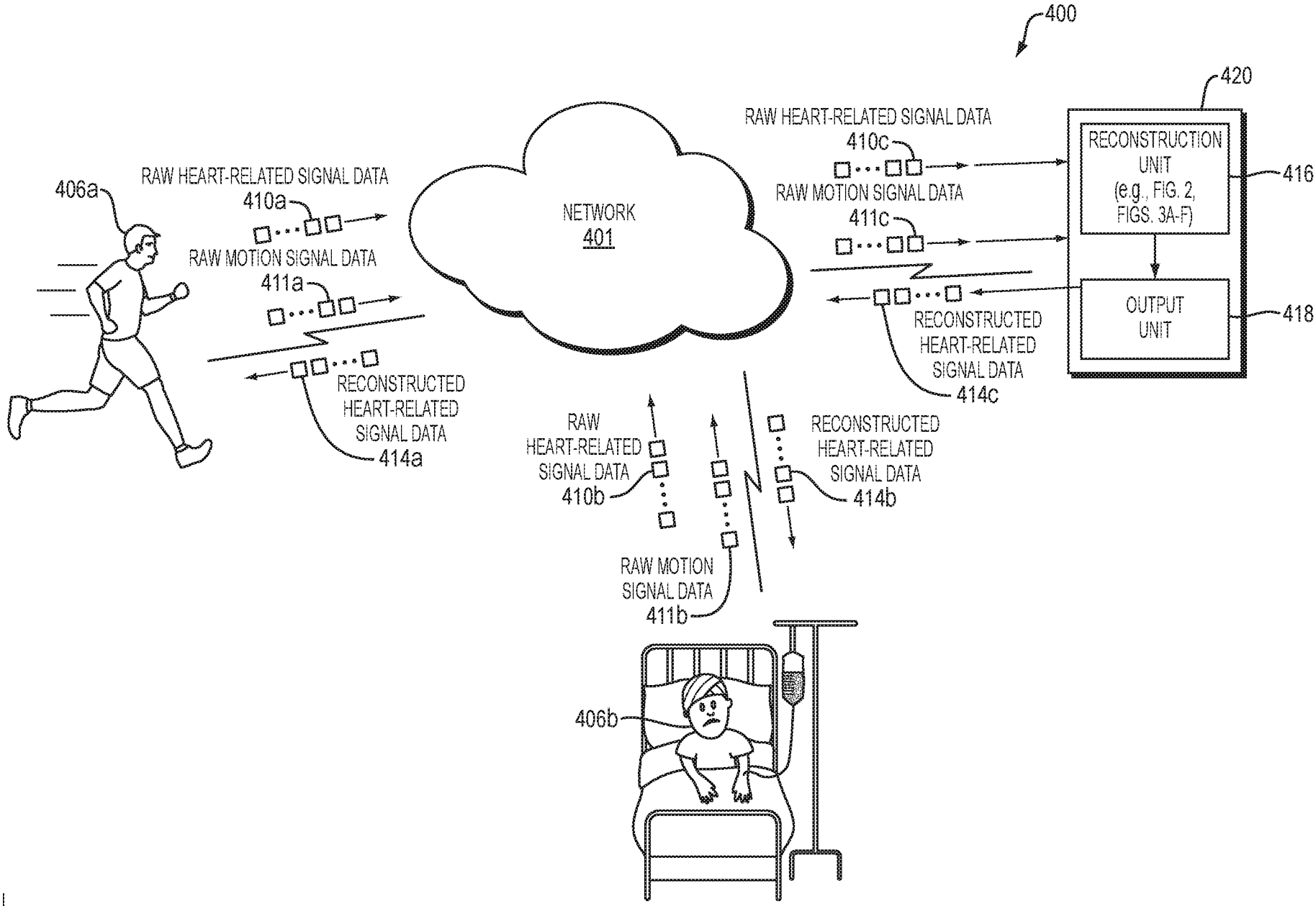

400
420
RECONSTRUCTION UNIT (e.g., FIG. 2, FIGS. 3A-F)
416
OUTPUT UNIT
418
NETWORK 401
406a
406b
RAW HEART-RELATED SIGNAL DATA
410a
RAW MOTION SIGNAL DATA
411a
RECONSTRUCTED HEART-RELATED SIGNAL DATA
414a
RAW HEART-RELATED SIGNAL DATA
410c
RAW MOTION SIGNAL DATA
411c
RECONSTRUCTED HEART-RELATED SIGNAL DATA
414c
RAW HEART-RELATED SIGNAL DATA
410b
RAW MOTION SIGNAL DATA
411b
RECONSTRUCTED HEART-RELATED SIGNAL DATA
414b

FIG. 4

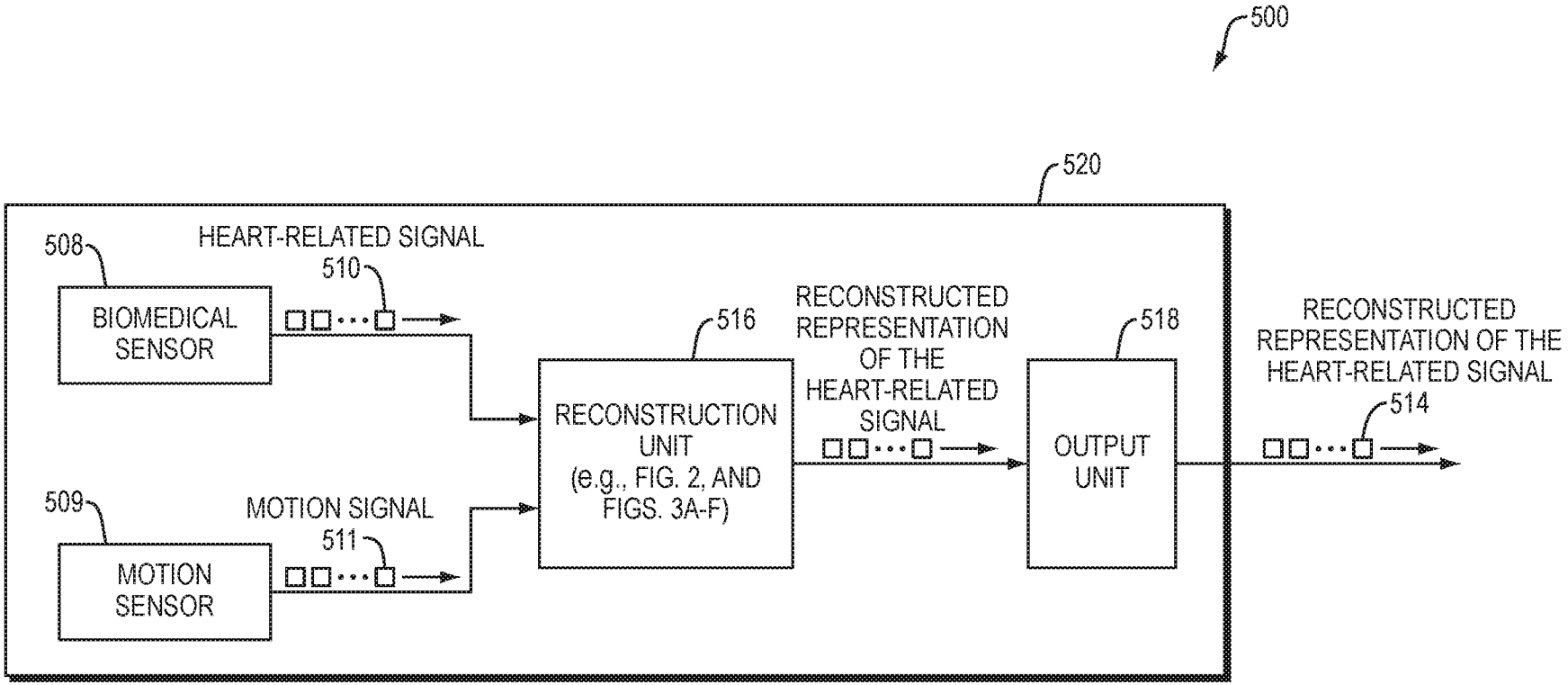

500
520
508
HEART-RELATED SIGNAL
510
BIOMEDICAL SENSOR
516
RECONSTRUCTED REPRESENTATION OF THE HEART-RELATED SIGNAL
518
RECONSTRUCTED REPRESENTATION OF THE HEART-RELATED SIGNAL
514
RECONSTRUCTION UNIT (e.g., FIG. 2, AND FIGS. 3A-F)
OUTPUT UNIT
509
MOTION SIGNAL
511
MOTION SENSOR

FIG. 5

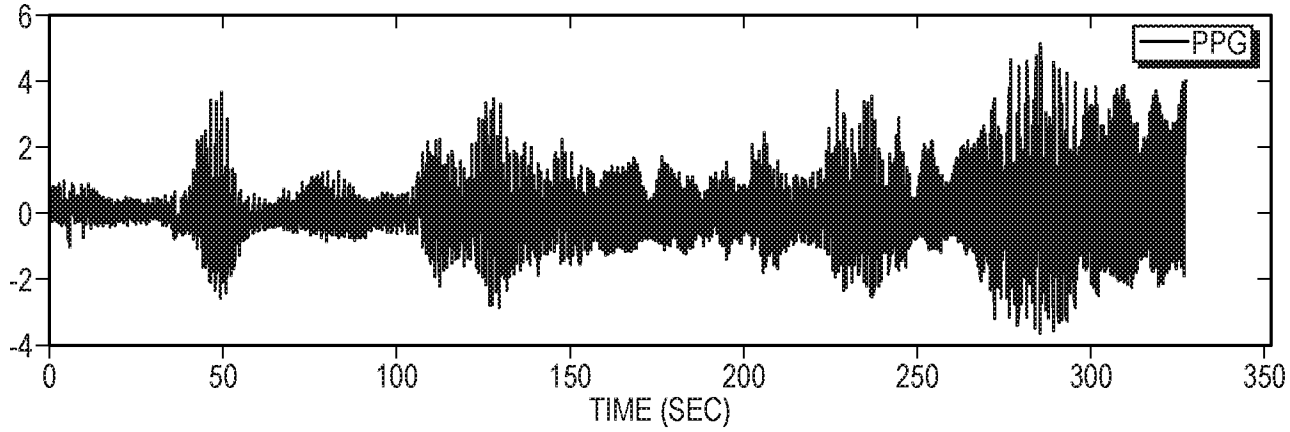

PPG
6
4
2
0
-2
-4
0
50
100
150
200
250
300
350
TIME (SEC)

FIG. 6A

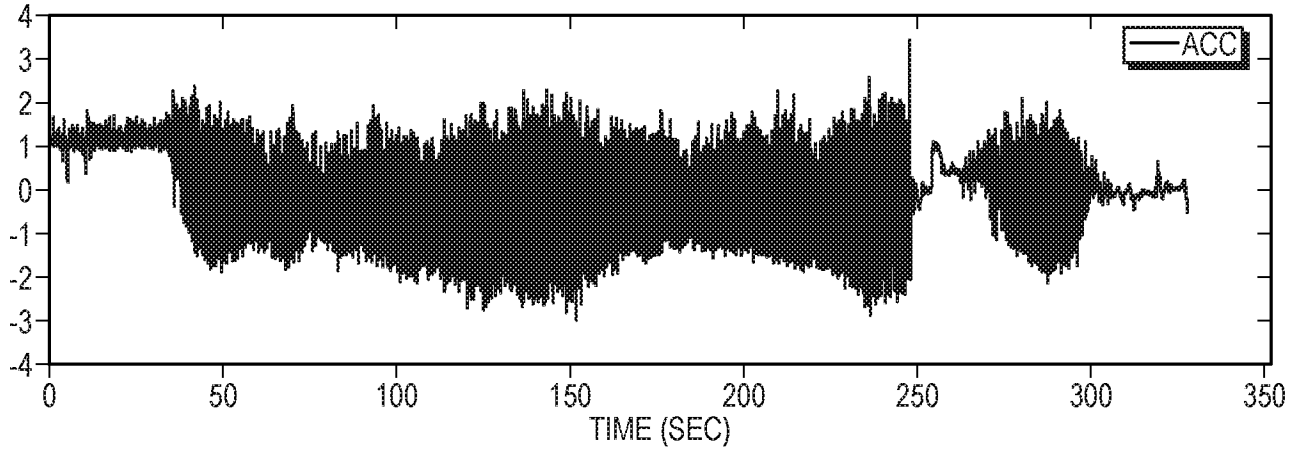

ACC
4
3
2
1
0
-1
-2
-3
-4
0
50
100
150
200
250
300
350
TIME (SEC)

FIG. 6B

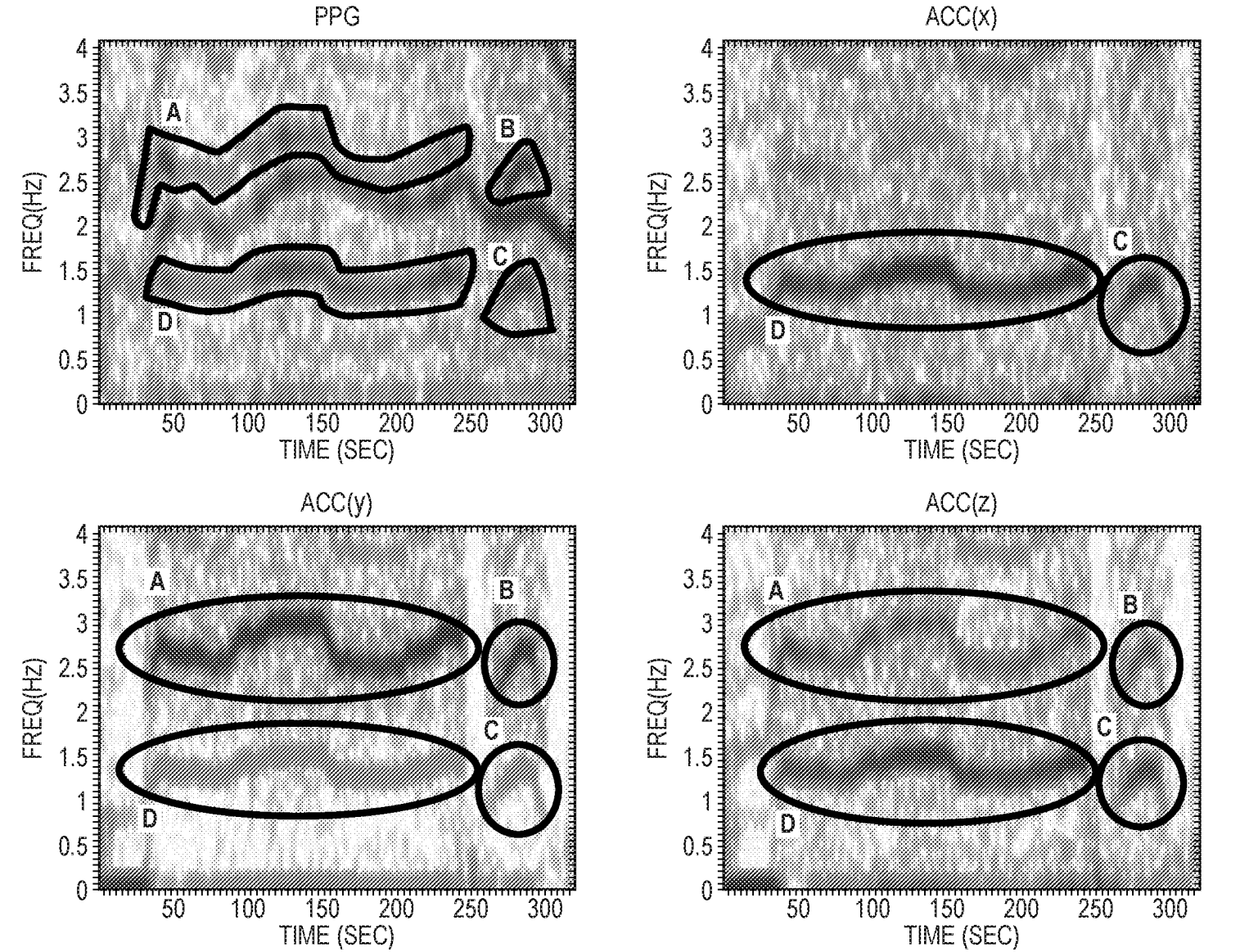

PPG
ACC(x)
ACC(y)
ACC(z)
FREQ(HZ)
TIME (SEC)
A
B
C
D
0
0.5
1
1.5
2
2.5
3
3.5
4
50
100
150
200
250
300

FIG. 6C

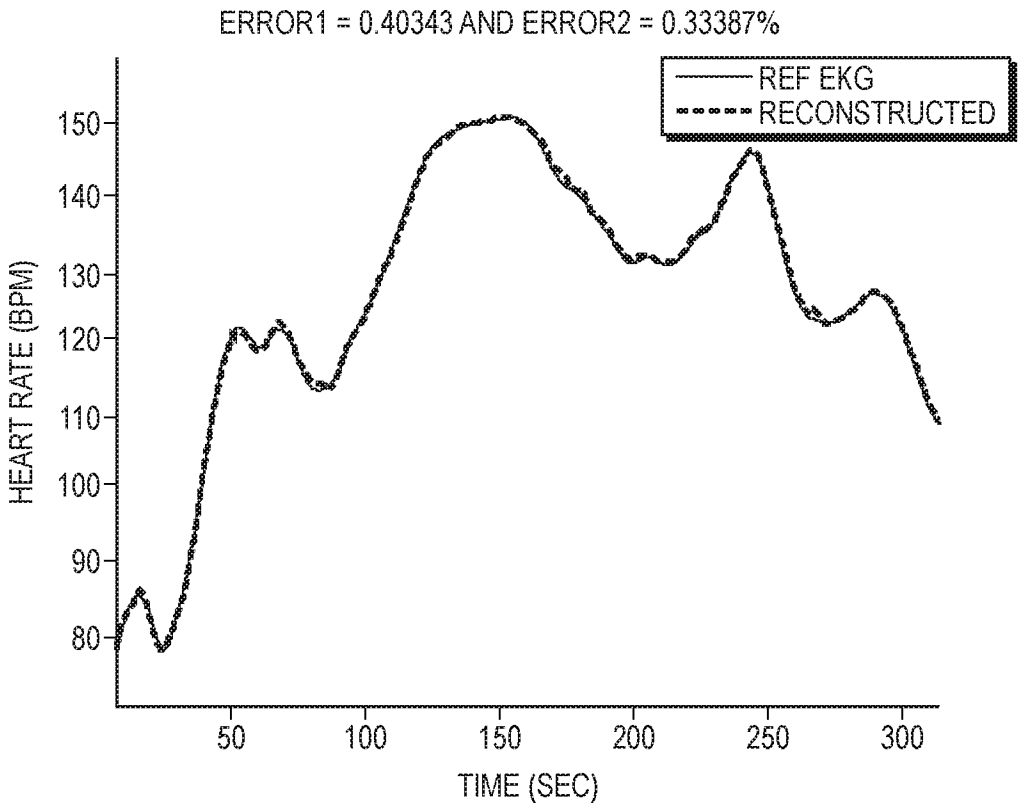

ERROR1 = 0.40343 AND ERROR2 = 0.33387%
REF EKG
RECONSTRUCTED
HEART RATE (BPM)
150
140
130
120
110
100
90
80
50
100
150
200
250
300
TIME (SEC)

FIG. 9

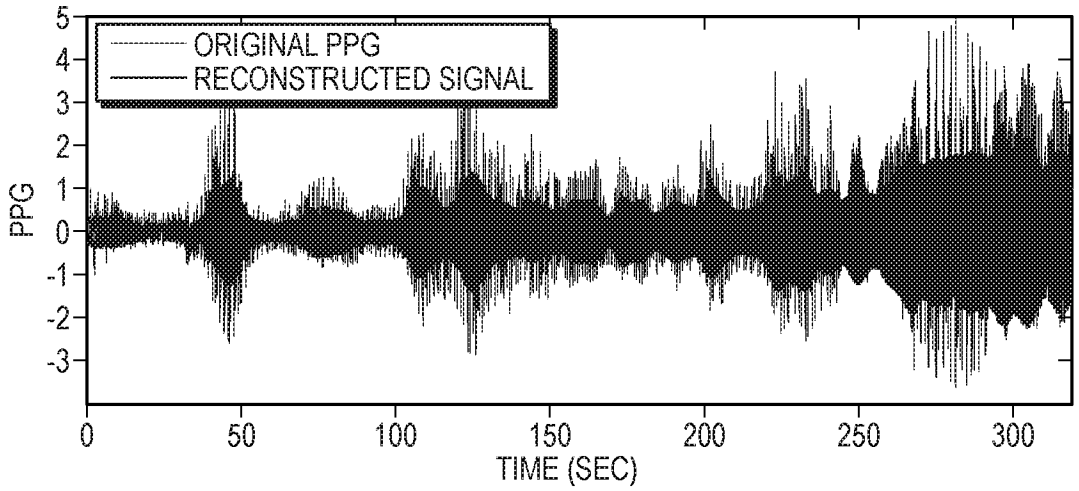


FIG. 10A

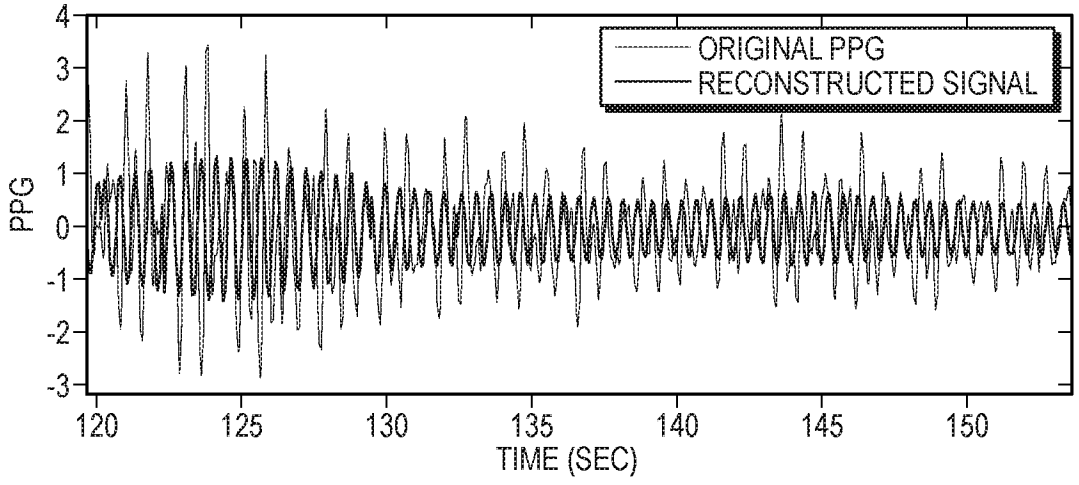


FIG. 10B

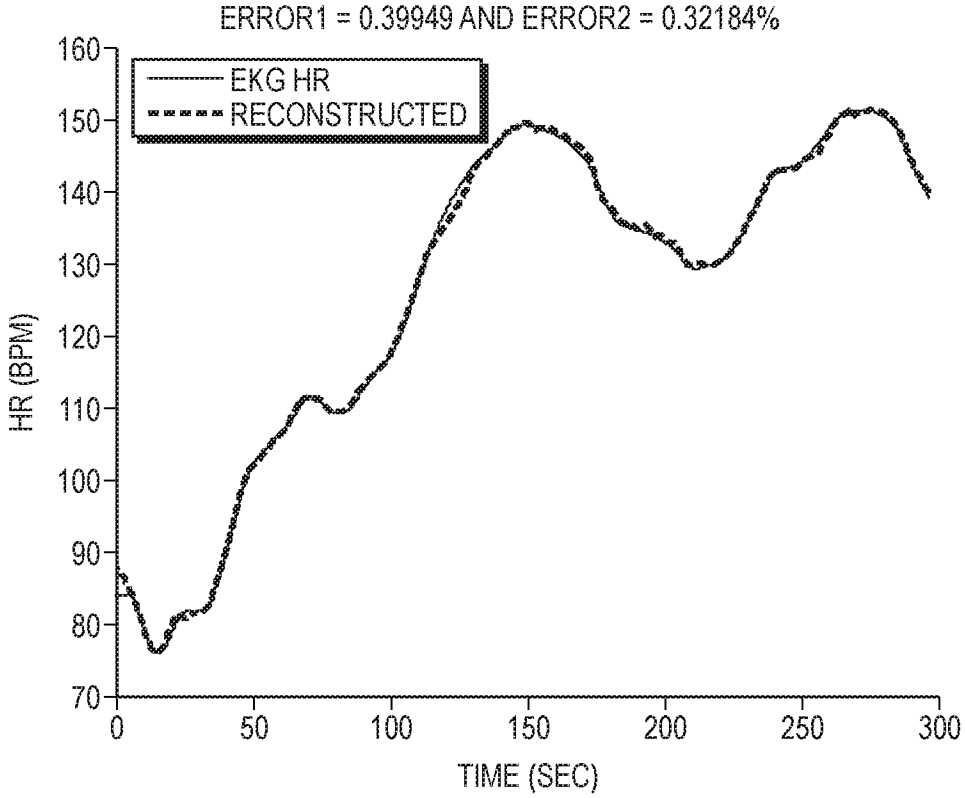


FIG. 12A

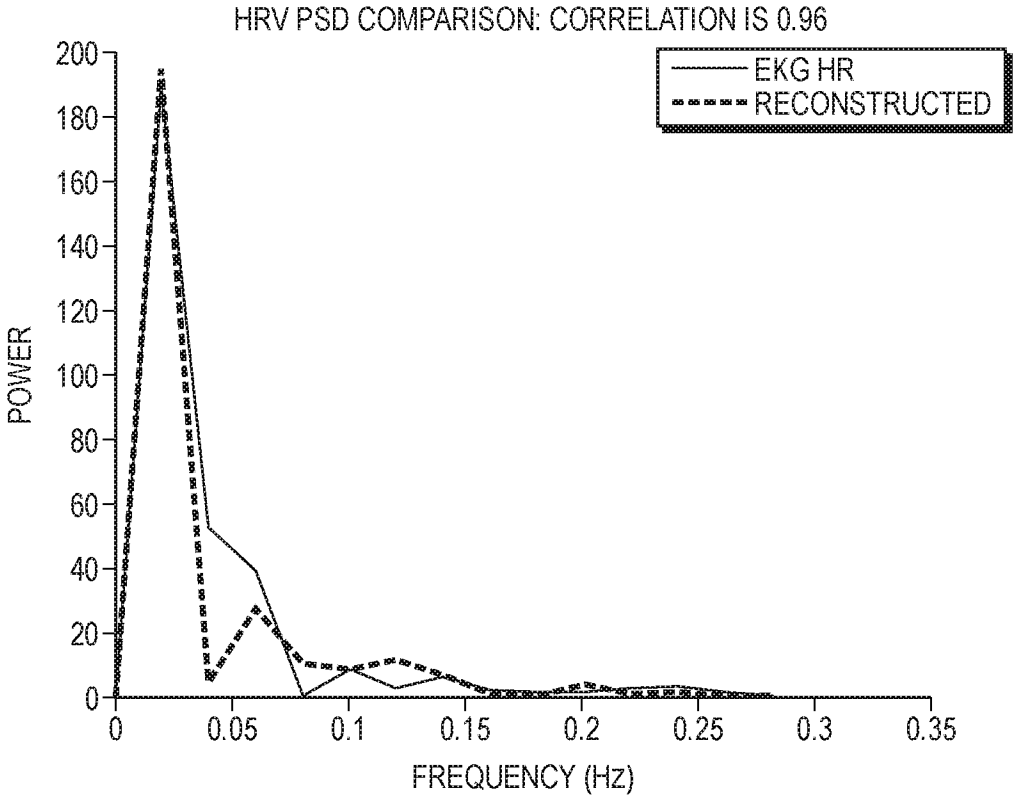


FIG. 12B

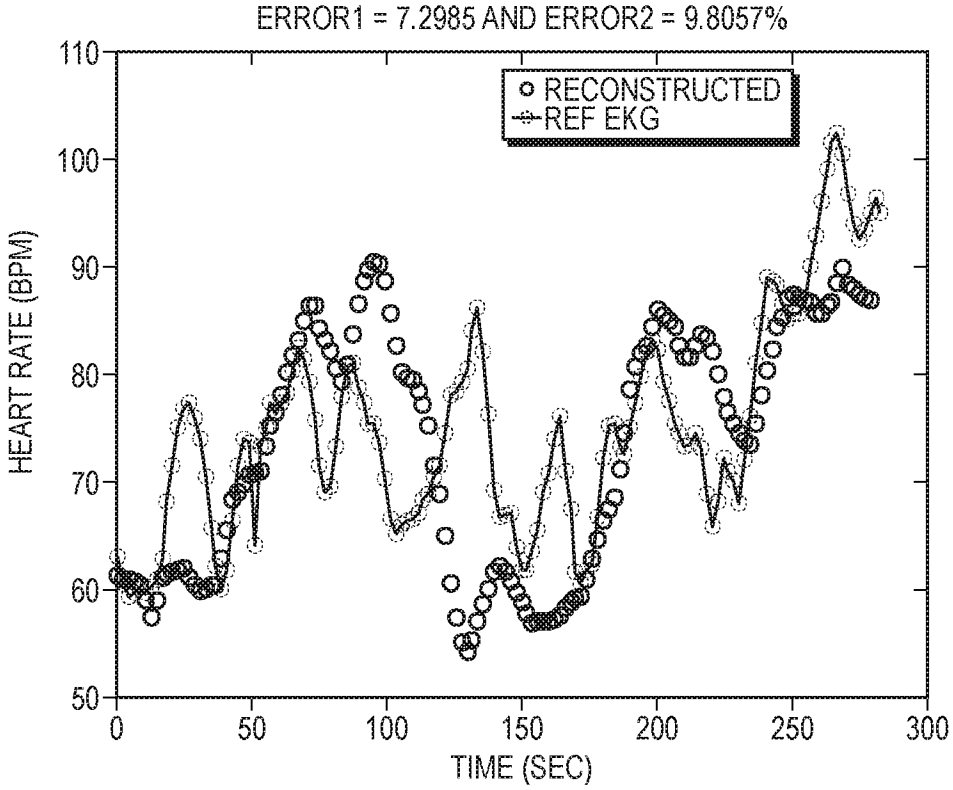


FIG. 13A

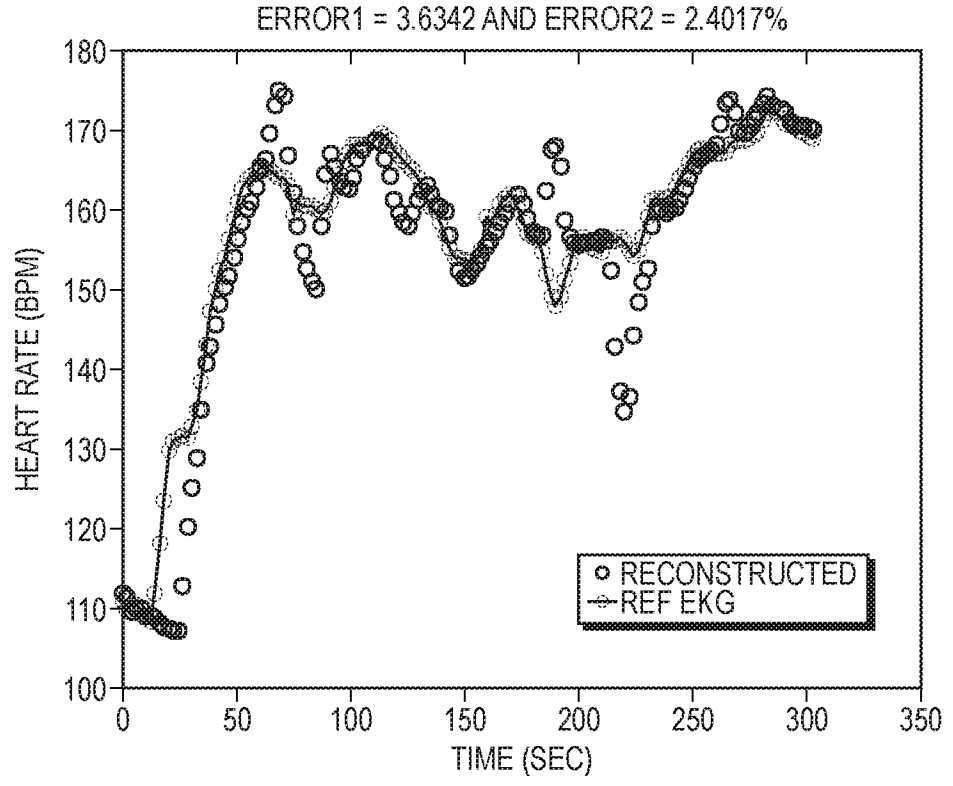


FIG. 13B

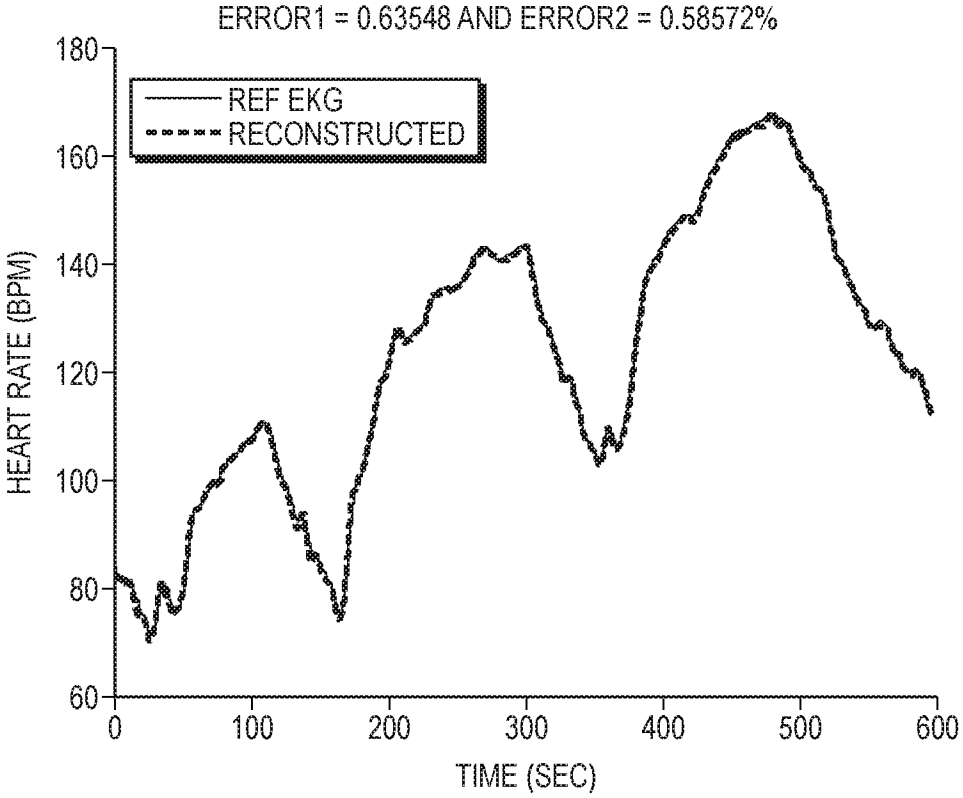


FIG. 14A

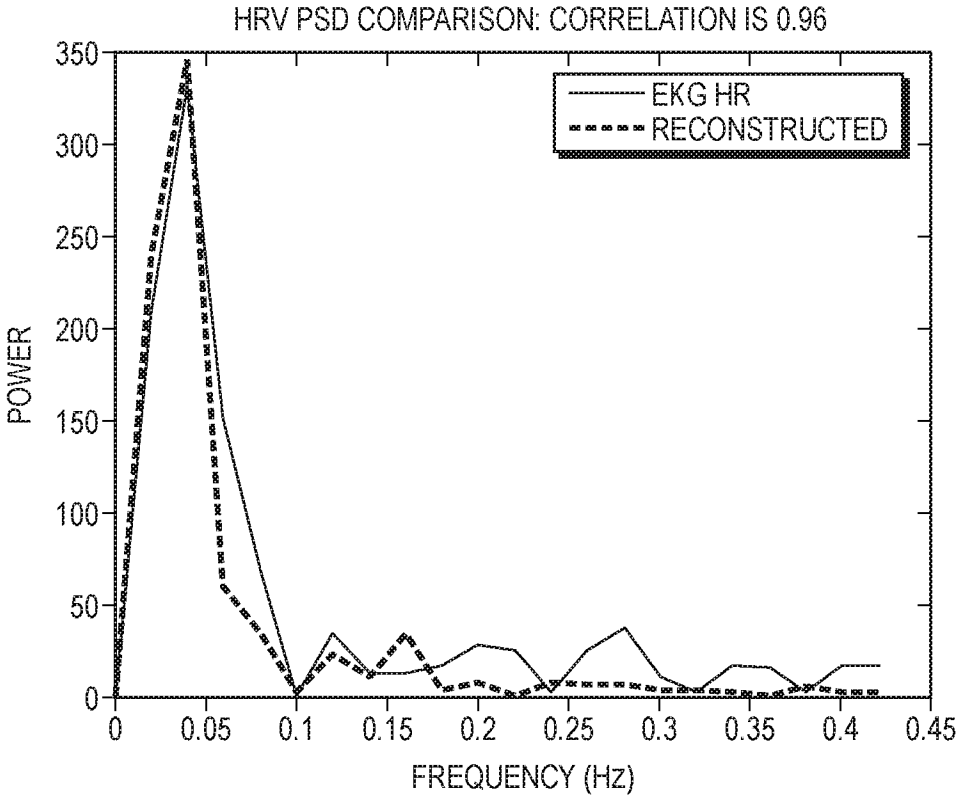


FIG. 14B

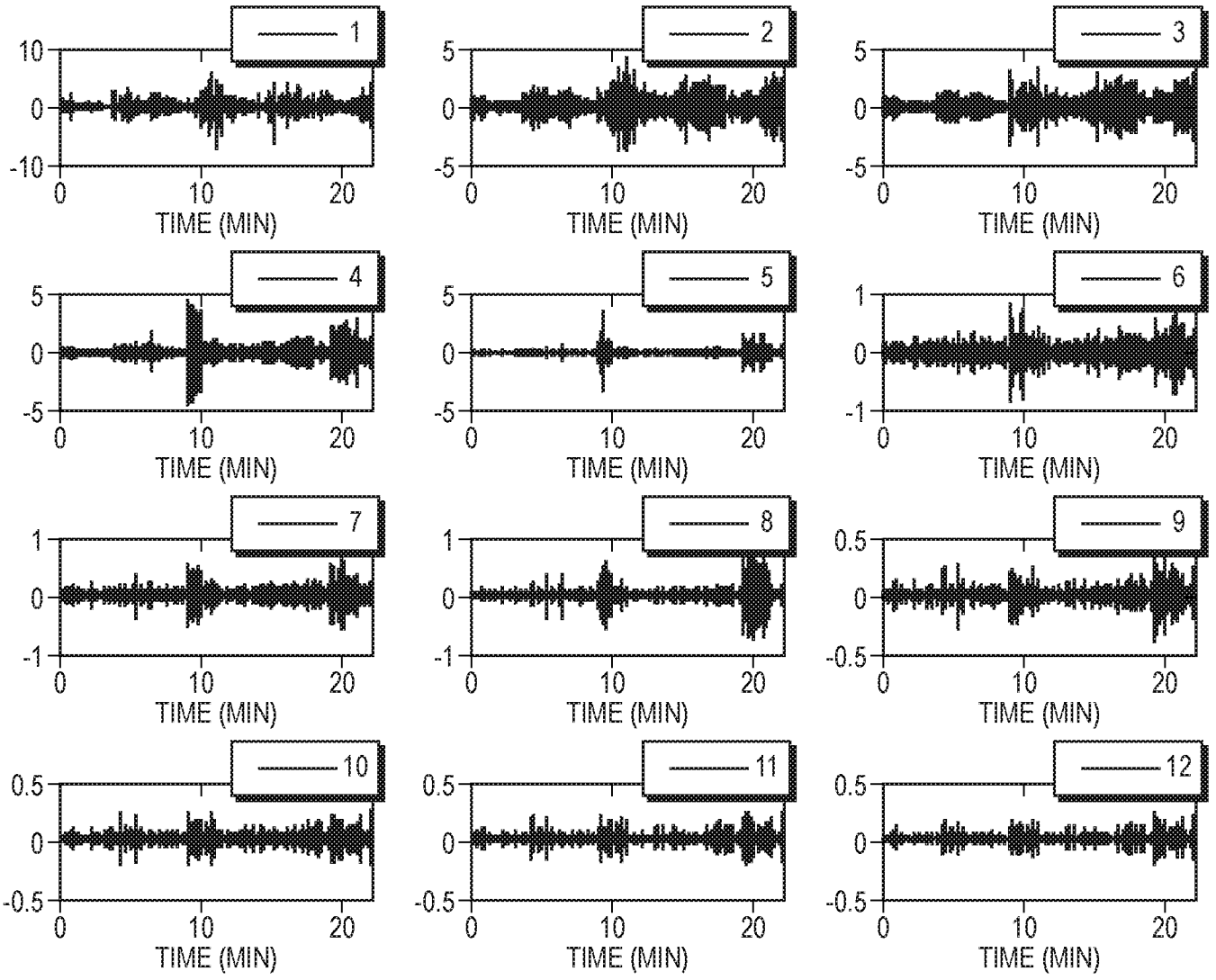


FIG. 16

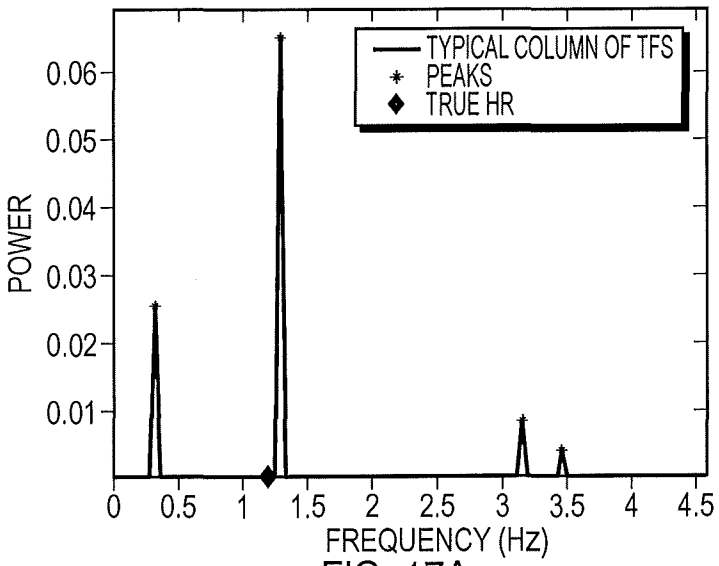


FIG. 17A

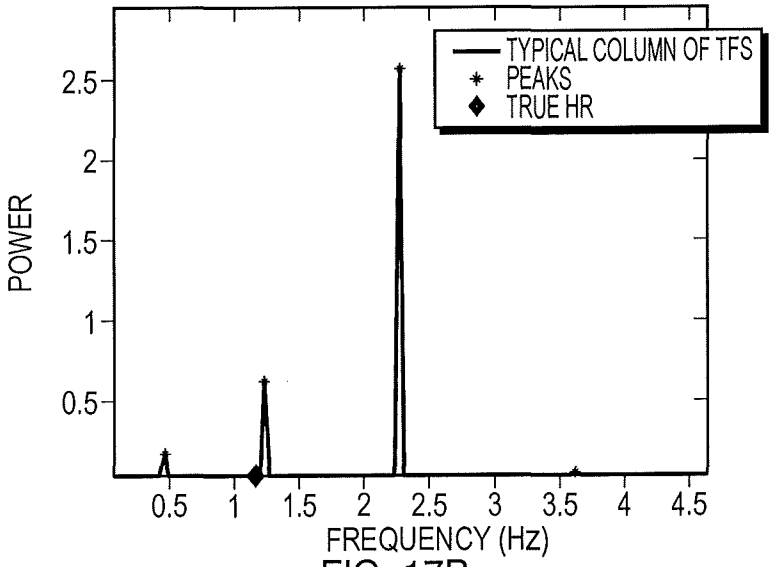


FIG. 17B

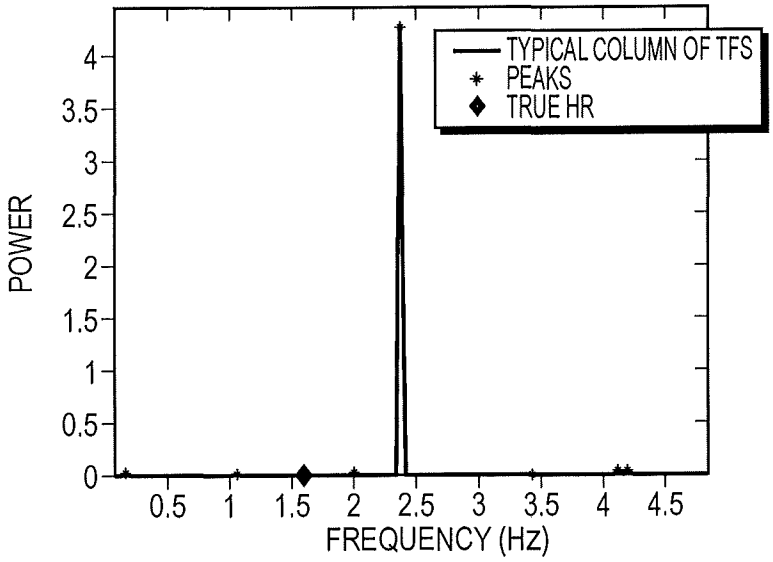


FIG. 17C

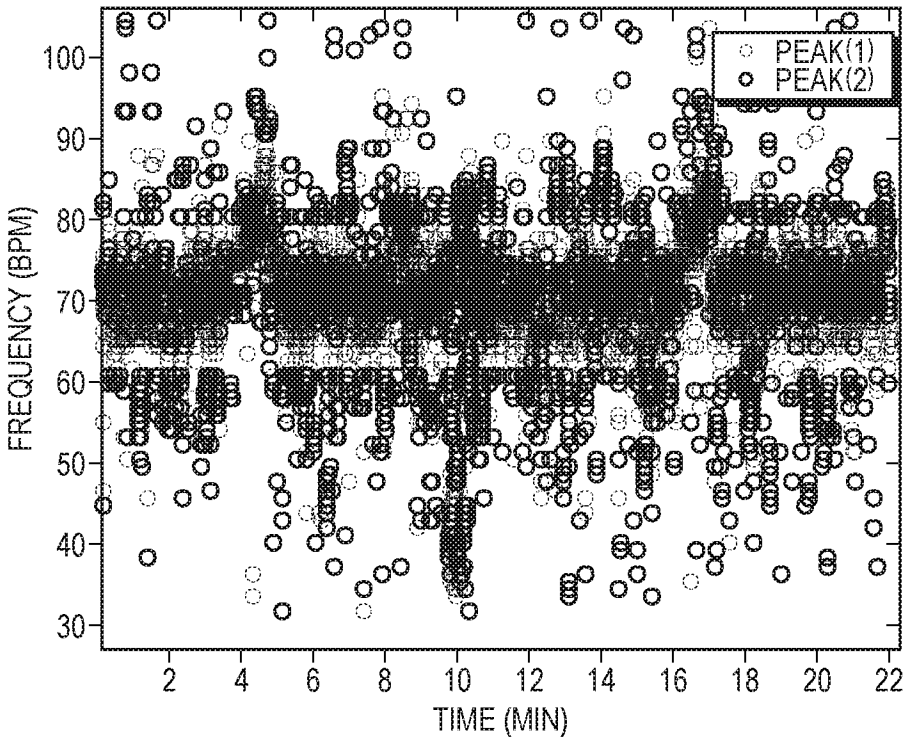


FIG. 18A

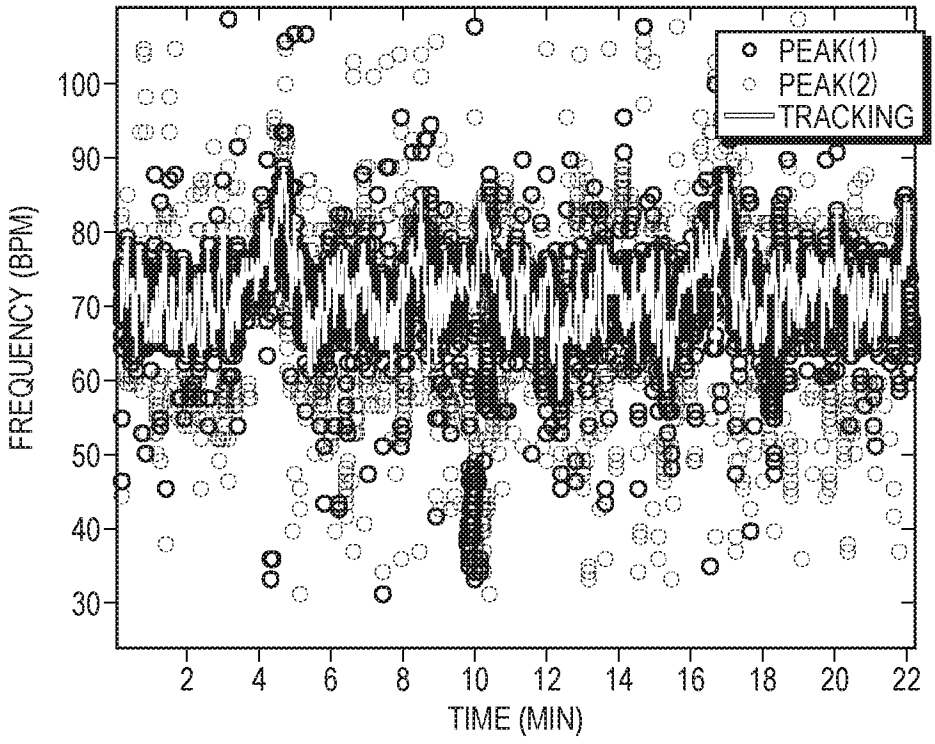


FIG. 18B

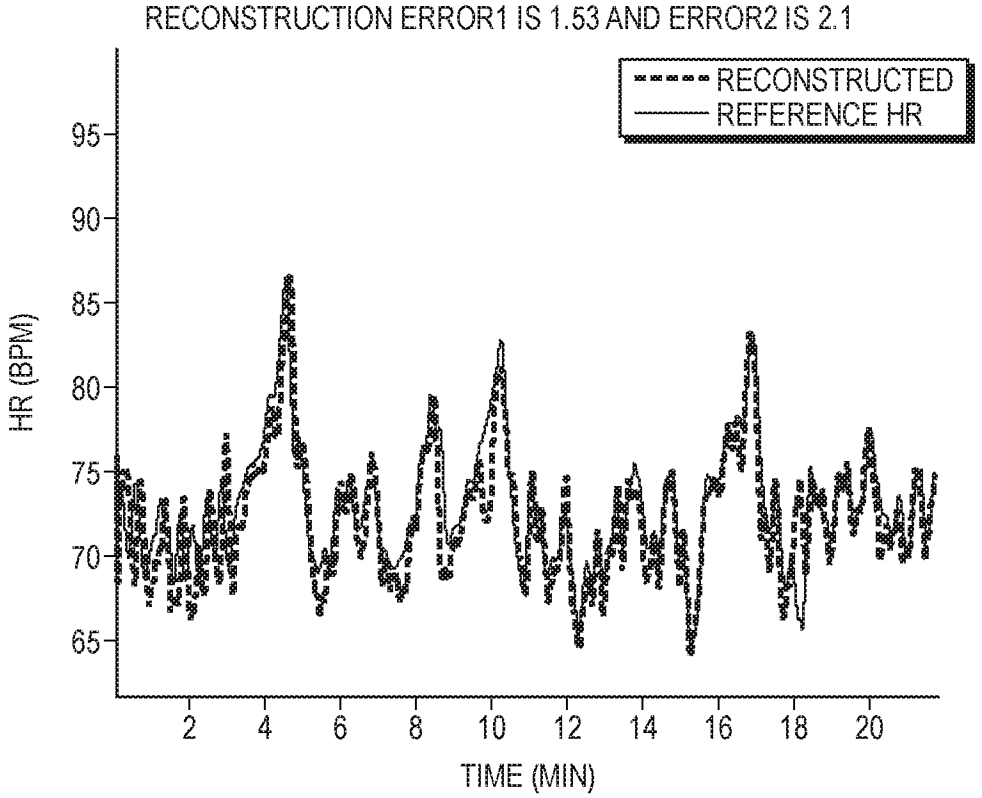


FIG. 19A

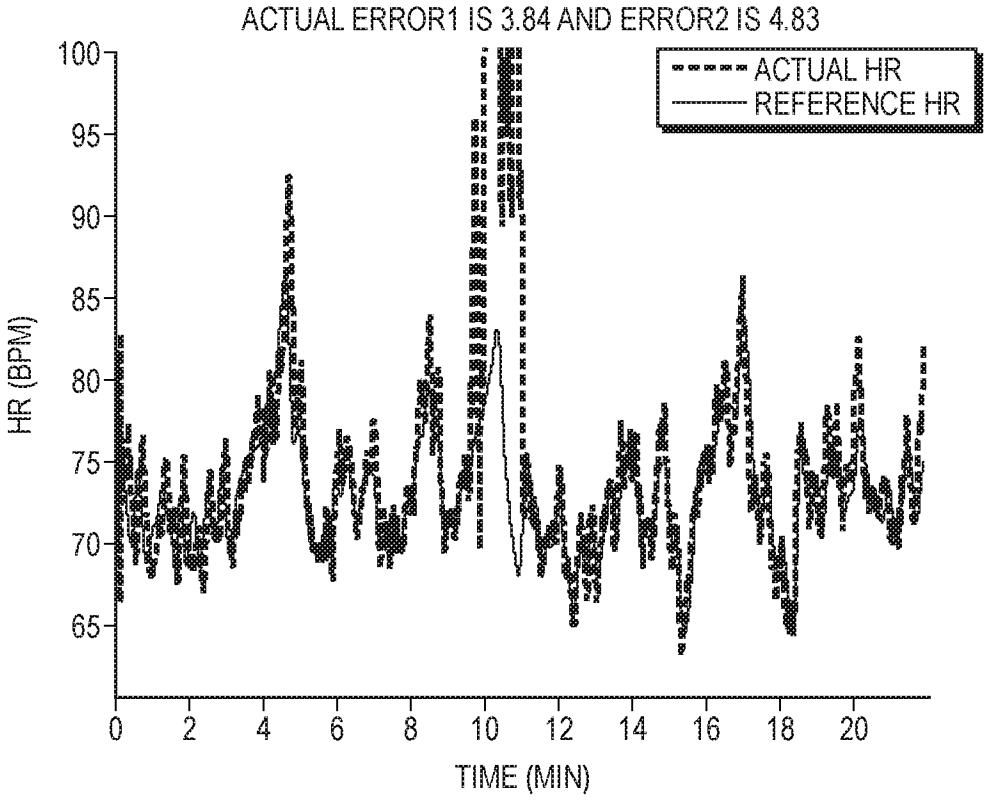


FIG. 19B

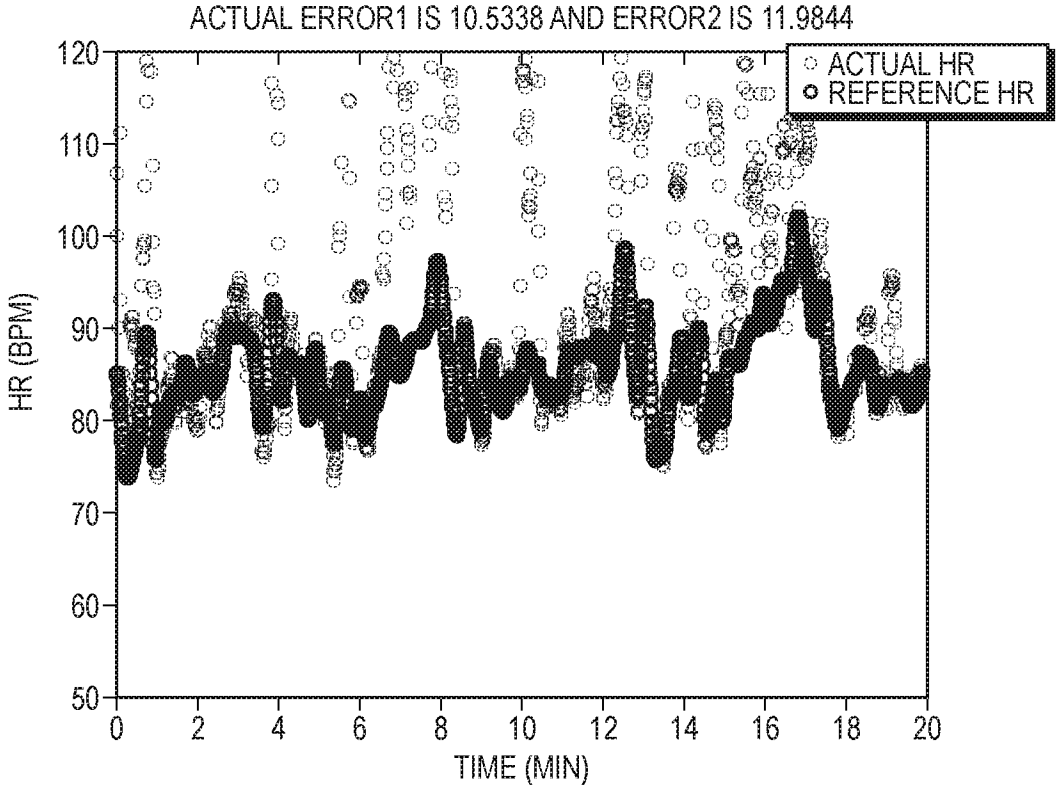


FIG. 22A

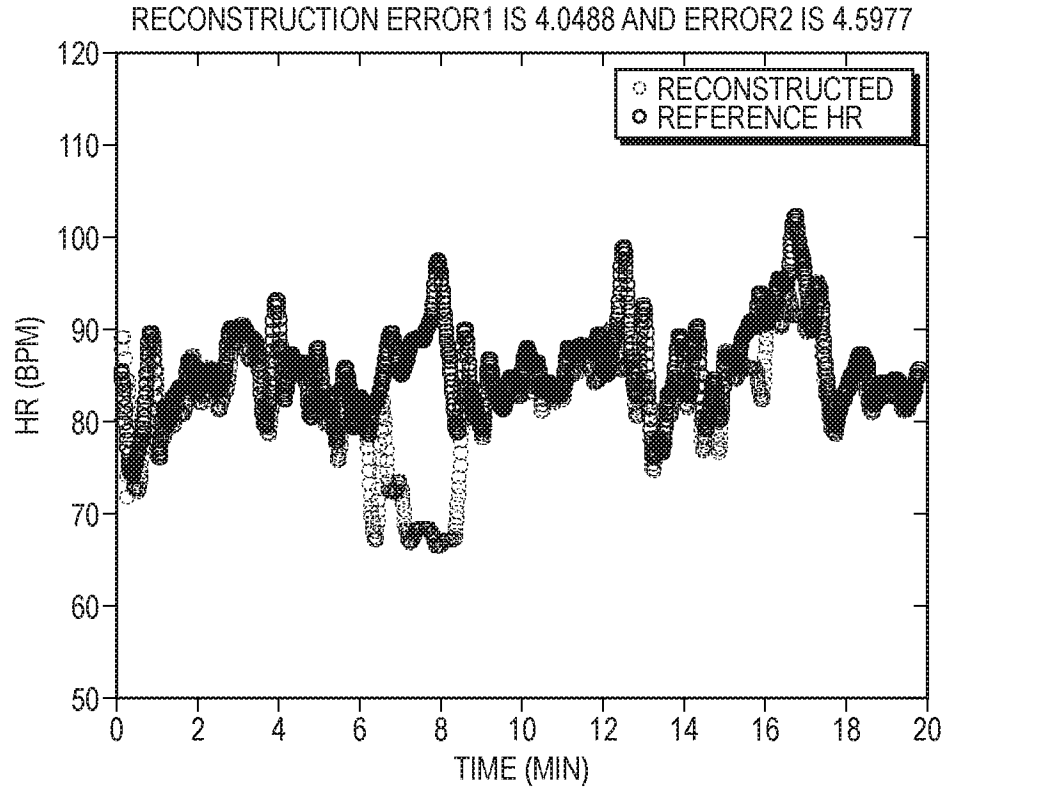


FIG. 22B

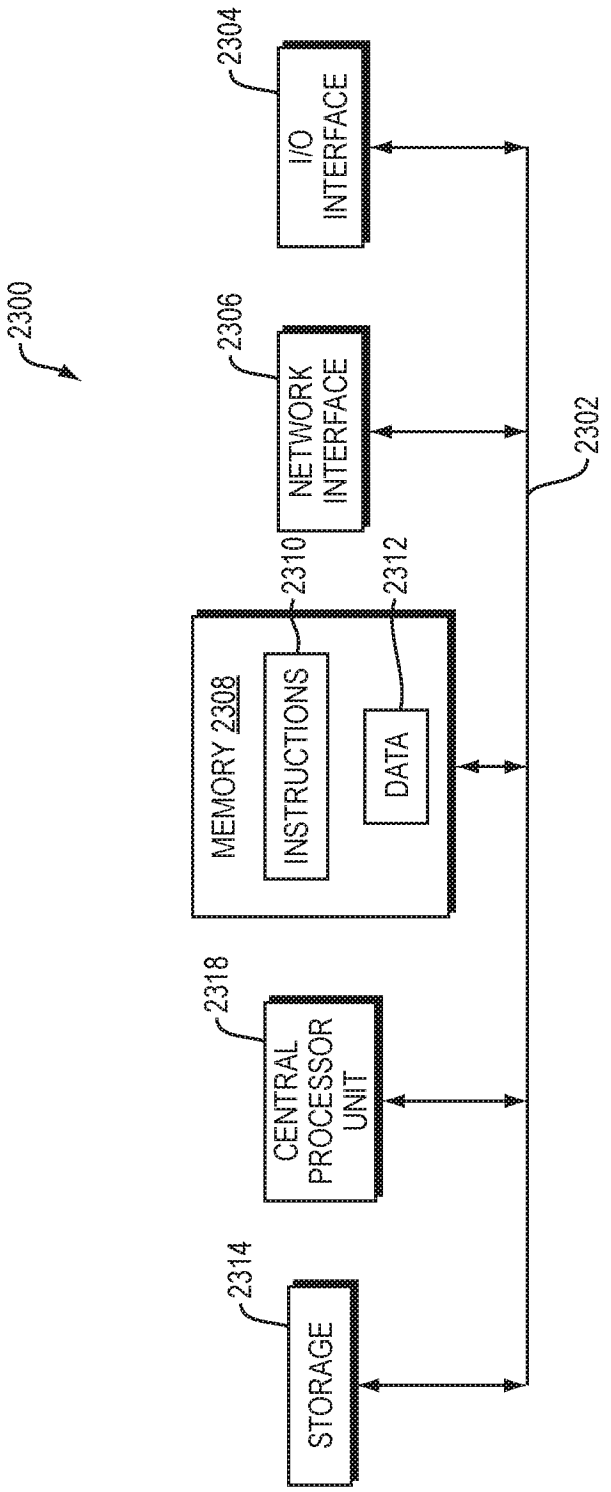

2300
2304
I/O INTERFACE
2306
NETWORK INTERFACE
2302
2310
2312
MEMORY 2308
INSTRUCTIONS
DATA
2318
CENTRAL PROCESSOR UNIT
2314
STORAGE

FIG. 23

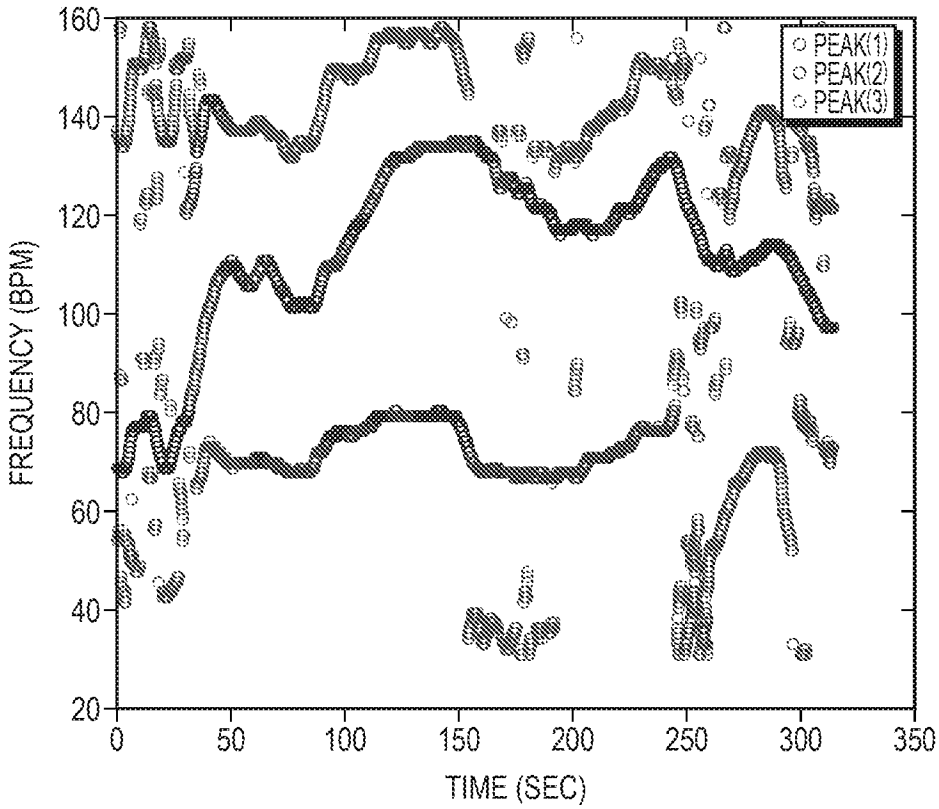

160
140
120
100
80
60
40
20
FREQUENCY (BPM)
0
50
100
150
200
250
300
350
TIME (SEC)
PEAK(1)
PEAK(2)
PEAK(3)

FIG. 7

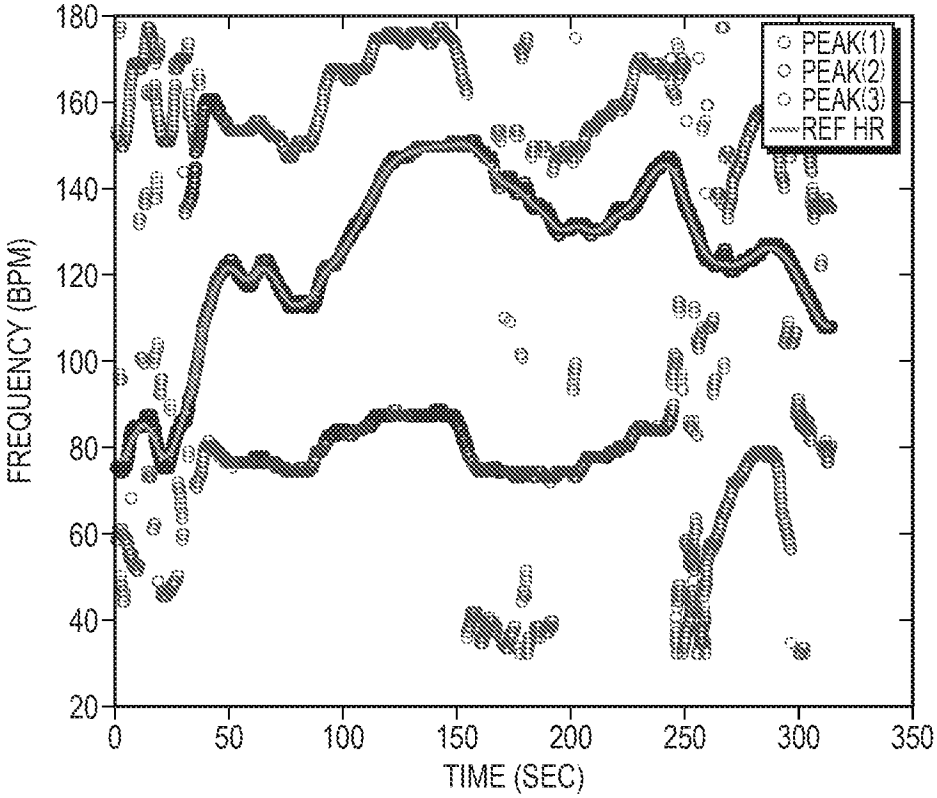

PEAK(1)
PEAK(2)
PEAK(3)
REF HR
FREQUENCY (BPM)
TIME (SEC)
180
160
140
120
100
80
60
40
20
0
50
100
150
200
250
300
350

FIG. 8A

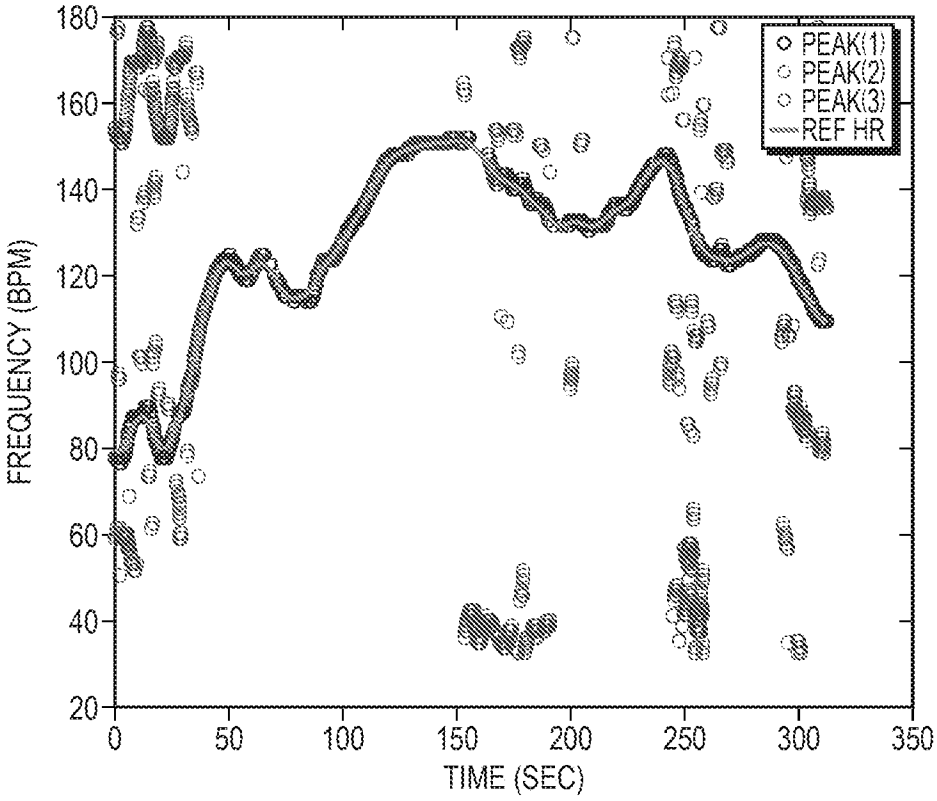

PEAK(1)
PEAK(2)
PEAK(3)
REF HR
FREQUENCY (BPM)
TIME (SEC)
180
160
140
120
100
80
60
40
20
0
50
100
150
200
250
300
350

FIG. 8B

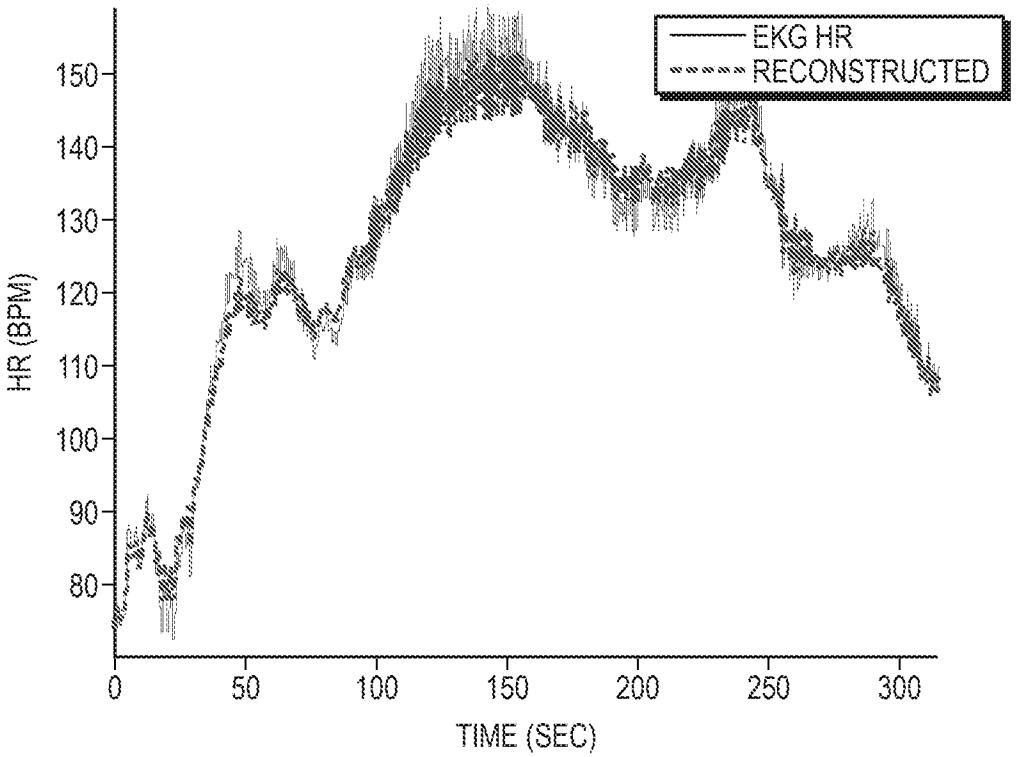


FIG. 11A

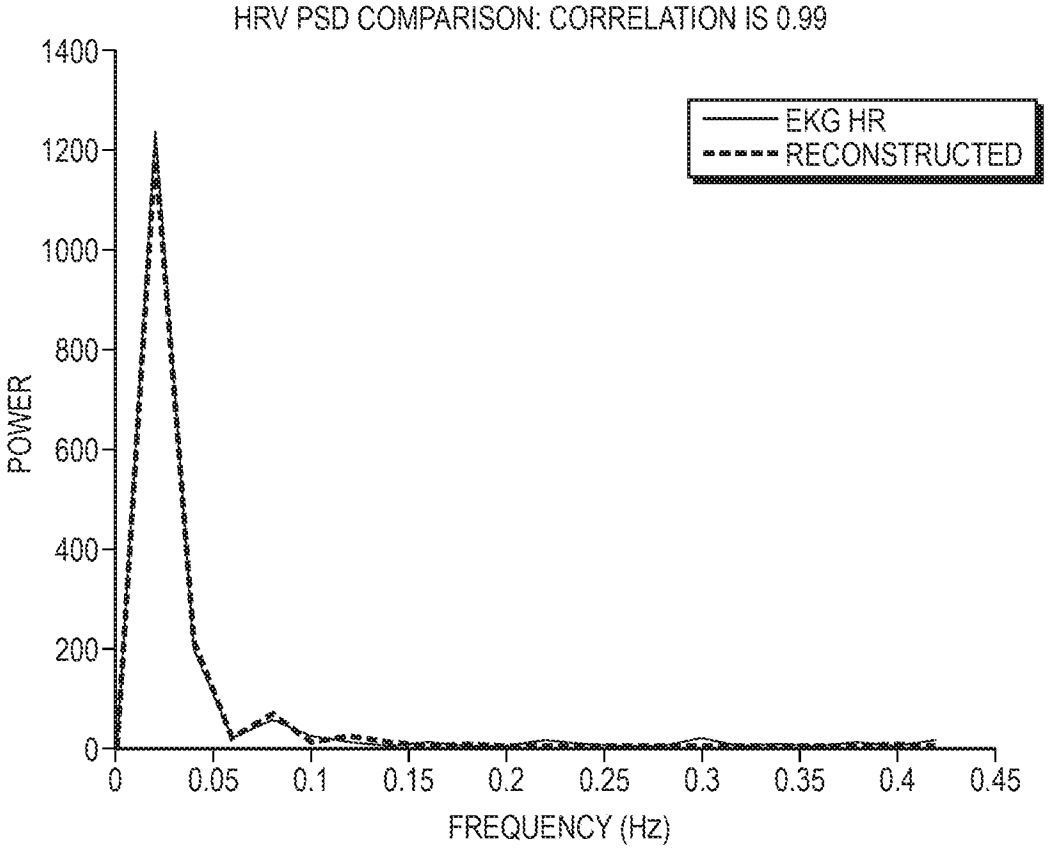


FIG. 11B

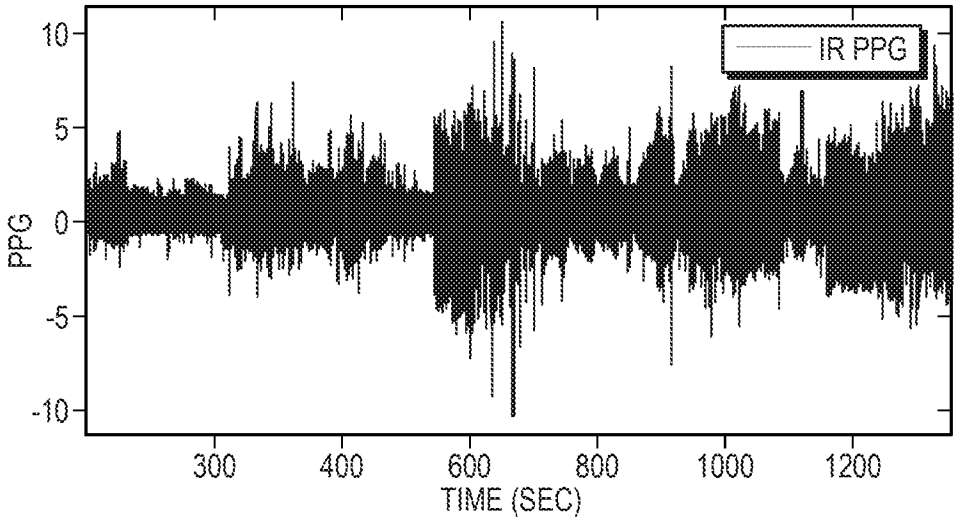


FIG. 15A

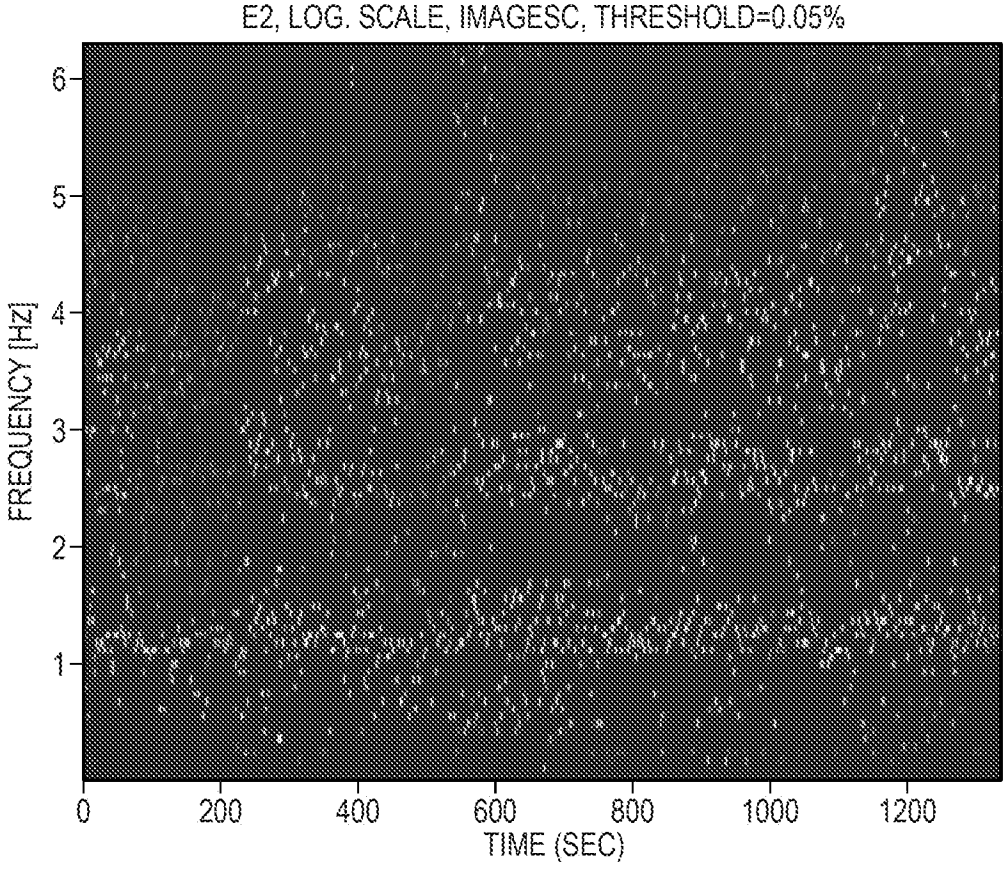


FIG. 15B

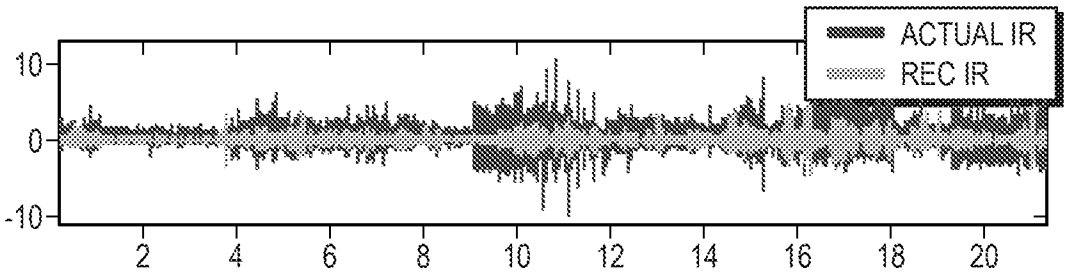


FIG. 20A

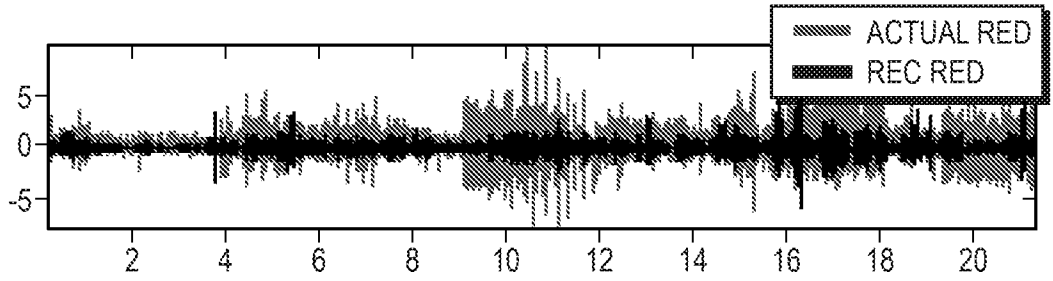


FIG. 20B

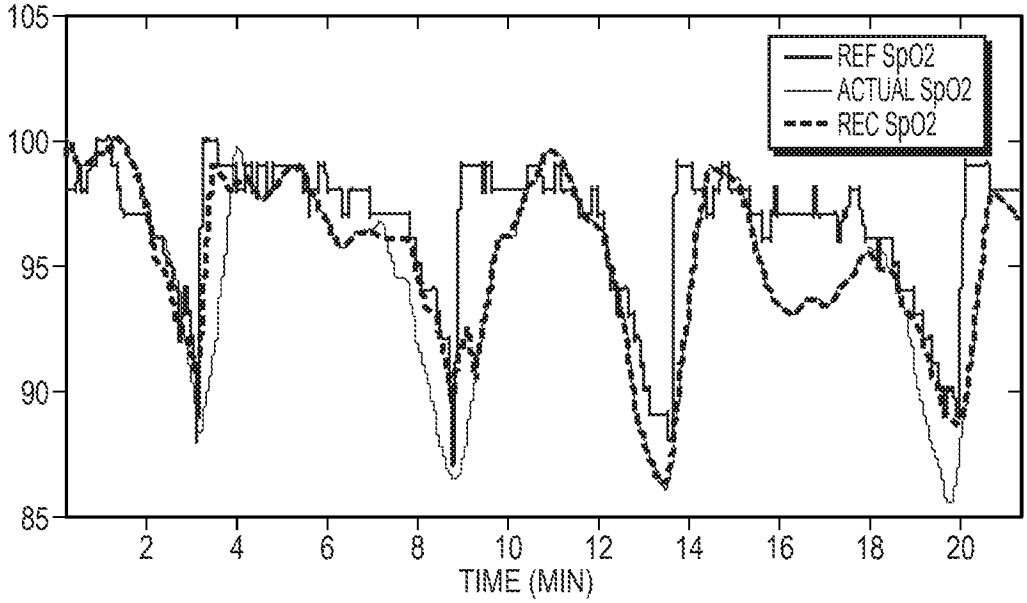


FIG. 20C

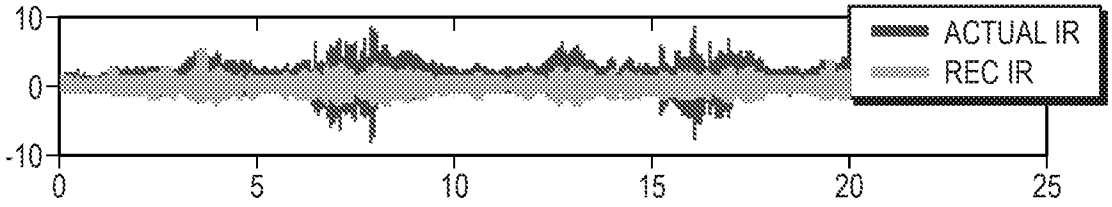


FIG. 21A

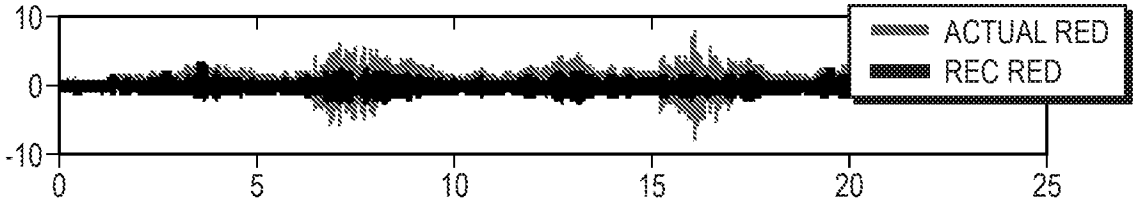


FIG. 21B

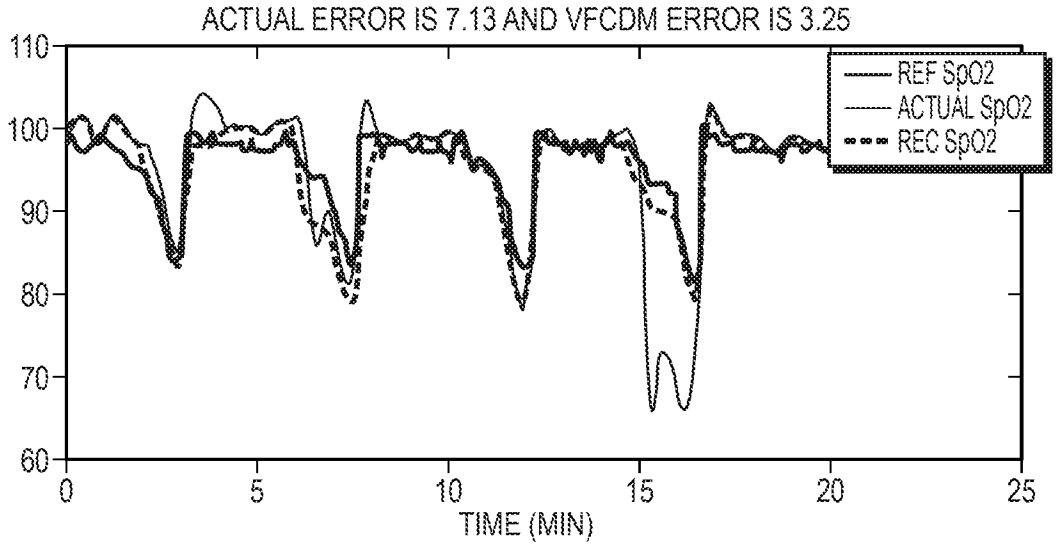


FIG. 21C

Electronic Patent Application Fee Transmittal

Application Number:	15178089
Filing Date:	09-Jun-2016
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Filer:	Mark B Solomon/Katie Norris
Attorney Docket Number:	4147.1020-002 (15-089)

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	70	70
Utility Search Fee	2111	1	300	300
Utility Examination Fee	2311	1	360	360
Pages:				
Claims:				
Claims in excess of 20	2202	53	40	2120
Miscellaneous-Filing:				
Late Filing Fee for Oath or Declaration	2051	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2920**

Electronic Acknowledgement Receipt

EFS ID:	26783966
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	30-AUG-2016
Filing Date:	09-JUN-2016
Time Stamp:	15:18:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2920
RAM confirmation Number	1728
Deposit Account	080380
Authorized User	Norris, Katie

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Charge any Additional Fees required under 37 CFR 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	41471020002POATrans.pdf	93127 7427d34f2f76a11f58fc6684fbbb644e62f5f240	no	1
Warnings:					
Information:					
2	Power of Attorney	41471020002POA.PDF	50456 788d9abbda3002cea5f1995ec5f44cd11216 3c1f	no	1
Warnings:					
Information:					
3		41471020002PreAmd.pdf	72784 6012d5523b81bd67c9dfa722d1acdc0bb1a 35930	yes	3

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Drawings-only black and white line drawings	2	2
Applicant Arguments/Remarks Made in an Amendment	3	3

Warnings:					
Information:					
4	Drawings-only black and white line drawings	41471020002AnnDrw.PDF	483537 0404e86136e2cb5836b705d337e78c8a566 54206	no	1
Warnings:					
Information:					
5	Miscellaneous Incoming Letter	41471020002Reply.pdf	117794 236b8aae1c4a6cb0299d9bc02d42c5d449e 343f8	no	3

Warnings:					
Information:					
6	Drawings-only black and white line drawings	41471020002RepDrwsBW.PDF	7115367 834a37ebe535c663fd9c4bd270e202cae0008a10	no	20
Warnings:					
The page size in the PDF is too large. The pages should be 8.5 x 11 or A4. If this PDF is submitted, the pages will be resized upon entry into the Image File Wrapper and may affect subsequent processing					
Information:					
7	Drawings-other than black and white line drawings	41471020002RepDrwsColor.pdf	1759903 49ae3cb0372d17a54db971bed5935133b23d3d98	no	6
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	38935 89ca3a27e62f86b886de26e9647d376435b2ef71	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	9731903	

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.

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B or equivalent) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5. If the Power of Attorney by Applicant form is not accompanied by this transmittal form or an equivalent, the Power of Attorney will not be recognized in the application.

Application Number	15/178,089
Filing Date	June 9, 2016
First Named Inventor	Seyed M. A. Salehizadeh
Title	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals
Art Unit	3766
Examiner Name	Not Yet Assigned
Attorney Docket Number	4147.1020-002

SIGNATURE of Applicant or Patent Practitioner

Signature	/Mark B. Solomon, Reg. No. 44348/	Date	8/30/2016
Name	Mark B. Solomon	Telephone	(978) 341-0036
Registration Number	44,348		

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

☒ *Total of 1 forms are submitted.

Docket No.: 4147.1020-002 (15-089)

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in U.S. Application No. 15/178,089 filed on June 9, 2016.

☒ I hereby appoint Practitioners associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

021005

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A or equivalent):

Name	Registration Number		Name	Registration Number

Please recognize or change the correspondence address for the above-identified patent to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box below):

University of Connecticut

☐ Inventor or Joint Inventor (title not required below)
☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
☐ Person Who Otherwise Shows Sufficient Proprietary Interest (*e.g.*, a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document)(provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent
The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity)

Signature	Charles D. Goodwin	Date	6-29-2016
Name	Charles D. Goodwin, Ph.D	Telephone	860-679-4536
Title	Director of Intellectual Property		

☒ Total of 1 forms are submitted

SCORE Placeholder Sheet for IFW Content

Application Number: 15178089 Document Date: 08/30/2016

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

- Drawings – Other than Black and White Line Drawings

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

To access the documents in the SCORE database, refer to instructions below.

At the time of document entry (noted above):

- Examiners may access SCORE content via the eDAN interface.
- Other USPTO employees can bookmark the current SCORE URL (http://Score.uspto.gov/ScoreAccessWeb/).
- External customers may access SCORE content via the Public and Private PAIR interfaces.

Form Revision Date: September 30, 2013

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/178,089	06/09/2016	3766	2920	4147.1020-002 (15-089)	73	3

CONFIRMATION NO. 7605

UPDATED FILING RECEIPT

21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133



Date Mailed: 09/09/2016

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Seyed M. A. Salehizadeh, Coventry, CT;
Ki H. Chon, Mansfield Center, CT;
Yeonsik Noh, Willington, CT;

Applicant(s)

University of Connecticut, Farmington, CT;

Power of Attorney: The patent practitioners associated with Customer Number 021005

Domestic Priority data as claimed by applicant

This appln claims benefit of 62/299,944 02/25/2016
and claims benefit of 62/172,862 06/09/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/28/2016

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/178,089**

Projected Publication Date: 12/15/2016

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/178,089	06/09/2016	Seyed M. A. Salehizadeh	4147.1020-002 (15-089)

CONFIRMATION NO. 7605

21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

INFORMAL NOTICE

OC000000085640207

Date Mailed: 09/09/2016

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Seyed M. A. Salehizadeh
  Ki H. Chon
  Yeonsik Noh

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**.

/ebekele/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/178,089

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	70		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	360		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	73 minus 20 =	* 53	x 40 =	2120	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 210 =	0.00			
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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	2850		TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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 found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/178,089	06/09/2016	Seyed M. A. Salehizadeh	4147.1020-002 (15-089)

CONFIRMATION NO. 7605

POA ACCEPTANCE LETTER

21005
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

OC000000085640080

Date Mailed: 09/09/2016

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/30/2016.

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**.

/ebekele/

Substitute for form 1449B/PTO **INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** October 21, 2016 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER	CONFIRMATION NO. 7605	GROUP 3766

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	2008/0109041 A1	05-08-2008	de Voir
	2.	2009/0069703 A1	03-12-2009	Takla, *et al.*
	3.	2011/0066041 A1	03-17-2011	Pandia, *et al.*
	4.	2012/0123232 A1	05-17-2012	Najarian, *et al.*
	5.			
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	17.			
	18.			

Copies of issued U.S. Patents and Published U.S. Applications are not required and are not being provided. We are not listing separately any prior U.S. Patent Office communications regarding the cited documents because the Examiner has access to any such actions through PAIR.

EXAMINER	DATE CONSIDERED

Substitute for form 1449B/PTO **INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** October 21, 2016 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER	CONFIRMATION NO. 7605	GROUP 3766

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	WO 03/000125	01-03-2003	Cardiodigital Limited
	2.	EP 1 724 684	11-22-2006	BUSI Incubateur d'entreprises
	3.	WO 2012/100175	07-26-2012	Worcester Polytechnic Institute
	4.	EP 2 792 297	10-22-2014	Stichting IMEC Nederland
	5.			
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	20.			

EXAMINER	DATE CONSIDERED

Petitioner Ex. 1004, 0179

Substitute for form 1449B/PTO **INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** October 21, 2016 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER	CONFIRMATION NO. 7605	GROUP 3766

Examiner's Initials	Cite No.	**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*
	1.	Zhang, *et al.*, "Novel QRS Detection by CWT for ECG Sensor," *Biomedical Circuits and Systems Conference* pages 211-214 (2007).
	2.	
	3.	
	4.	
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	17.	

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EXAMINER	DATE CONSIDERED

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 January 2003 (03.01.2003)

PCT

(10) International Publication Number
WO 03/000125 A1

(51) International Patent Classification[7]: A61B 5/00, G06F 17/00

(21) International Application Number: PCT/GB02/02843

(22) International Filing Date: 21 June 2002 (21.06.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0115284.2 22 June 2001 (22.06.2001) GB
0206382.4 19 March 2002 (19.03.2002) GB

(71) Applicant *(for all designated States except US)*: **CARDIODIGITAL LIMITED** [GB/GB]; 18 Blantyre Terrace, Edinburgh EH10 5AE (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ADDISON, Paul, Stanley** [GB/GB]; 58 Buckstone Crook, Edinburgh EH10 6UR (GB). **WATSON, James, Nicholas** [GB/GB]; 116 Lochview Drive, Hogganfield, Glasgow G33 1QF (GB).

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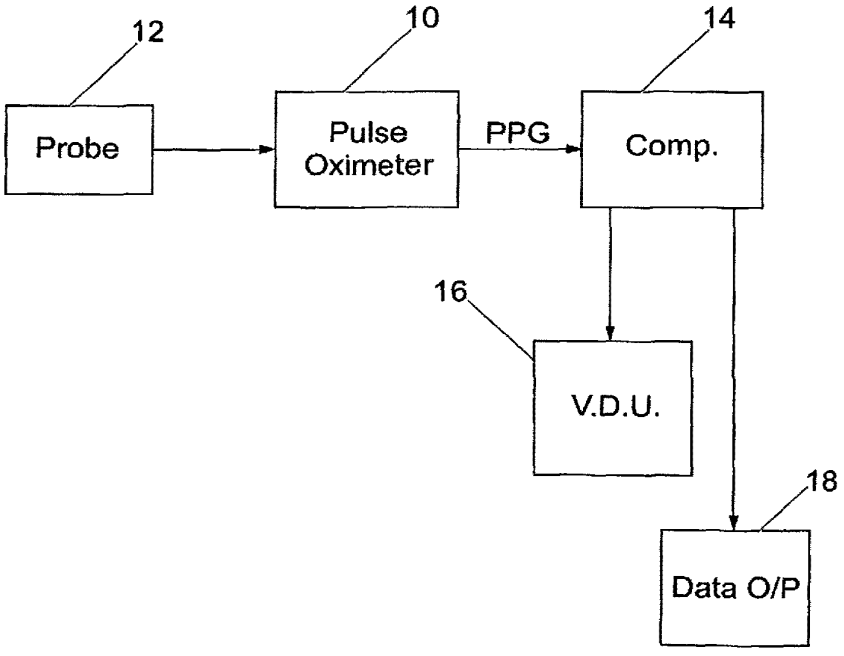
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT,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

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: WAVELET-BASED ANALYSIS OF PULSE OXIMETRY SIGNALS



(57) Abstract: A pulse oximetry signal, suitably a photoplethysmogram (PPG), is decomposed by wavelet transform techniques, and the decomposed signal analysed to provide selected physiological data. The signal may be processed to remove noise, artefacts, or transient features. Information on respiration may also be recovered.

WO 03/000125 A1

BNSDOCID: <WO_____03000125A1_I_>

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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.

BNSDOCID: <WO_____03000125A1_I_>

'Wavelet-Based Analysis of Pulse Oximetry Signals'

Field of Invention

The present invention relates to a method of analysis of medical signals, and in particular to a method of decomposition of signals used in pulse oximetry. Specifically the invention relates to an improved method of denoising such signals and in the extraction of clinically useful information from such signals including the monitoring and analysis of patient respiration.

Background

Oximetry is an optical method for measuring oxygenated haemoglobin in blood. Oximetry is based on the ability of different forms of haemoglobin to absorb light of different wavelengths. Oxygenated haemoglobin (HbO_2) absorbs light in the red spectrum and deoxygenated or reduced haemoglobin (RHb)

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absorbs light in the near-infrared spectrum. When red and infrared light is passed through a blood vessel the transmission of each wavelength is inversely proportional to the concentration of HbO_2 and RHb in the blood.

Pulse oximeters can differentiate the alternating light input from arterial pulsing from the constant level contribution of the veins and other non-pulsatile elements. Only the alternating light input is selected for analysis. Pulse oximetry has been shown to be a highly accurate technique.

The contemporary pulse oximeter unit normally provides three outputs:

1. the arterial oxygen saturation
2. the heart rate
3. a fluctuating time series - the pulse oximeter trace or *plethysmographic waveform*

The normal pulse oximeter waveform - the photoplethysmogram (PPG) - bears a strong resemblance to an arterial pressure waveform complete with dichrotic notch. A schematic of a typical pulse oximeter trace from a finger probe is shown in Figure 1a. The repeating double humped (with a notch A in-between) nature of the waveform is evident in the plot. Often, the second hump disappears and a signal such as that in Figure 1b is obtained. This may indicate a clinical condition such as reduced arterial compliance. Often, for this

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type of signal, there is a marked change in the gradient of the falling waveform (i.e. a kink) as indicated by the arrow B in the plot.

Figure 2 contains a plot of three simultaneously acquired signals acquired from a patient. These are: a finger pulse oximetry trace, an ear pulse oximetry trace and an ECG. These 10 second segments have been cut from a much longer signal. Note the significant drift associated with the pulse oximetry traces.

Summary of the Invention

The invention provides a method of measuring physiological parameters, as defined in claim 1, and also provides a method of processing a pulse oximetry signal, as defined in claim 2.

From another aspect, the invention provides a physiological measurement system as defined in claim 22.

Preferred features and advantages of the invention will be apparent from the other claims and from the following description.

The invention in its preferred forms provides a method for the decomposition of pulse oximetry signals using wavelet transforms which allows for underlying characteristics which are of clinical use to be displayed and measured. The method utilises wavelet transforms to decompose the signal in

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wavelet space. The wavelet decomposition of one or more or a combination of signals can then be used to:

(a) construct a wavelet visualisation of the signal - the preferred method being that which uses wavelet energy surfaces plotted against the location parameter *b* and the inverse of the dilation parameter *a*. This visualisation would highlight salient information in a more useful form for clinical diagnosis (e.g. see 2D and 3D scalograms in figures described below). This form of information presentation should facilitate the interpretation of such signals. It is envisaged that the clinician would be provided with a real time display of the scalogram.

(b) provide, through the position and amplitude of features in the scalogram, measurable characteristics of the signal for estimation of the health of the monitored patient. These characteristics may include wavelet-based parameters, including ratios, for the determination of oxygen saturation. This is important for the determination of the correct therapy for the patient.

(c) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) a method for measuring the cardiovascular system compliance.

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(d) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) a method for detecting the presence and location of pertinent features (e.g. maxima, minima, notch, kink, etc.) and timescales within the pulse oximetry signal and use of this information for a clinically useful purpose.

(e) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) a method for identifying features of the wavelet power spectrum which can be used as clinical markers of the health of the patient at the time of data collection

(f) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) a method for identifying features which can be used as clinical markers of the future health of the patient, that is as markers of the subsequent deterioration or improvement of the health of the patient. These markers will be incorporated within a prediction algorithm.

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(g) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) a method for detecting and monitoring the patient breathing signal. This method would be suitable for the monitoring the regularity of the breathing pattern and patient breathing rate where high levels of noise and erroneous artefact affects the signal. This information to be used in conjunction with other relevant clinical information for clinically useful purposes.

(h) provide, using information derived from the wavelet transform (i.e. from the transform, scalogram (energy density) normalised scalogram, wavelet power spectrum, modulus maxima, wavelet ridges, phase representation, etc.) an accurate method for detecting and monitoring the patient breathing rate. This information to be displayed on the pulse oximeter device. This information to be used in conjunction with other relevant clinical information for clinically useful purposes.

(i) provide a method for the disassociation of artefact from the pertinent signal components, where artefact includes noise, coherent signal, movement artefact and if required breathing artefact. The preferred method of performing this would be a modulus maxima technique.

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(j) provide a method for the classification of the current status of the patient's health based on the wavelet transform features and incorporating a suitable classification method. The optimal combination of features will be employed. The classification methods may include non-parametric Bayesian classification methods, neural networks, etc. and also include preprocessing discriminant analysis techniques such as principle component analysis and/or linear discriminant analysis for reducing the dimensionality of multidimensional data.

(k) provide a method for the prediction of the future status of the patient's health based on the wavelet transform features and incorporating a suitable classification method. The optimal combination of features will be employed. The classification methods may include non-parametric Bayesian classification methods, neural networks, etc. and also include preprocessing discriminant analysis techniques such as principle component analysis and/or linear discriminant analysis for reducing the dimensionality of multidimensional data.

Embodiments of the invention will now be described, by way of example only, with reference to the drawings:

Figure 1(a): Arterial Pulse and Pulse Oximetry Signal, as discussed above.

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Figure 1(b) Arterial Pulse and Pulse Oximetry Signal, as discussed above.

Figure 2: The Three Collected traces: Top - Ear pulse oximetry signal, Middle - Finger pulse oximetry signal, Lower - ECG.

Figure 3(a): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10 minutes into the recording. Top: the pulse oximetry trace. Bottom: the scalogram. Standard Morlet wavelet with ω_0=5.5

Figure 3(b): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10 minutes into the recording. The Phase plot. Standard Morlet wavelet with ω_0=5.5

Figure 3(c): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10 minutes into the recording. Top: the modulus maxima plot. Bottom: the ridge plot. Standard Morlet wavelet with ω_0=5.5

Figure 3(d): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10 minutes into the recording. Top: the pulse oximetry trace. Bottom: the scalogram. Complete Morlet wavelet with ω_0=3

Figure 3(e): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10

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minutes into the recording. The Phase plot. Complete Morlet wavelet with ω_0=3

Figure 3(f): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the ear 10 minutes into the recording. Top: the modulus maxima plot. Bottom: the ridge plot. Complete Morlet wavelet with ω_0=3

Figure 4(a): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. Top: the pulse oximetry trace. Bottom: the scalogram. Standard Morlet wavelet with ω_0=5.5

Figure 4(b): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. The Phase plot. Standard Morlet wavelet with ω_0=5.5

Figure 4(c): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. Top: the modulus maxima plot. Bottom: the ridge plot. Standard Morlet wavelet with ω_0=5.5

Figure 4(d): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. Top: the pulse oximetry trace. Bottom: the scalogram. Complete Morlet wavelet with ω_0=3

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Figure 4(e): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. The Phase plot. Complete Morlet wavelet with ω_0=3

Figure 4(f): Wavelet analysis of a 2 second segment of pulse oximetry signal taken from the finger 10 minutes into the recording. Top: the modulus maxima plot. Bottom: the ridge plot. Complete Morlet wavelet with ω_0=3

Figure 5: Region Segmentation in Phase Space

Figure 6(a): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=5.5. Original Signal.

Figure 6(b): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=5.5. Scalogram

Figure 6(c): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=5.5. Phase Plot

Figure 6(d): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=5.5. Cropped Scalogram

Figure 6(e): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=5.5. The original trace (top); the reconstructed trace (middle); the denoised and detrended trace (bottom).

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Figure 7(a): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=2. Original Signal.

Figure 7(b): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=2. Phase Plot

Figure 7(c): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=2. Original and reconstructed signals

Figure 7(d): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=2. Blow up of Figure 7(c)

Figure 7(e): Wavelet Denoising and Detrending. Morlet Wavelet ω_0=2. Three different high frequency cut-off thresholds - increasing from top to bottom.

Figure 8(a): Scalogram showing the breathing ridge

Figure 8(b): A Collapsed Scalogram showing the breathing and heart rates.

Figure 9(a): The Analysis of a Plethysmogram Breathing Experiment Sub-Study:Pulse oximeter trace.

Figure 9(b): The Analysis of a Plethysmogram Breathing Experiment Sub-Study: The Modulus of the trace in Figure 9(a) showing ridges associated with pulse and breathing.

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Figure 9(c): The Analysis of a Plethysmogram Breathing Experiment Sub-Study: the phase associated with the breathing ridges in Figure 9(b).

Figure 10(a): Phase following of respiration

Figure 10(b): Showing the steps of constant phase minima across scales.

Figure 11(a): Frequency Modulation of the dominant cardiac frequency bands

Figure 11(b): Amplitude Modulation of the dominant cardiac frequency bands

Figure 11(c): Individual Breathing features resolved using a low oscillation wavelet (One such feature indicated by arrow.)

Figure 12: A schematic diagram of the signal, its transformation as a scalogram, the associated wavelet power spectrum.

Figure 13: Partitioning of the test data. Power is plotted against entropy at the frequency levels given. An arbitrary separation line has been plotted (dashed) in the plot.

Figure 14(a): Graphical illustration of Bayesian Classification of 'ill' and 'healthy' data sets.

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Figure 14(b): Graphical illustration of Bayesian Classification of 'ill' and 'healthy' data sets

Figure 15: Top: PPG signal. Lower Plot: The wavelet transform modulus maxima plot corresponding to the signal.

Figure 16: Top: A raw PPG signal. Lower Plot: The wavelet transform (threshold) filtered trace with individually isolated freatures of the trace marked by vertical lines.

Figure 17: A block schematic of an exemplary system for implementing the method of the invention.

The Wavelet transform

Wavelet transforms allow a signal to be decomposed such that both the frequency characteristics and the location of particular features in a time series may be highlighted simultaneously. This overcomes the basic shortcoming of Fourier analysis, where the spectrum only contains globally averaged information thus leading to location specific features in the signal being lost. The complete analysis of a signal requires the deduction of both the frequency make up and temporal location of the signal components. The limitation of Fourier (spectral-only) methods can be partly overcome by introducing a sliding time window which localises the analysis in time. This local or Short Time Fourier Transform (STFT) provides a degree of temporal resolution by highlighting

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changes in spectral response with respect to time. However, this method is always a compromise between temporal and frequency resolution (higher frequency resolution means lower temporal resolution, and vice versa) due to the fixed window width associated with it. The nature of the wavelet transform is such that it is well suited to the analysis of signals in which a more precise time resolution is required for higher frequencies than for lower ones. By employing a variable width window, it effectively zooms in on the temporal signal when analysing higher frequencies, providing higher resolution where necessary.

The wavelet transform of a continuous real-valued time signal, $x(t)$, with respect to the wavelet function, ψ, is defined as

$$T(a,b) = \frac{1}{\sqrt{a}} \int_{-\infty}^{\infty} \psi^* \left(\frac{t-b}{a} \right) x(t) dt \qquad (1)$$

where t is time, a is the dilation parameter, b is the location parameter, $\psi^*((t-b)/a)$ is the complex conjugate of the analysing wavelet used in the convolution and $x(t)$ is the signal under investigation which, in this application, is the PPG signal obtained from the pulse oximeter. The wavelet transform can therefore be thought of as the cross-correlation of the analysed signal with a wavelet function that has been translated by a value b and dilated by a factor a.

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Contemporary literature suggests two methods of wavelet analysis using either *discrete* or *continuous* transforms. The *discrete* wavelet transform necessitates the use of orthonormal wavelets, and dilation levels are set in the form of integer powers of two. This provides a rapid method of signal decomposition, and guarantees energy conservation and exact signal reconstruction. However, the discrete transform is limited by loss of both time and frequency resolution due to the dyadic nature of the transform. Conversely, the *continuous* wavelet transform does provide high resolution. Thus, proper use of wavelet analysis demands identification of the correct wavelet and transform type for the given application. The inherent redundancy in the continuous wavelet method, although computationally more intensive, increases clarity in the transform space and allows for greater temporal resolution at high dilations. For this reason we prefer to employ a continuous wavelet transform in our method. Note that in practice a discretised approximation to the continuous wavelet transform integral may be employed based on the FFT algorithm where the wavelet convolution in (1) is performed as a product in Fourier space (via the convolution theorem) hence speeding up the computation.

Any wavelet function may be used in the analysis. In the examples given here we employ complex Morlet wavelets. We define the complete Morlet wavelet as

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$$\psi(t) = \frac{1}{\sqrt[4]{\pi}}\left(e^{i\omega_o t} - e^{-\frac{\omega_o^2}{2}}\right)e^{-\frac{t^2}{2}} \qquad (2)$$

where ω_o is the central frequency of the mother wavelet, t is time, i is the complex number $(-1)^{1/2}$. The second term in the brackets is known as the correction term, as it corrects for the non-zero mean of the complex sinusoid of the first term. In practice it becomes negligible for values of $\omega_o > 5$. Most investigators concentrate on wavelet transforms with ω_o in the range 5~6, where it can be performed without the correction term since it becomes very small. In this case, the Morlet wavelet becomes

$$\psi(t) = \frac{1}{\sqrt[4]{\pi}} e^{i\omega_o t} e^{-\frac{t^2}{2}} \qquad (3)$$

This truncated Morlet wavelet is invariably used in the literature and often referred to as simply the *Morlet wavelet*. Here we use the name, 'standard Morlet wavelet', for this simplified form of equation 3 and 'complete Morlet wavelet', for the complete form given by equation 2.

Modulus maxima and ridges correspond to loci of local maxima and minima in the wavelet transform. These are useful in detecting singularities and following instantaneous frequencies. A vast amount of information is contained within the continuous wavelet transform $T(a,b)$. This can be condensed

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considerably by considering only local maxima and minima of the transform. Two definitions of these maxima are commonly used in wavelet analysis practice, these are:

1 - Wavelet *ridges*, defined as

$$\frac{d\left(\left|T(a,b)^2\right|/a\right)}{da}=0 \qquad (4)$$

which are used for the determination of instantaneous frequencies and amplitudes of signal components. Notice that this definition of a ridge uses the rescaled scalogram $|T(a,b)|^2/a$ as it leads to a simpler analytical solution relating the ridge to the instantaneous frequency when a standard Morlet wavelet is employed as the analysing wavelet.

2 - Wavelet *modulus maxima*, defined as

$$\frac{d\,|T(a,b)|^2}{db}=0 \qquad (5)$$

are used for locating and characterising singularities in the signal. (Note that equations 4 and 5 also include inflection points with zero gradient. These can be easily removed when implementing the modulus maxima method in practice.)

In the present invention described here we use modulus maxima and ridges as defined above, however, any reasonable definition of the loci of the maxima

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and minima of the transform may be incorporated within the method.

Details of the Method

Figures 3 and 4 show some results from preliminary wavelet analysis undertaken on short segments of pulse oximeter traces. Figure 3 corresponds to an ear probe signal and Figure 4 to a finger probe signal.

The left hand column (Figures 3(a),3(b),3(c), 4(a),4(b),4(c)) in each figure corresponds to the analysis performed using the standard Morlet wavelet with ω_0=5.5 and the right hand column (Figures 3(d),3(e),3(f),4(d),4(e),4(f)) corresponds to the analysis performed using the complete Morlet wavelet with ω_0=3. These ω_0=3 wavelets are much better for the temporal isolation of signal features.

The scalograms in Figures 3(a),3(d),4(a) and 4(d) are plotted below the original signals. The ω_0=5.5 plots exhibit more compactness in frequency as evidenced by the thinner horizontal high energy band corresponding to the 'beat' frequency of the pulse oximeter signal. Also evident are regular dips corresponding to the kinks in the signal. The ω_0=3 plots exhibit more temporal compactness where the dominant band contains undulation peaks which correspond to the repeating temporal pattern of the signal.

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The phase plots are given below the scalograms in Figures 3 and 4 and provide information on the local matching of the wavelet with the signal. All phase plots shown exhibit regular repeating structure. The ω_0=3 phase plot is considerably less cluttered than the ω_0=5.5 plot due to less oscillatory nature of the wavelet used.

The lower plots in Figures 3 and 4 show the modulus maxima (top) and ridges (bottom) associated with the wavelet transform. These provide information concerning the location of temporal features and the instantaneous frequency of the signal respectively. Both methods allow for pertinent information within the highly redundant continuous wavelet transform to be presented (and hence extracted) in a more compact form. This information can be used within advanced filtering and prediction algorithms.

Elements of the Signal in Wavelet Space

Figure 5 contains one of the phase plots in Figure 4 blown up and split into four distinct regions. At the very low frequency range (region B-L) there is no obvious local coherent matching of the wavelet with the signal (see below for more information concerning this region). At the next lower frequency range (region P_1) the phase plots exhibit a smooth repeating pattern corresponding to the regular pulsing of the signal. Above this range these undulations split into two, (region P_2) where the location of this new split corresponds to the marked

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change in slope (the kink) occurring at the decreasing part of the pulse oximeter waveform (it would correspond to the location of the notch for a double humped waveform). At the highest frequencies (region N) the phase changes become more irregular in their occurrence and correspond to the smaller fluctuations in the signal (e.g. high frequency noise, high frequency movement artefact, etc.) The features within each region could be further partitioned using advanced filtering techniques, for example incorporating wavelet modulus maxima or wavelet ridge filtering technology.

Wavelet Detrending and Denoising and the Elucidation of Breathing Artefact

Figure 6a shows a 35 second segment of pulse oximeter waveform. There is obvious drift in the signal. The corresponding scalogram and phase plots are given in Figures 6b and 6c respectively for a Morlet decomposition with ω_0=5.5. Figures 6d and 6e illustrate a simple wavelet-based method for detrending and denoising the signal where the scalogram is essentially cropped, i.e. the high and low wavelet bandpass centre frequencies are set to zero. This removes both the very small and very large period fluctuations associated with noise and drift respectively. Figure 6e shows, from top to bottom, the original signal, the reconstructed signal using all the scalogram information (a check) and the denoised and detrended signal reconstructed from the cropped scalogram in Figure 6d. More

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advanced detrending and denoising includes filtering methodologies based on the wavelet transform modulus maxima and ridges, including methods to follow the ridges and other wavelet based features pertaining to the pulse and breathing signals through time.

Figure 7 contains the decomposition of the same signal as that in Figure 6, this time using a complete Morlet wavelet with $\omega_0=2$. The improved temporal isolation of the pulse features is apparent in the wavelet space scalogram of Figure 7a. In addition, the phase plot of Figure 7b shows a regular period oscillation at around 0.4 Hz particularly well. This, 2.5 second, periodicity corresponds to the regular breathing pattern of the patient- denoted as region B in the figure. In fact, we have separated the B-L region that was indicated in Figure 5 into region B - breathing - and region L - other lower frequency signal components including drift. The denoising and detrending of the signal is carried out in the same way as in the previous figure to give the denoised and detrended signal shown in the lower plot of Figure 7c. Figure 7d shows a blow up of the first five seconds of the signals in Figure 7c. The smoothing of the signal is obvious in the lower plot. The choice of the upper frequency cut-off is critical in partitioning relevant signal artefacts from noise. Figure 7e shows three plots of the denoised and detrended signal where progressively higher cut-off thresholds have been used. This allows higher and higher frequency features back into the denoised signal.

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More on the elucidation of breathing artefact

Four, wavelet-based, methodologies may be employed for the monitoring of respiration and the extraction of the breathing rate from a standard pulse oximeter trace or photoplethysmograph (PPG) trace. These methodologies may be used independently, for example within an algorithm, or collectively using a polling mechanism. They are given as:

1. High amplitude banding.

When the breathing artefact is particularly pronounced, the breathing rate can be identified as a strong band or ridge of high transform values in the low (<1Hz) frequency range. The arrow in Figure 8(a) indicates one such ridge. In one preferred embodiment, this band can be identified by collapsing the scalogram down into two dimensions, as shown in Figure 8(b). This is a wavelet based power spectrum: the summation of coefficients across scales factored by the reciprocal of the square of the scale value ($1/a^2$). The primary assumptions made in this methodology are: (1) the dominant features in the filtered trace are cardiac components and (2) the breathing rate is less than the heart rate. Alternative assumptions can also be employed according to the clinical situation, e.g. PPGs from neonates.

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In another embodiment, the breathing ridge may be followed in wavelet space using standard ridge-following techniques. This allows sudden or short term changes in breathing rate to be identified and quantified in real time. Evidence for the applicability of this methodology is found in Figure 9. Here a pulse oximeter trace, Figure 9(a), is presented for a 60 second experiment. During the experiment the subject was instructed to half his breathing rate after 30 seconds. As can be seen in Figure 9(b), a breathing ridge is clearly identifiable. This ridge drops in frequency (right hand horizontal scale) after 30 seconds. By identifying the phase of the wavelet transform along the ridge a clear indication of the timing of each breath can be determined - see Figure 9(c).

2. Phase methods.

As shown above, the phase of the wavelet coefficients can be used to identify the timing of each breath. However, cross-scale correlation of phase values, particularly for scalograms of low oscillation wavelets, can also be used as an indicator for low frequency, low amplitude, breathing features within the PPG trace.

In Figure 10(a) a portion of the wavelet phase space scalogram is presented. As can be seen there is a very definite cross-scale correlation for the frequencies around the breathing rate - the dotted box (i.e. similar phase values are aligned

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vertically). By plotting the number of near zero modulus minima of the phase per scale against scale one can identify these areas of alignment as constant valued steps in the graph.

In the example of Figure 10(b) the scale (horizontal) axis is presented as the band pass centre frequency of that scale. This diagram plots the count of phase modulus minima per scale against scale. This is indicative of the cross scale correlation in the wavelet phase space and can be used to associate regions of the scalogram with physiological features (e.g. breathing and heart rate). This diagram is the count of phase minima of the scalogram shown in Figure 8.

As one can clearly see in this figure, the steps of constant phase count correlate extremely well with the wavelet spectrum peak positions of Figure 8(b) (the spectrum of the same trace as that of Figure 10(b)).

Note that the use of cross-correlation across scale can also be used to isolate individual features within the trace. See, for example, Figure 16, where individual pulse features within the trace have been identified by finding the dominant frequency associated with the heart rate then following the points of equal phase up to higher frequencies. These techniques cannot be performed using conventional STFT methods where the temporal resolution at high frequencies is inferior and phase

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values are relative to the STFT frame origin rather than the wavelet centre.

3. Frequency modulation.

In some cases the amplitudes of the breathing related features within the PPG are such that they cannot easily be isolated as independent features within the transform space (e.g. they are of small amplitude, close to the dominant cardiac signal, etc). However, their effects on the dominant cardiac features can be observed. This is shown in Figure 11(a) where the frequency of modulation corresponds to the breathing rate of the subject. Associated frequency of the cardiac features oscillate with a frequency identified as that of the breathing rate. This method cannot be utilised using standard Fourier techniques where temporal averaging reduces resolution in time so making identification of this modulation undetectable.

4. Amplitude modulation.

In some cases the amplitudes of the breathing related features within the PPG are such that they cannot easily be isolated as independent features within the transform space (e.g. they are of small amplitude, close to the dominant cardiac signal, etc). However, their effects on the dominant cardiac features can be observed. This is shown in Figure 11(b) where the frequency of amplitude modulation corresponds to the breathing rate of the subject.

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The amplitude dominant band corresponding to the cardiac features in wavelet space oscillates with a frequency identified as that of the breathing rate. Occasionally, when breaths are well separated individual breath features can be identified instead of a continuous, or modulated, band. This is particularly apparent when a low oscillation wavelet function is employed, as in Figure 11(c). Again, this method cannot be utilised using standard Fourier techniques where temporal averaging reduces resolution in time so making identification of this modulation undetectable.

Wavelet Feature Analysis

A scheme is described for the analysis of features derived from statistical measures of the wavelet transformed signal at a given frequency level or by following a time-frequency feature in wavelet space - where the transform can be represented as the actual transform values, the modulus of transform values, the squared transform values (the scalogram) or some other simple transformation of the wavelet transform values. In the preferred embodiment these features derived from the wavelet transform at a selected frequency level may include the power, mean, skew, kurtosis and entropy. In addition, these may be found for the peak frequency for each individual scalogram rather than a constant predefined frequency level, where peak frequency is defined as the frequency level containing the most power when integrated across the scalogram to

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produce a wavelet power spectrum. Figure 12 shows a schematic of the wavelet transform scalogram and the wavelet power spectrum obtained from integration along the time domain at each frequency level. The selected frequency level across which the statistical measures are obtained is shown dashed in the scalogram plot.

The algorithm allows the analysis of segments of the pulse oximetry signals. The algorithm also allows the visual inspection of the feature scatter in parameter space. The feature scatter is then used as input to a classification method e.g. a Bayesian classifier or neural network.

Figure 13 shows the scatter plot derived from a signal data set obtained from two groups of children. One of the groups comprised a number of 'controls' taken from healthy children and were of relatively short duration these are marked by a 'o' in the figure. The other group were acquired from admitted patients attending the accident and emergency department of a UK children's hospital. Trace segments were selected from a PPG signal from each child and then decomposed using a wavelet transform. The feature distribution within the resulting scalograms were then probed across levels. The graph in Figure 13 has been plotted with a logarithmic vertical axis to better separate the feature points in parameter space. This scaling is optional and linear scaling may better suit other chosen features. We can see from visual inspection

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that the controls are well separated from the admitted patients. The dashed line in the plot has been added for illustration and represents a possible separation line for dividing the two-dimensional data set into two classes.

In order to determine from a data set which illness severity the patient belongs to a Bayesian or other classification method may be employed. Figure 14 shows an example of the Bayesian classifier for the 'ill' and 'healthy' entropy data sets which gives a specificity of 84% and sensitivity of 81% for the determination of an 'ill' patient from a data sample. Figure 14(a) shows smoothed data PDF's (Probability Density Functions) corresponding to the Entropy data given by the horizontal axis of Figure 13. In Figure 14(b) Top plot: smoothed PDF's, Second top plot: smoothed PDF's weighted according to class prevalence, Second bottom plot: probability of observation stemming from class 'healthy' or 'ill', Bottom plot: the classifier training towards a 95% sensitivity for detecting 'ill' patients.

Note that the two data sets have been smoothed prior to the classification. The classifier may be trained using an iterative procedure and a risk matrix to enhance the sensitivity (say to 95% or above) at the expense of sensitivity. For example, for 96% sensitivity, a specificity of only 43% is attained for the entropy data set produce (lowest plot of Figure 14b).

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Combinations of feature vectors can produce enhanced specificity-sensitivity values but with the requirement of increased computational effort. Figure 13 contained a two-dimensional feature set (of power and entropy). The increased computational effort arising from the use of multidimensional feature sets can be remedied somewhat by reducing the number of components using, for example, principal component analysis or linear discriminant analysis during the preprocessing stage.

The use of features derived from wavelet transform are useful as clinical markers of current state of the patient health as shown in the example. The same classification method may also be used as a predictor of the future state of the patient's health by correlating future outcomes with wavelet feature data.

The classification method may also be extended to include other clinical parameters including triage category, capillary refill time, white cell count, age, etc.

The classification method may also be extended to further partition the data according to patient 'illness severity', where the system is initially trained on illness severities determined using suitable criteria by a clinician.

Usefulness in the Measurement of Compliance etc.

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The wavelet-based denoising and feature extraction described herein will allow for a more accurate analysis of the photoplethysmographic waveform when used in the measurement and monitoring of physiological parameters. An example of this is in the determination of arterial compliance using the shape of, and reference points within, the plethysmographic signal. Modulus maxima following can be used to determine the location and nature of pertinent characteristic points in the PPG, e.g. the beginning and end of the initial upslope of the PPG trace, maxima, minima, etc. This is shown schematically in Figure 15. Example PPG reference points used in the determination of clinically useful parameters are shown A,B,C,D and can be identified in the modulus maxima plot. The maxima lines can be used to better identify the characteristic points from within the signal.

In Figure 16 the lower plot shows the wavelet transform (filtered) trace with individually isolated features of the trace marked by vertical lines. Note these have been identified through cross scale correlation of phase. Note also that peaks and troughs have been differentiated through the phase value - near zero corresponding to peaks and near $\pm\pi$ corresponding to troughs.

Implementation

Figure 17 illustrates schematically one system for implementing the method of the invention.

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A pulse oximeter 10 of known type has a probe 12 for obtaining readings from the finger, ear lobe or other suitable part of a patient. The pulse oximeter outputs a raw PPG signal to a computer 14 which carries out the wavelet transforms and associated analysis as discussed above. The computer 14 can output both the raw PPG signal and the results of processing the PPG signal to a VDU 16 and/or provide an output in the form of data at 18. The data output 18 may be in the form of a link to a remote location, a data carrier such as a disc or tape, or any other suitable format.

The mathematics of wavelet transforms are well described in the literature and known to those of ordinary skill in the art, and are not further described herein.

The immediately convenient manner of implementing the present invention is by connecting a computer to an existing pulse oximeter, as shown in Figure 17. It will be readily apparent, however, that the invention could equally well be implemented by combining a pulse oximeter with suitable computational resources within a single, stand-alone instrument; or by passing the PPG signal from a conventional pulse oximeter over a data communications link to a remote computer which could be shared with other users.

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CLAIMS

1. A method of measuring physiological parameters, comprising using a pulse oximeter to obtain a pulse oximetry signal, decomposing the pulse oximetry signal by wavelet transform analysis, and deriving one or more physiological parameters from the decomposed signal.

2. A method of processing a pulse oximetry signal, in which the pulse oximetry signal is decomposed by wavelet transform analysis.

3. A method according to claim 1 or claim 2, in which the pulse oximetry signal is a photoplethysmogram (PPG).

4. A method as claimed in any preceding claim, including the steps of deriving the wavelet energy surfaces of the pulse oximeter signal, and plotting the surfaces against a location parameter and a scale parameter.

5. A method as claimed in any preceding claim, including the steps of deriving the wavelet transform modulus of the pulse oximeter signal, and plotting the modulus against a location parameter and a scale parameter.

6. A method as claimed in claim 4 or claim 5, in which the scale parameter is a characteristic

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frequency of the wavelet used in the decomposition.

7. A method as claimed in claim 4 or claim 5, in which the scale parameter is the wavelet dilation.

8. A method as claimed in any preceding claim, including visually displaying information derived from the pulse oximetry signal by the wavelet transform analysis.

9. A method as claimed in claim 8, in which said information is displayed in real time.

10. A method as claimed in claim 8 or claim 9, in which said information includes one or more of:

the distribution of energies within the pulse oximetry signal,

coherent structures in the processed signal,

a contour plot of the decomposed waveform,

a surface plot of the decomposed waveform, and

a 2D or 3D energy scalogram.

11. A method according to any of claims 8 to 10, in which the unprocessed pulse oximetry signal is also displayed.

12. A method according to any preceding claim, in which the processing of the pulse oximetry

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signal is effective to derive information relating to respiration.

13. A method according to claim 12, in which respiration information is derived from high amplitude ridges using ridge-following methods.

14. A method according to claim 12, in which the respiration information is derived by phase methods.

15. A method according to claim 14, in which the respiration information is derived by cross-scale correlation of phase values.

16. A method according to claim 12, in which the respiration information is derived by analysis of amplitude or frequency modulation.

17. A method according to any preceding claim, in which the processing of the pulse oximetry signal is effective to remove at least one of noise, artefact, and transient features.

18. A method according to claim 17, in which said removal employs inverse transformation of the cropped transform.

19. A method according to claim 17, in which said removal employs wavelet ridge methods.

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20. A method according to claim 17, in which said removal employs modulus maxima methods.

21. A method according to any preceding claim, in which information from the transform is used to determine the present or predicted severity of illness of a subject.

22. A physiological measurement system comprising:

a pulse oximeter which includes an optical probe and circuit means connected to the probe to derive a pulse oximetry signal from a subject when the probe is applied to the subject, and

signal processing means arranged to receive the pulse oximetry signal and to process the signal by wavelet transform techniques.

22. A system according to claim 21, in which the signal processing means is arranged to process the pulse oximetry signal by the method of any of claims 3 to 21.

23. A system according to claim 21 or claim 22, further including a visual display unit operable to display the pulse oximetry signal and information derived therefrom in real time.

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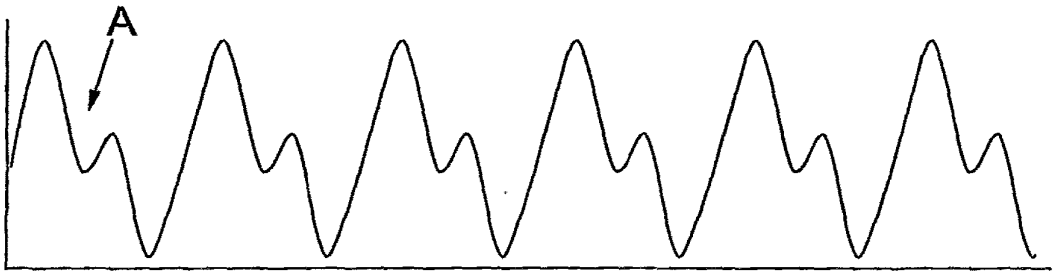


Fig. 1a

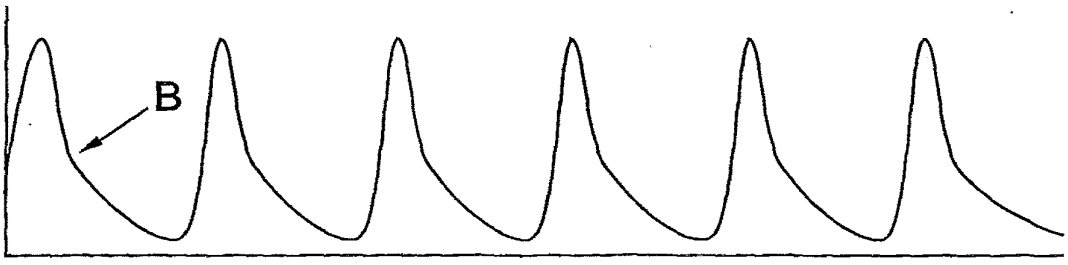


Fig. 1b

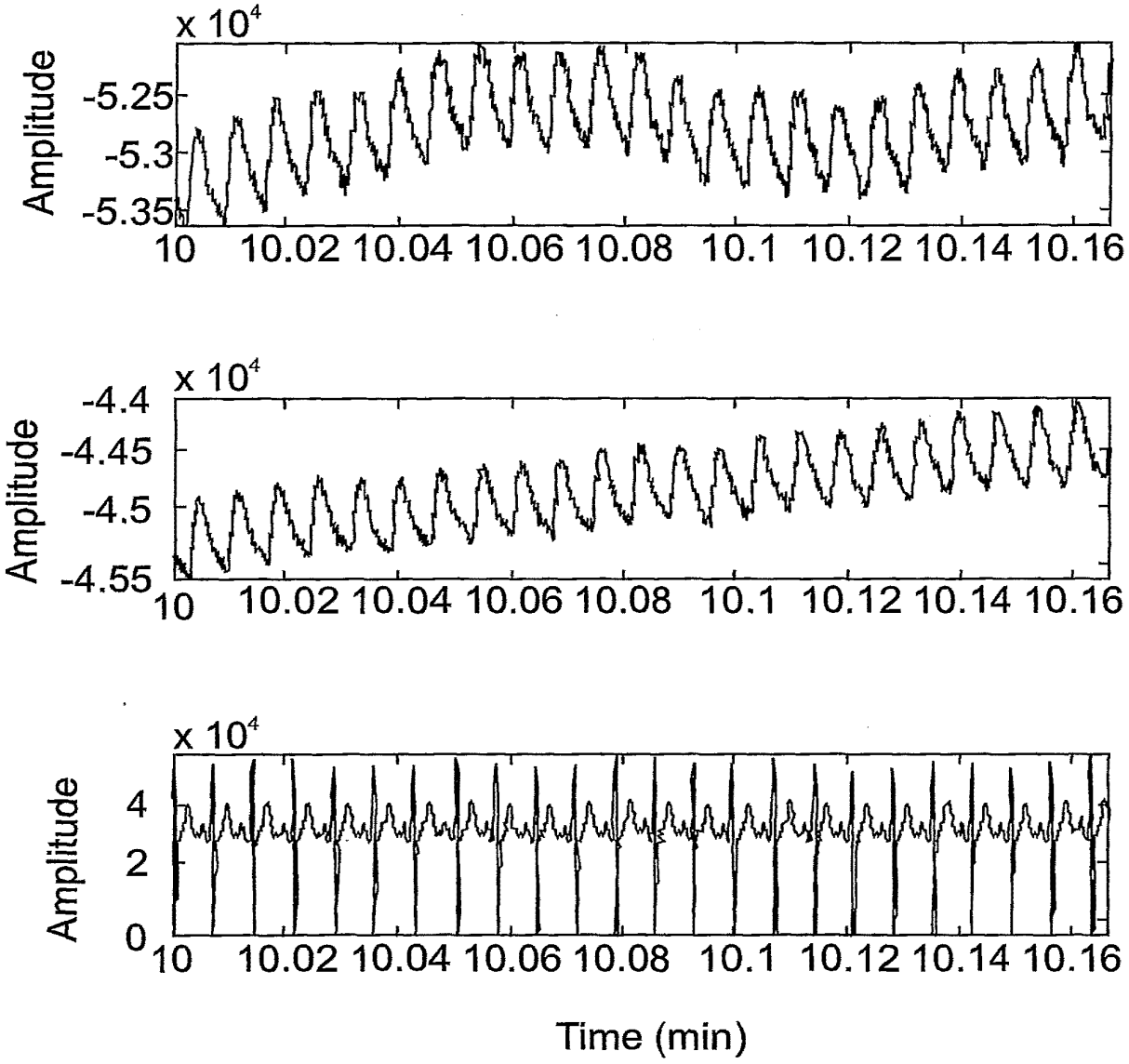
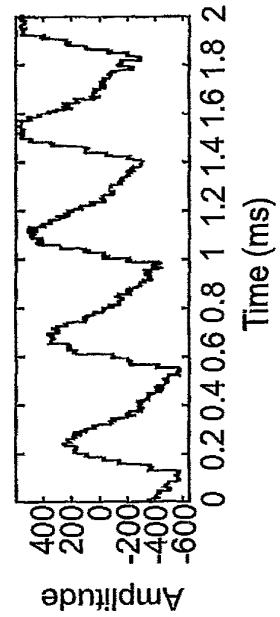

x 10^4
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-5.3
-5.35
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x 10^4
Amplitude
-4.4
-4.45
-4.5
-4.55
10 10.02 10.04 10.06 10.08 10.1 10.12 10.14 10.16
x 10^4
Amplitude
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2
0
10 10.02 10.04 10.06 10.08 10.1 10.12 10.14 10.16
Time (min)

Fig. 2

Petitioner Ex-1004, 0220



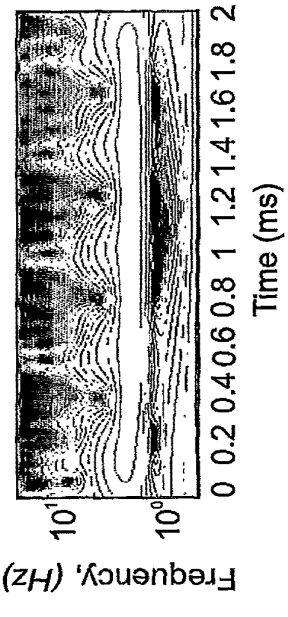
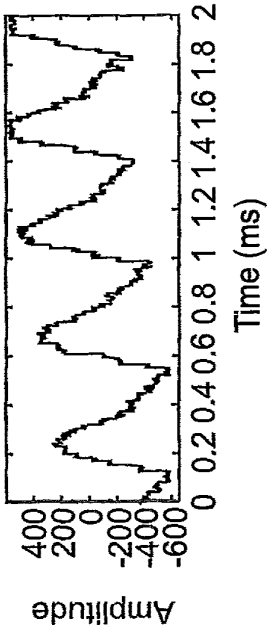


Fig. 3d



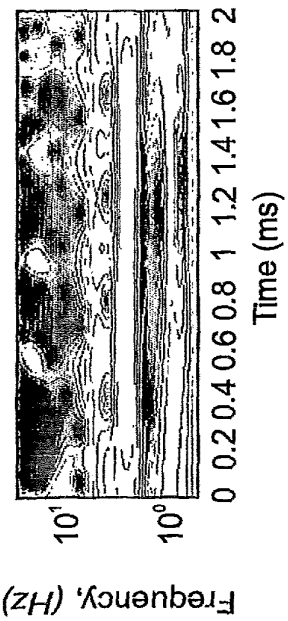


Fig. 3a

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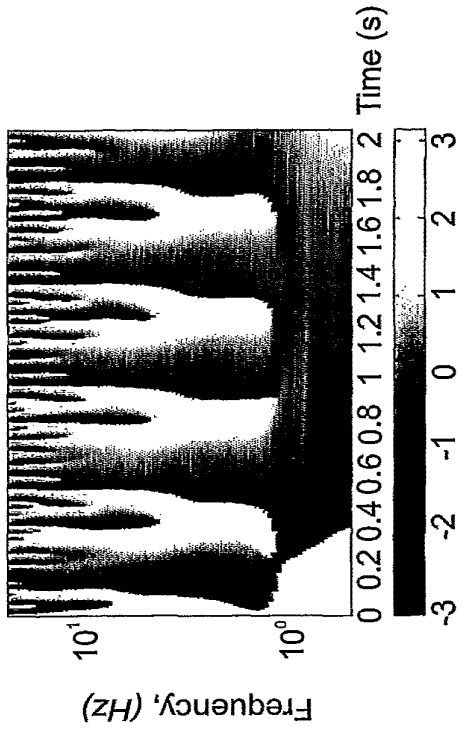


Fig. 3e

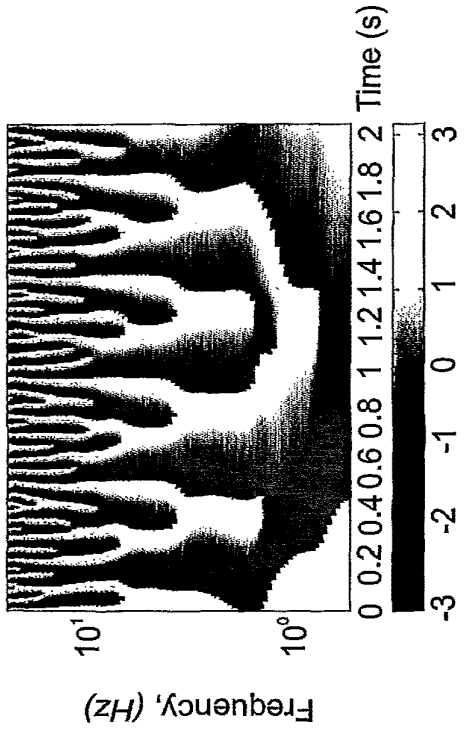
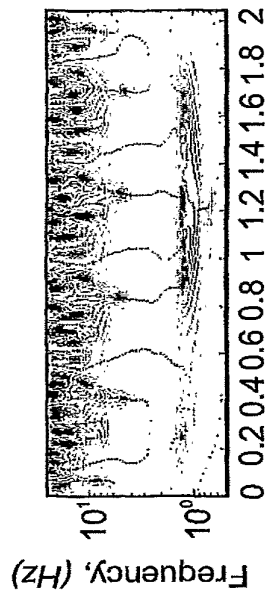


Fig. 3b

Petitioner Ex-1004, 0221

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Petitioner Ex-1004, 0222



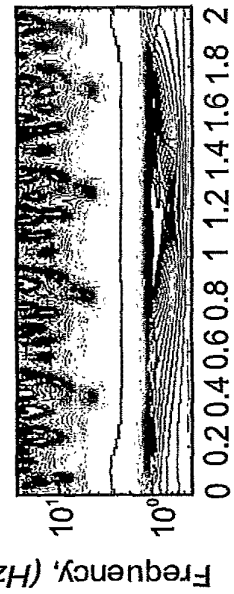
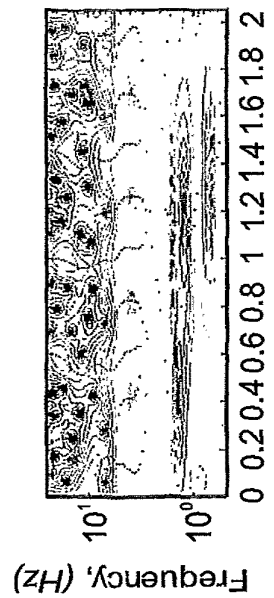


Fig. 3f



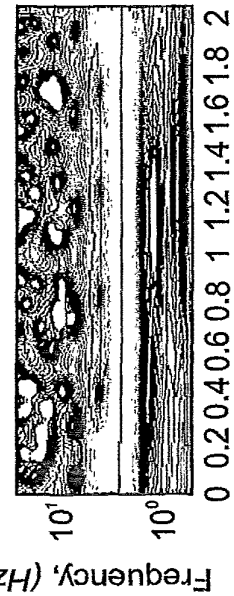


Fig. 3c

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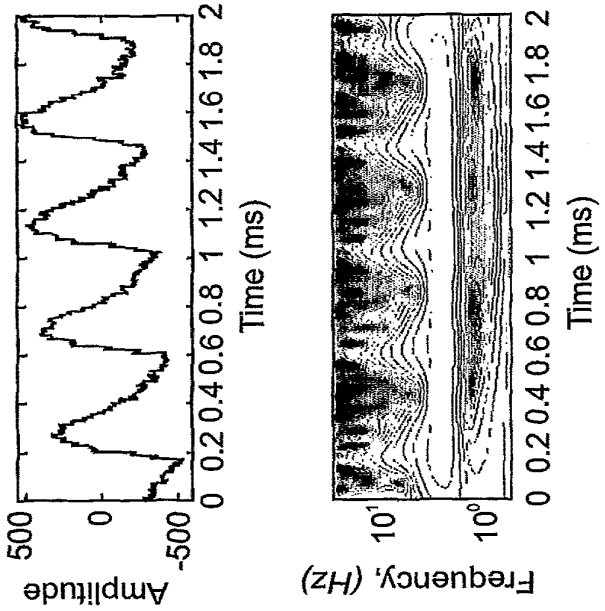


Fig. 4d

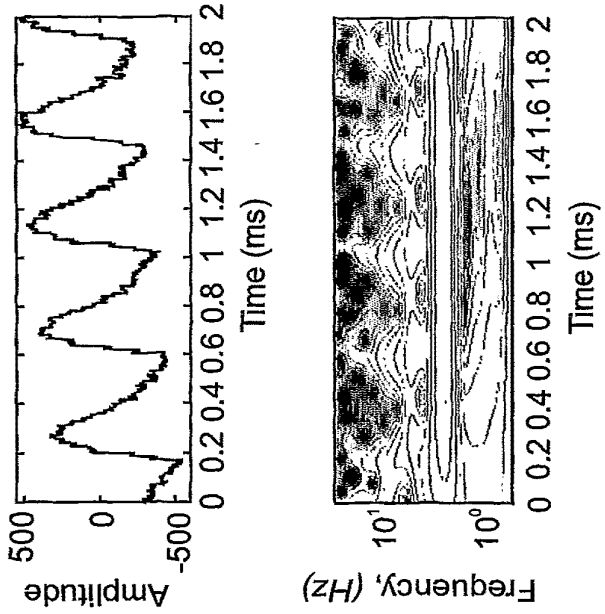


Fig. 4a

Petitioner Ex-1004, 0223

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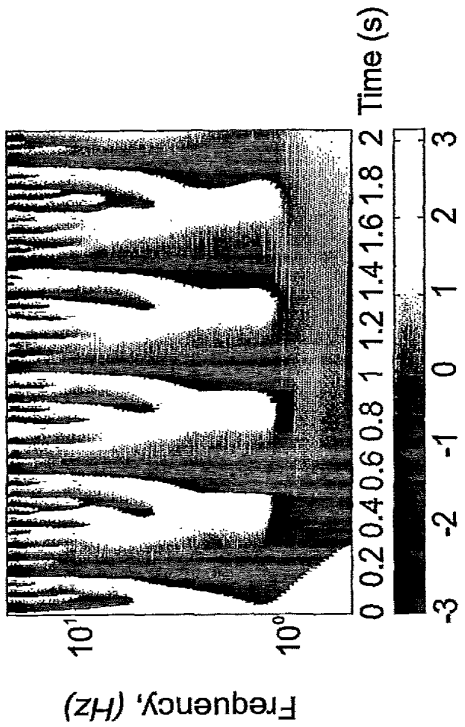


Fig. 4e

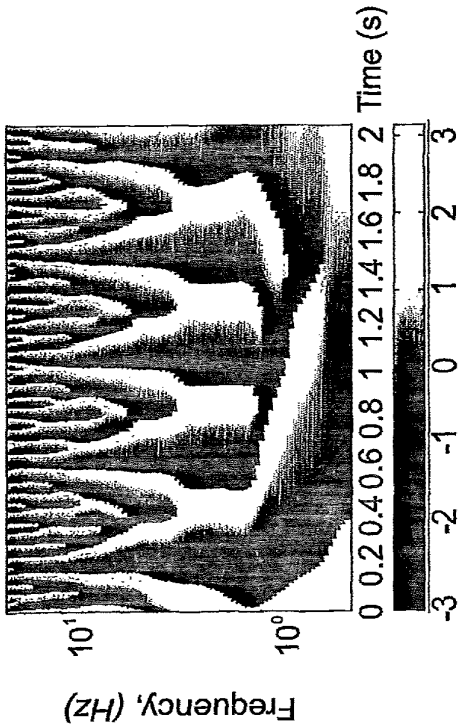


Fig. 4b

Petitioner Ex-1004, 0224

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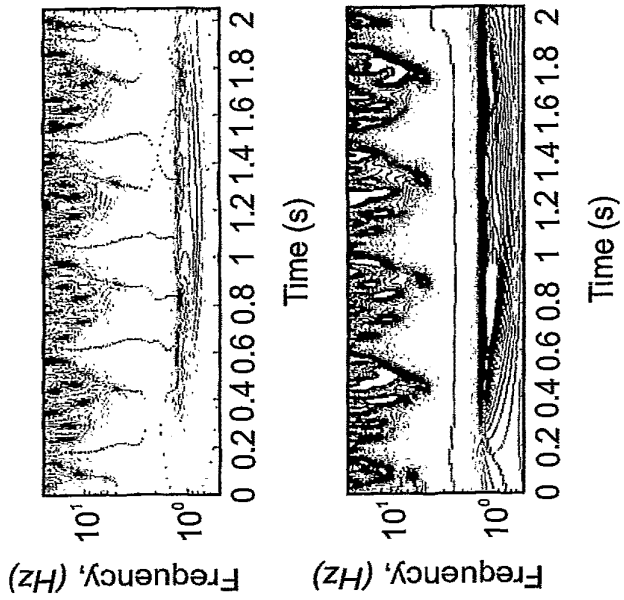


Fig. 4f

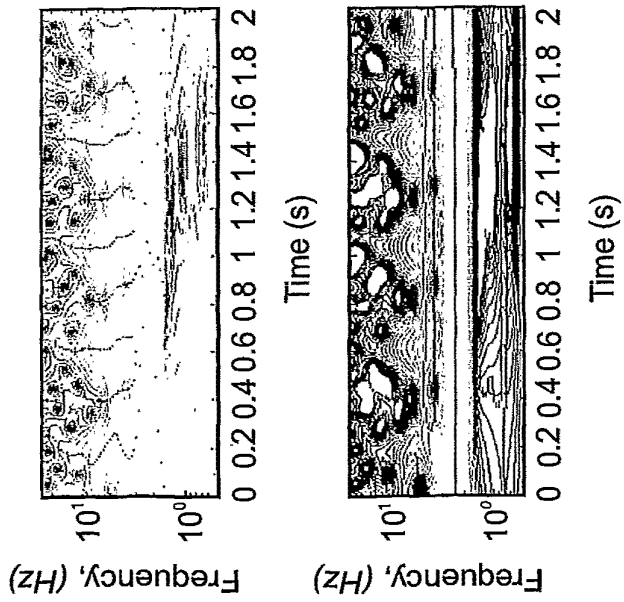


Fig. 4c

Petitioner Ex-1004, 0225

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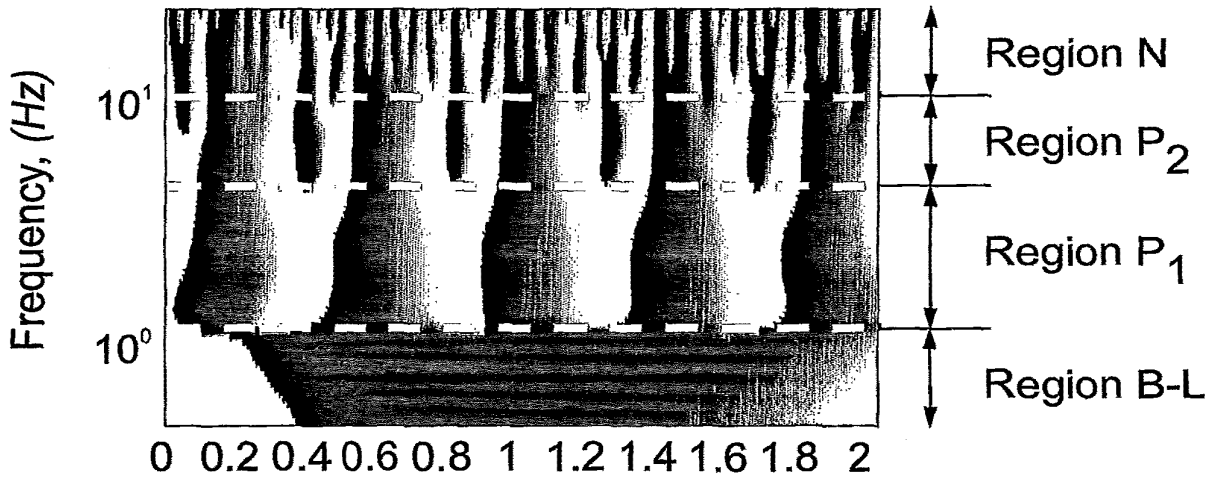

Frequency, (Hz)
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10^0
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Region N
Region P_2
Region P_1
Region B-L

Fig. 5

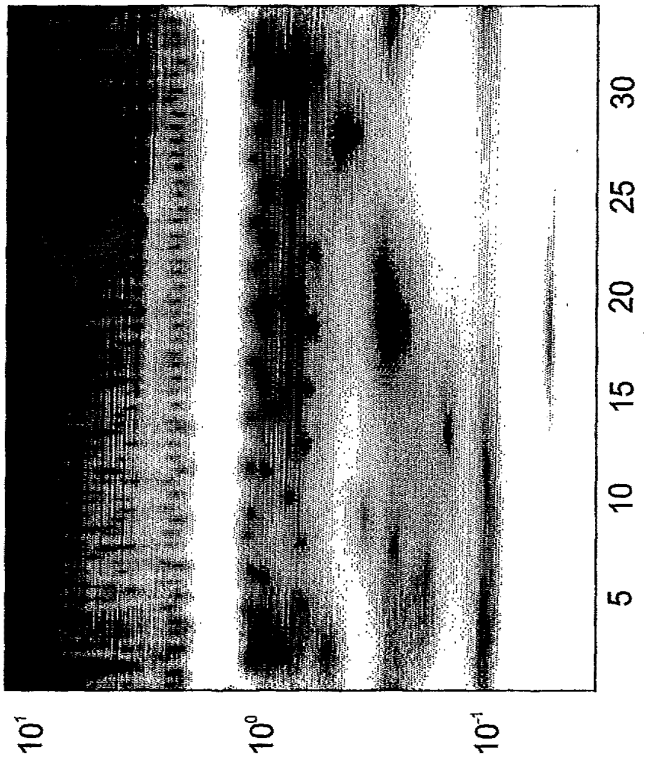


Fig. 6b

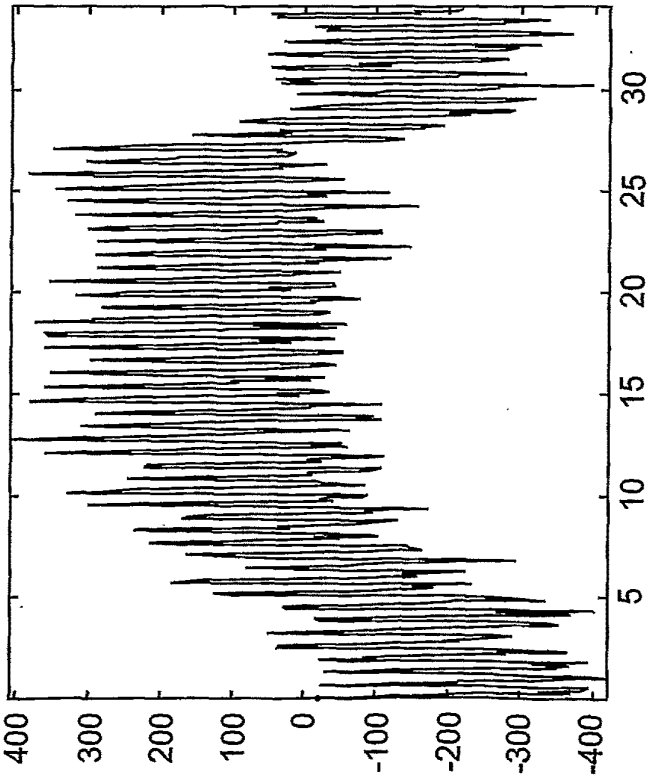


Fig. 6a

BNSDOCID: <WO_____03000125A1_I_>

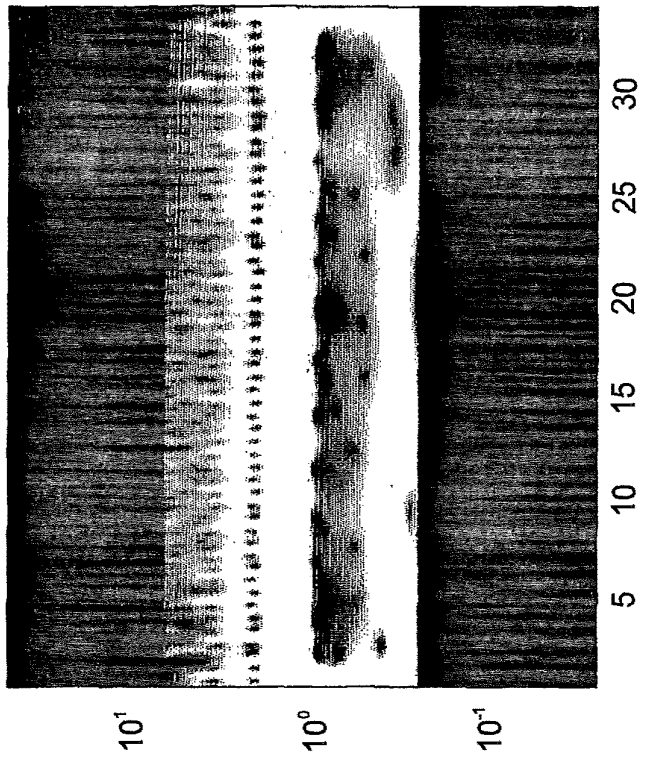


Fig. 6d

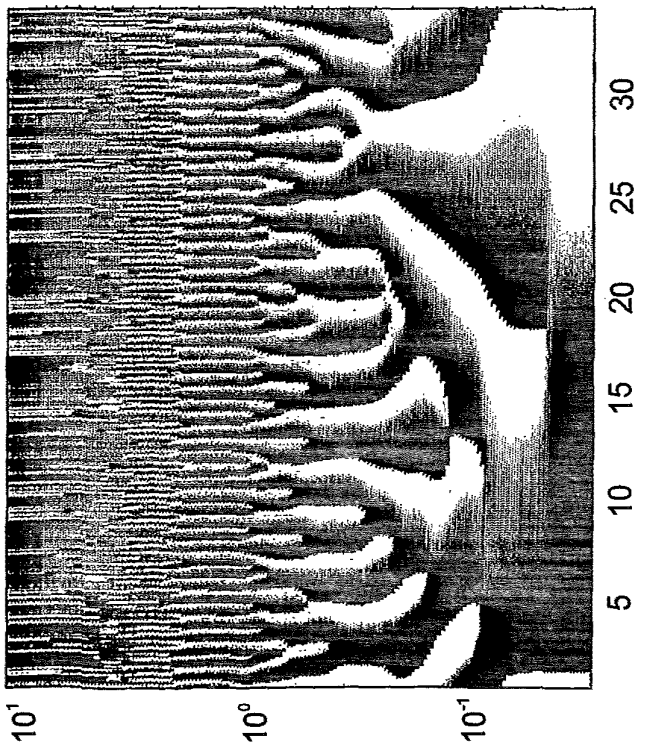


Fig. 6c

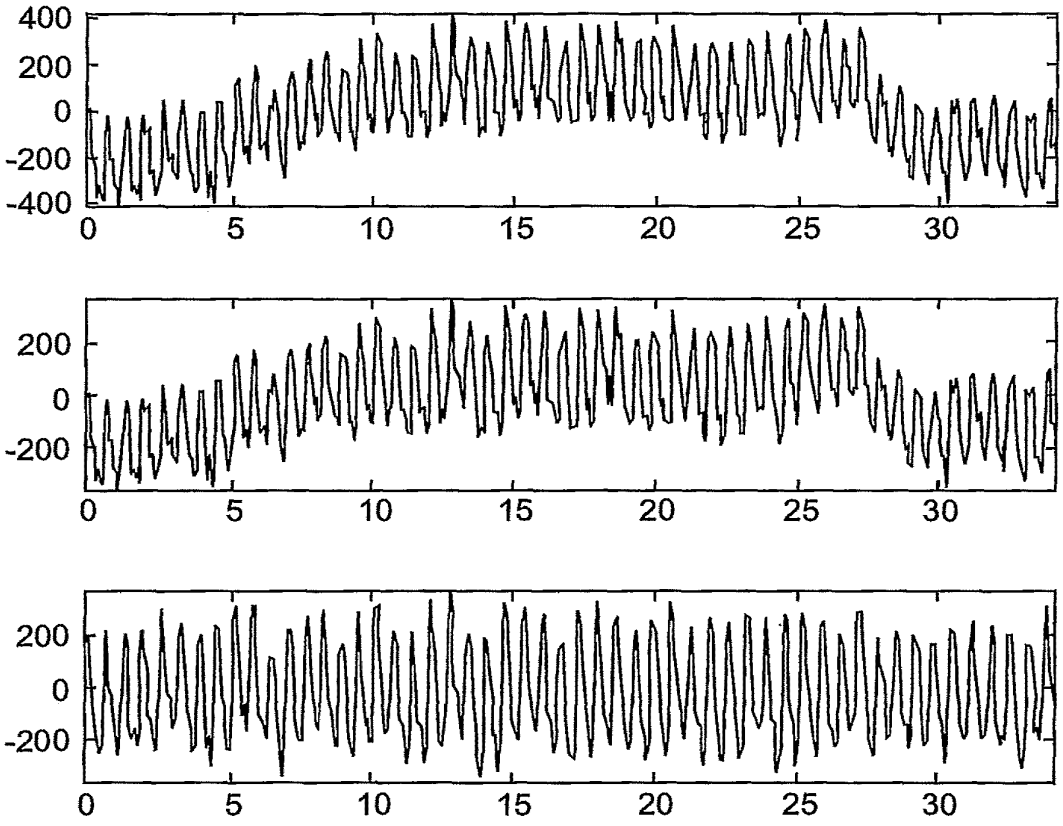


Fig. 6e

Petitioner Ex-1004, 0229

BNSDOCID: <WO_____03000125A1_I_>

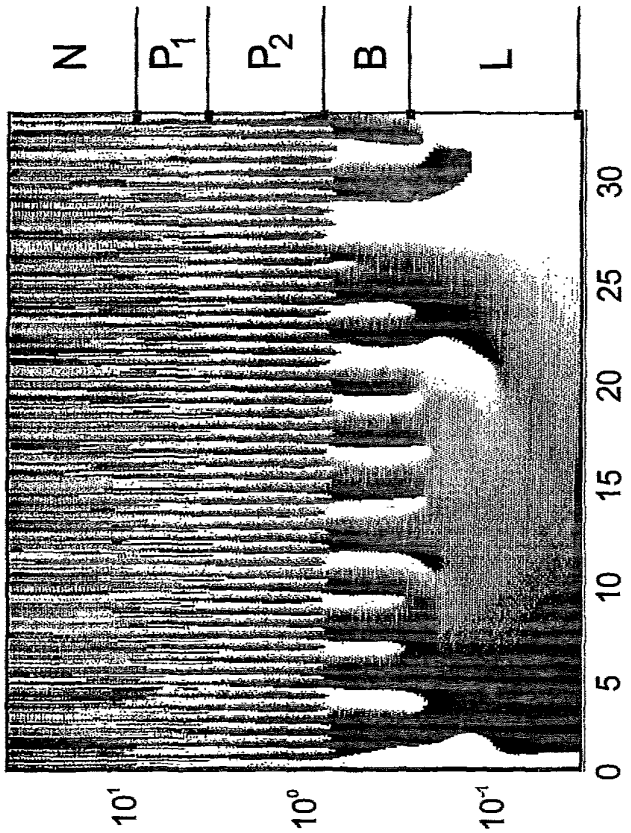


Fig. 7b

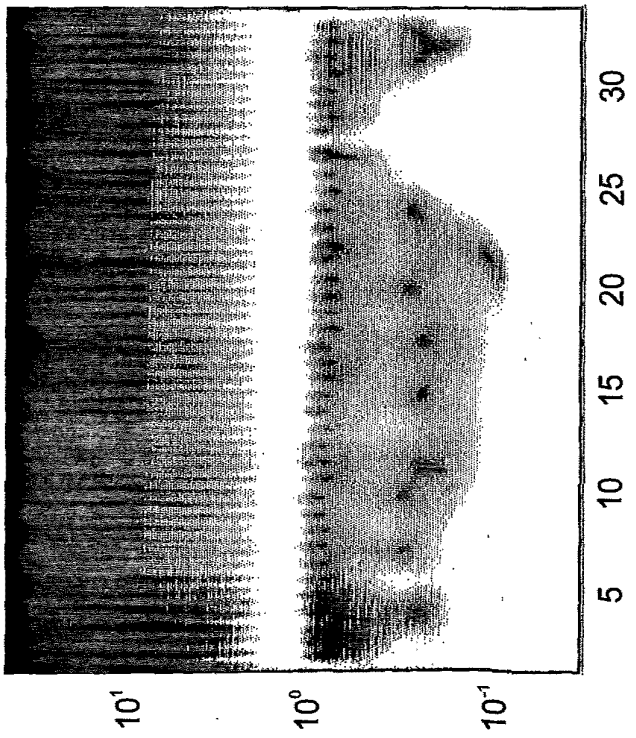


Fig. 7a

Petitioner Ex-1004, 0230

BNSDOCID: <WO_____03000125A1_I_>

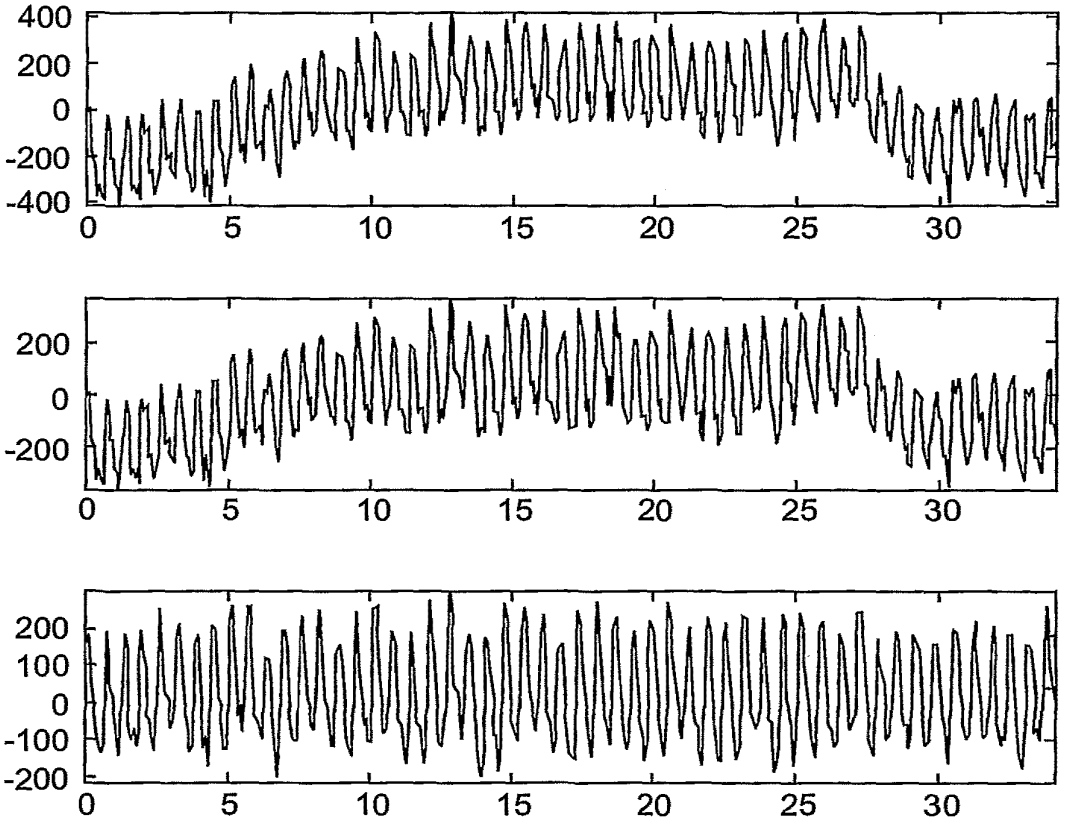


Fig. 7c

Petitioner Ex-1004, 0231

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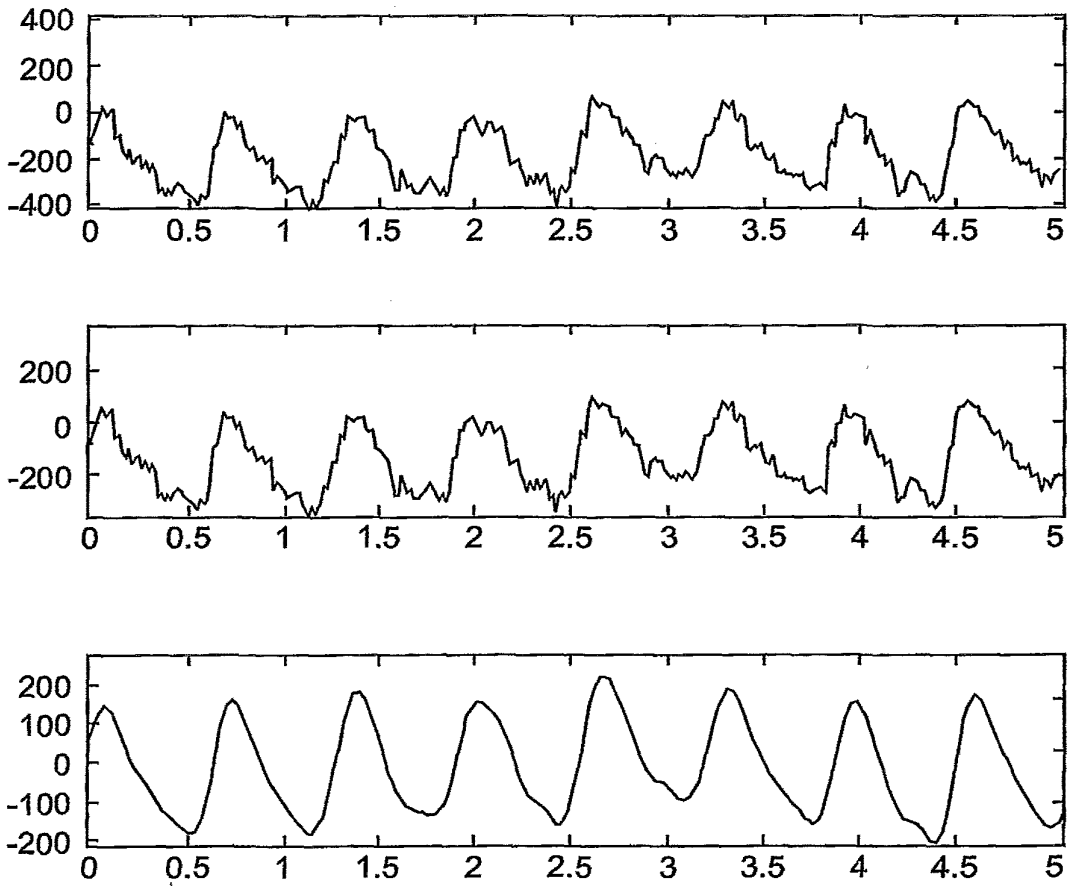

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Fig. 7d

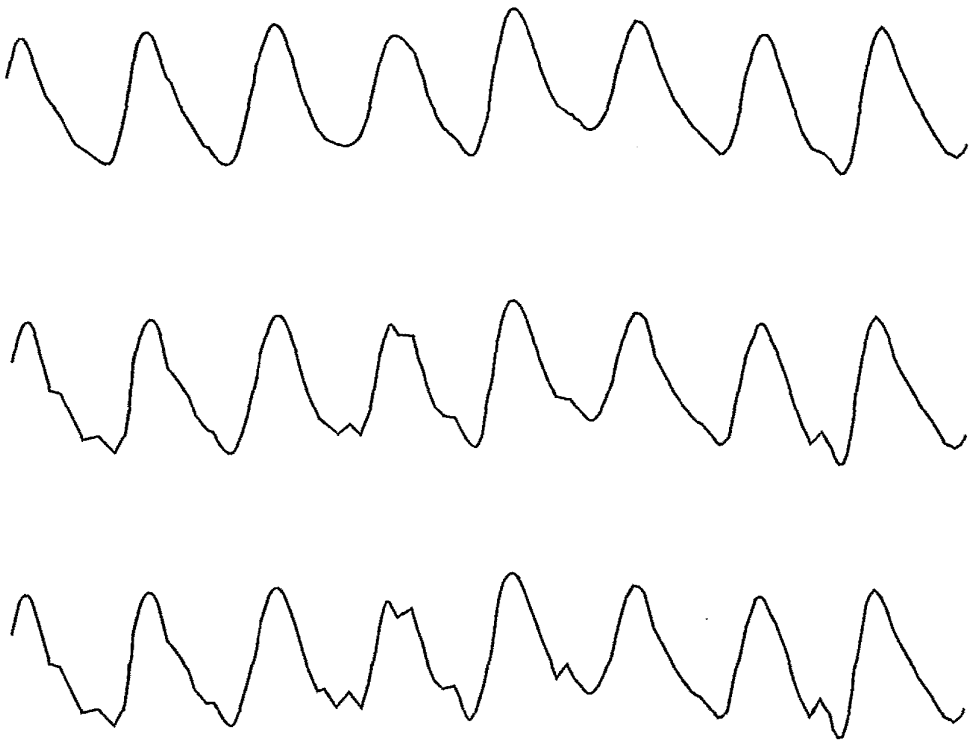


Fig. 7e

Petitioner Ex-1004, 0233

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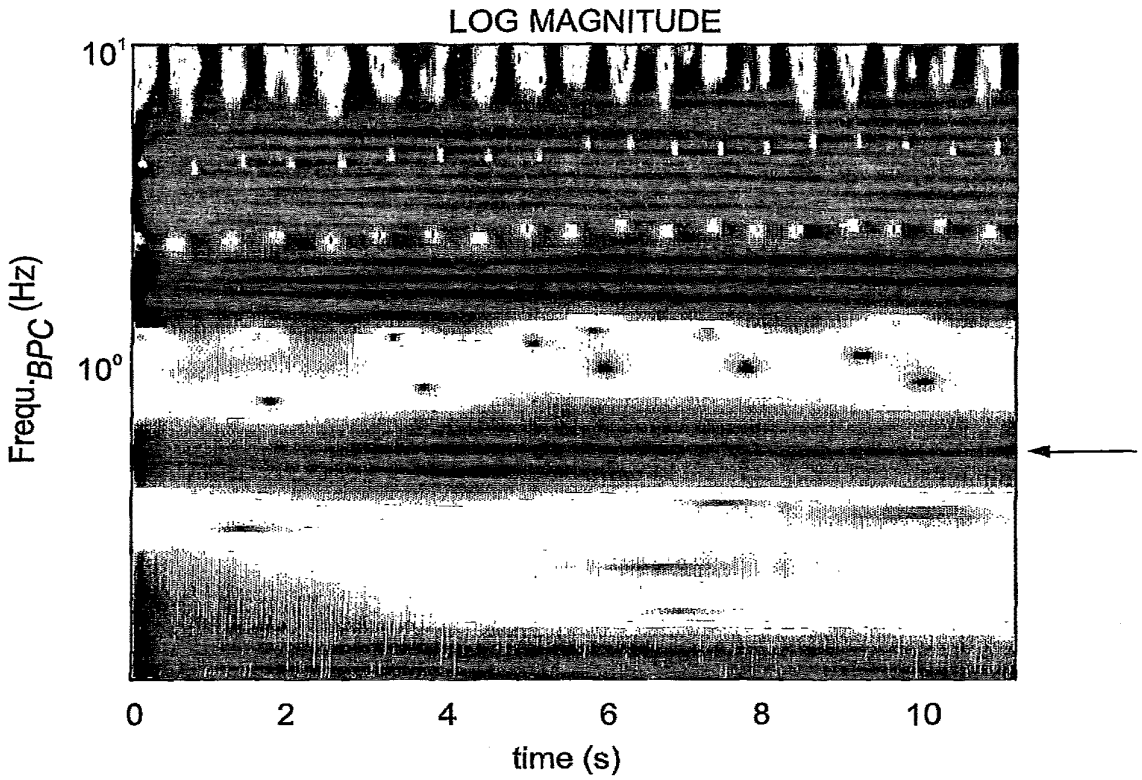


Fig. 8a

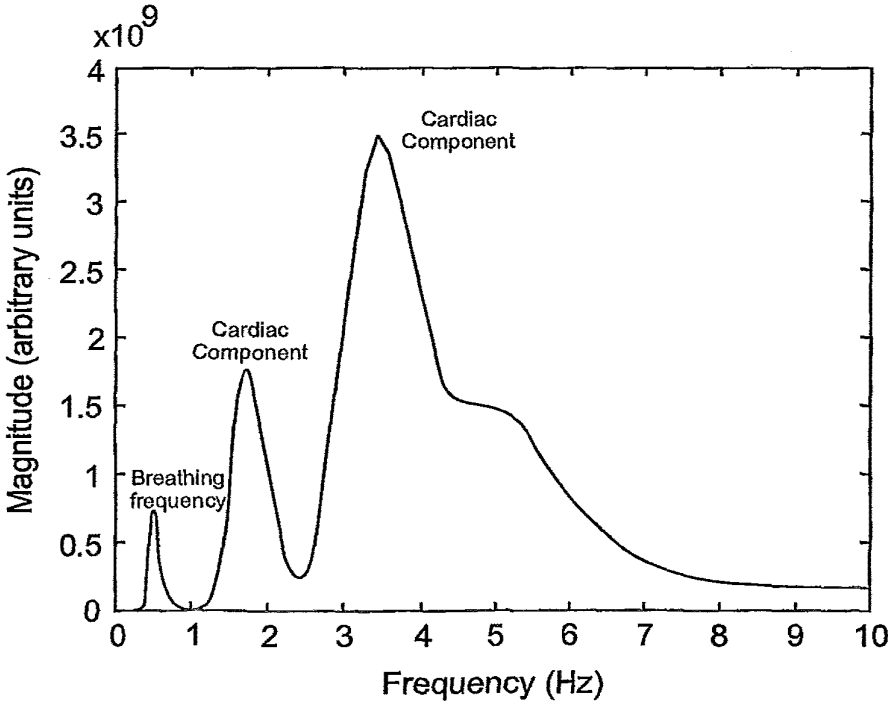


Fig. 8b

Petitioner Ex-1004, 0234

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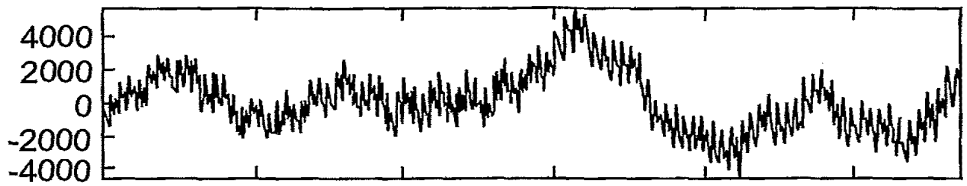


Fig. 9a

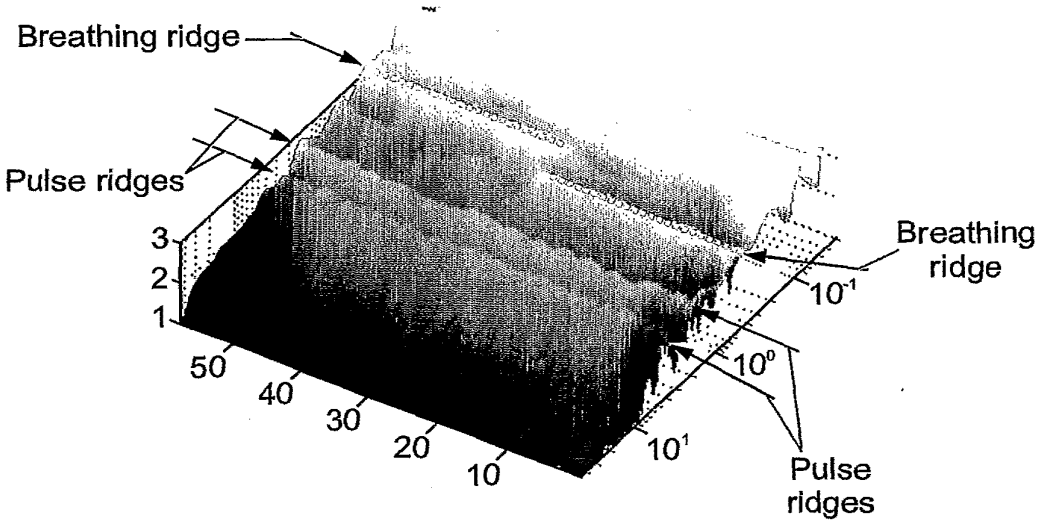


Fig. 9b

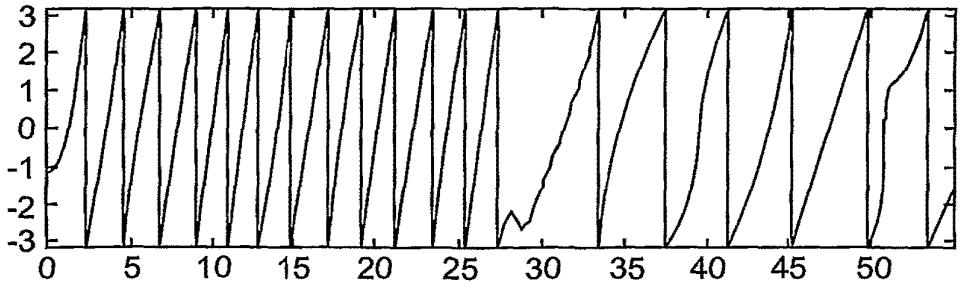


Fig. 9c

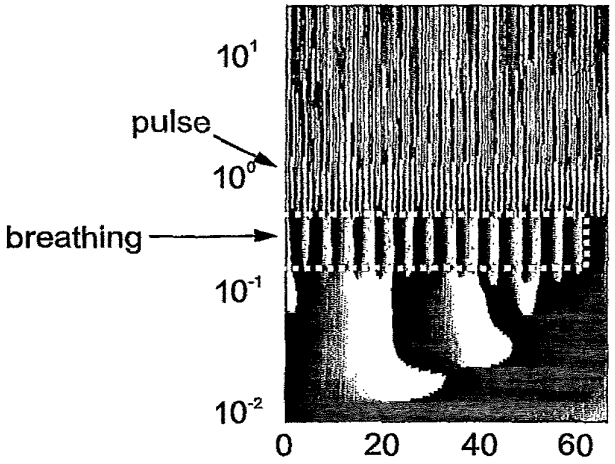


Fig. 10a

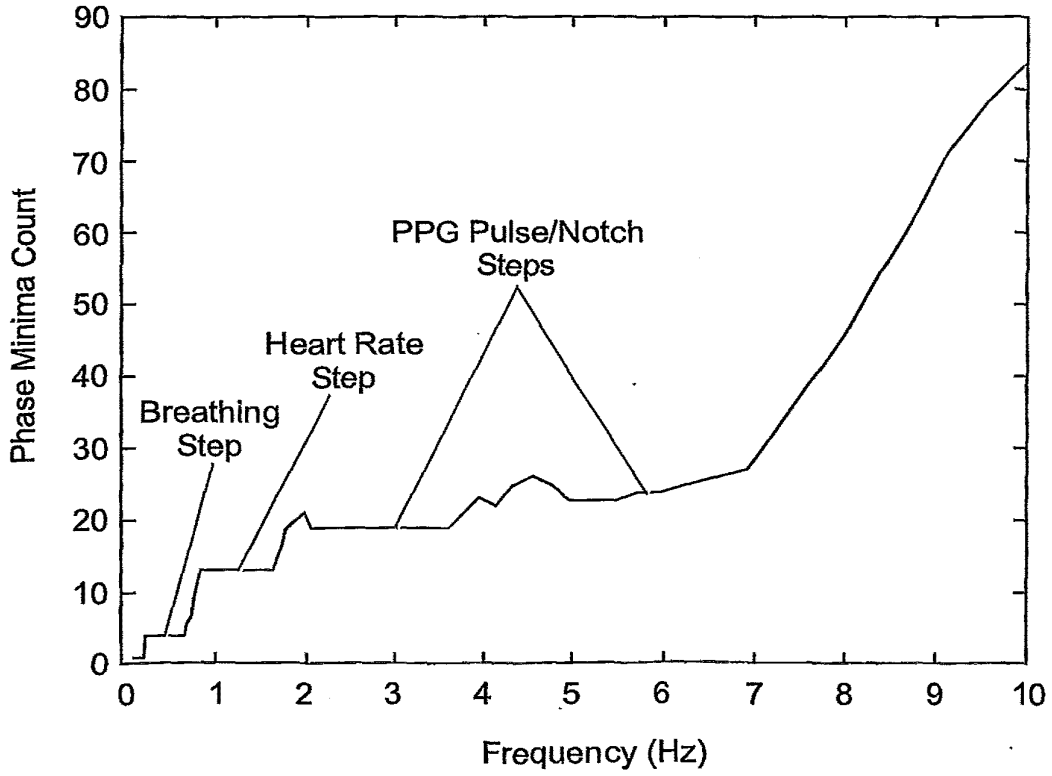


Fig. 10b

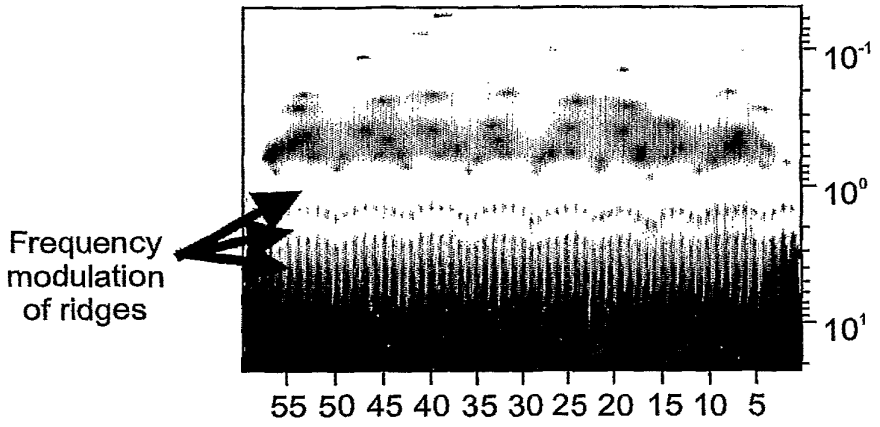


Fig. 11a

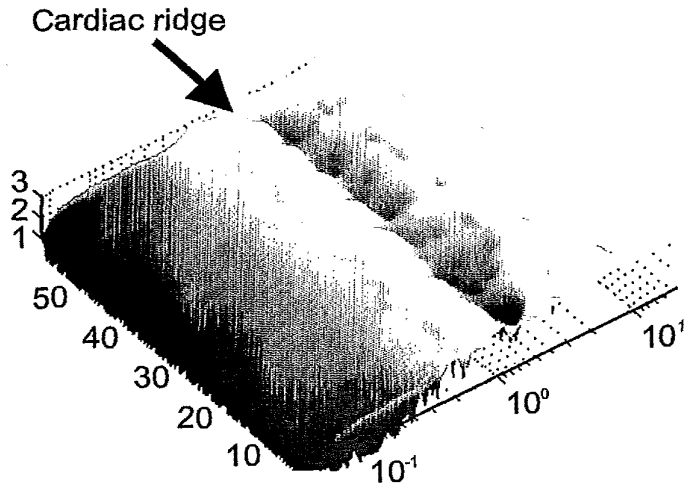


Fig. 11b

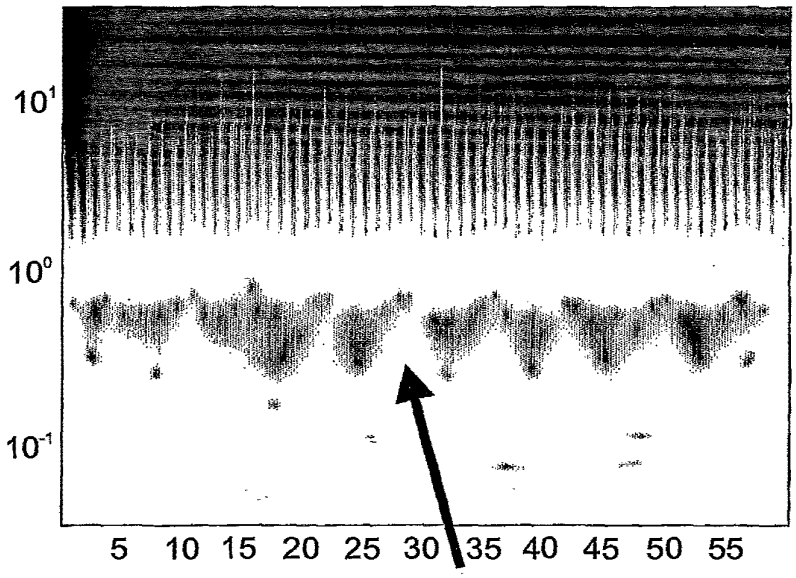


Fig. 11c

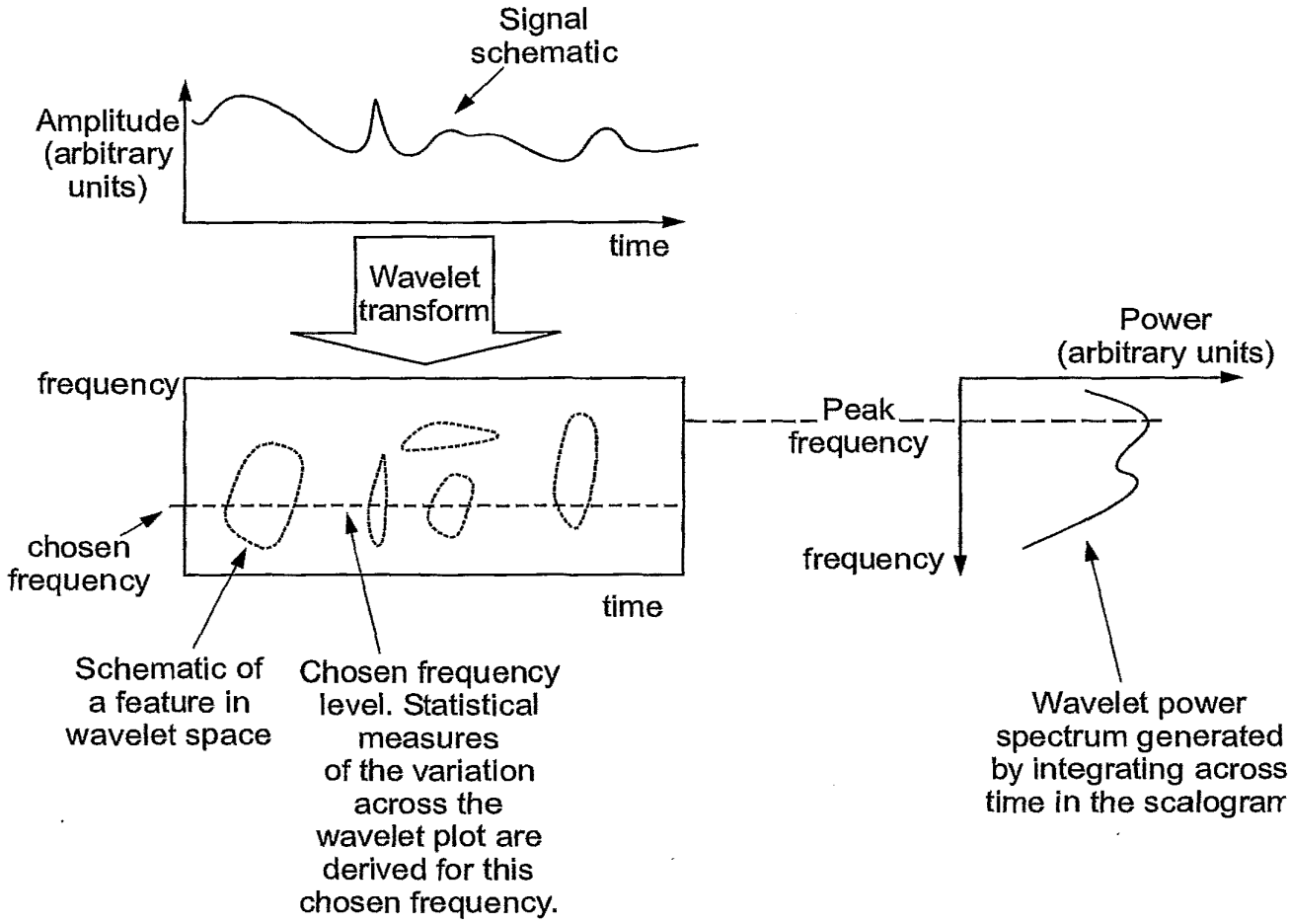
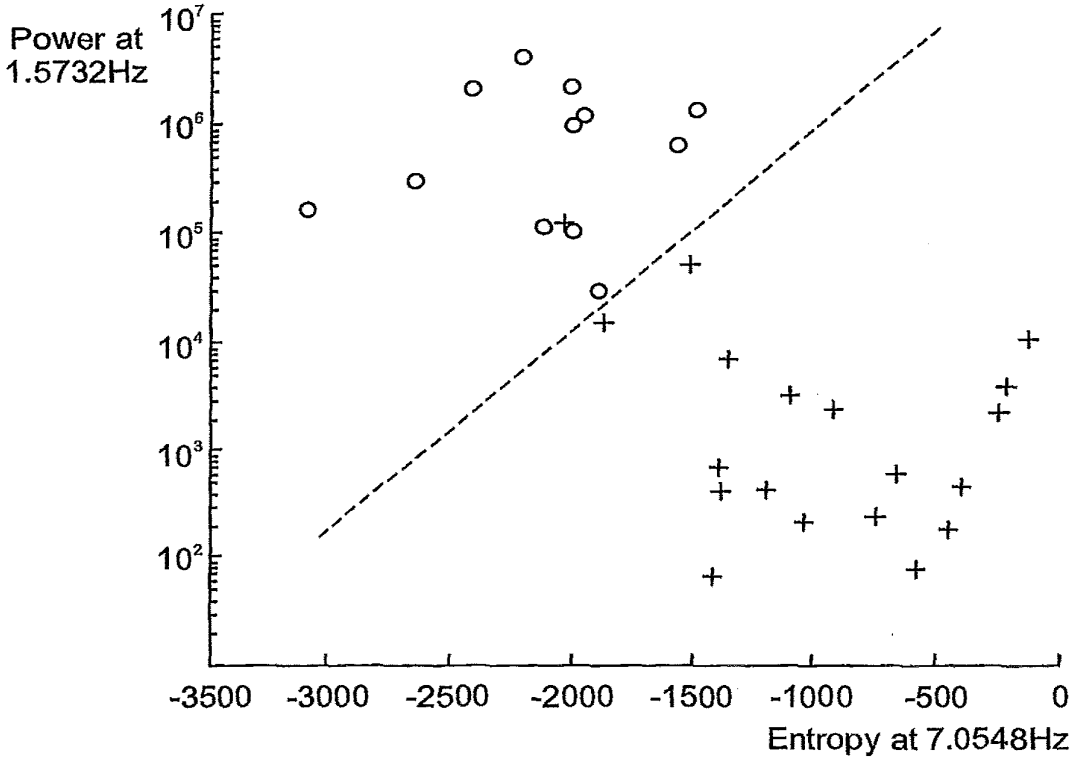

Signal schematic
Amplitude (arbitrary units)
time
Wavelet transform
frequency
chosen frequency
time
Schematic of a feature in wavelet space
Chosen frequency level. Statistical measures of the variation across the wavelet plot are derived for this chosen frequency.
Power (arbitrary units)
Peak frequency
frequency
Wavelet power spectrum generated by integrating across time in the scalogram

Fig. 12



Legend:

'o' - healthy controls.
'+' - children attending the accident and emergency department

Fig. 13

Petitioner Ex-1004, 0240

BNSDOCID: <WO_____03000125A1_I_>

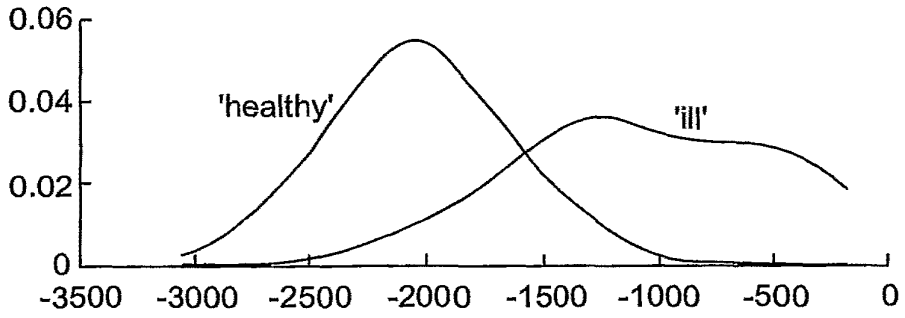


Fig. 14a

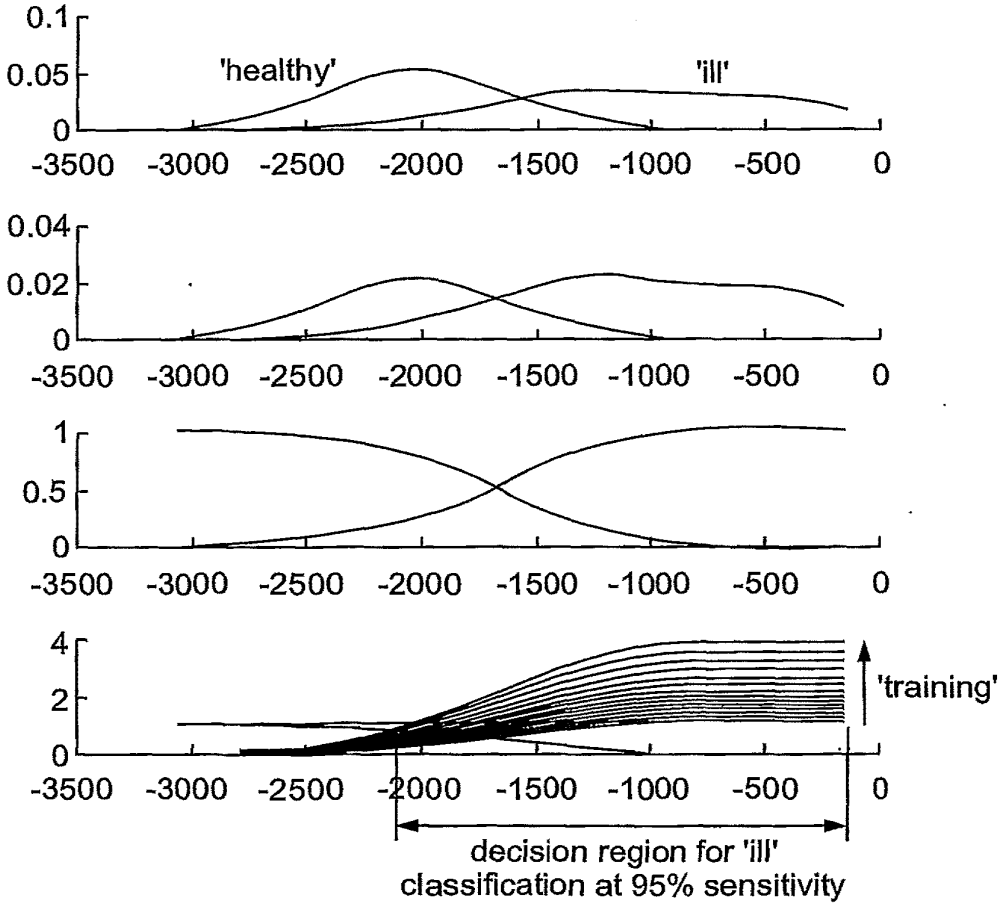


Fig. 14b

Petitioner Ex-1004, 0241

BNSDOCID: <WO_____03000125A1_I_>

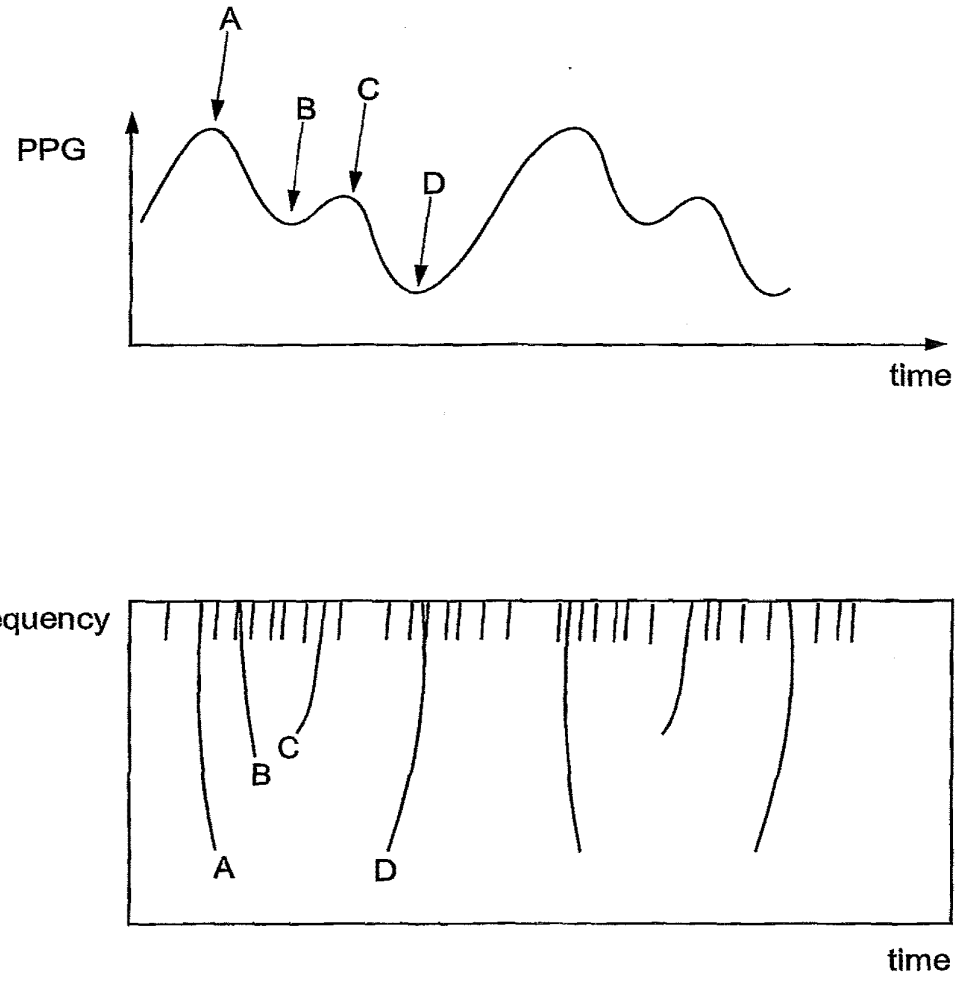


Fig. 15

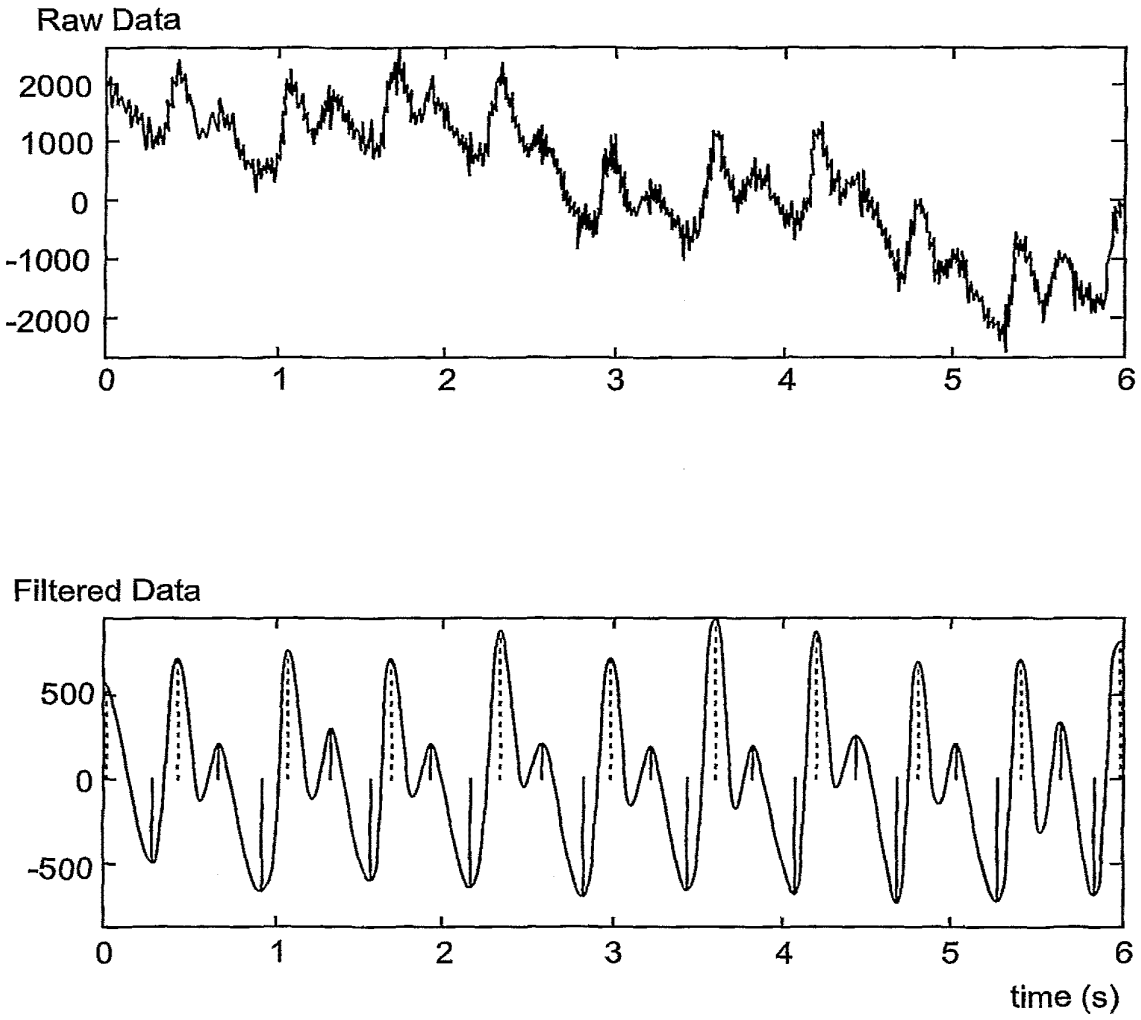


Fig. 16

Petitioner Ex-1004, 0243

BNSDOCID: <WO_____03000125A1_I_>

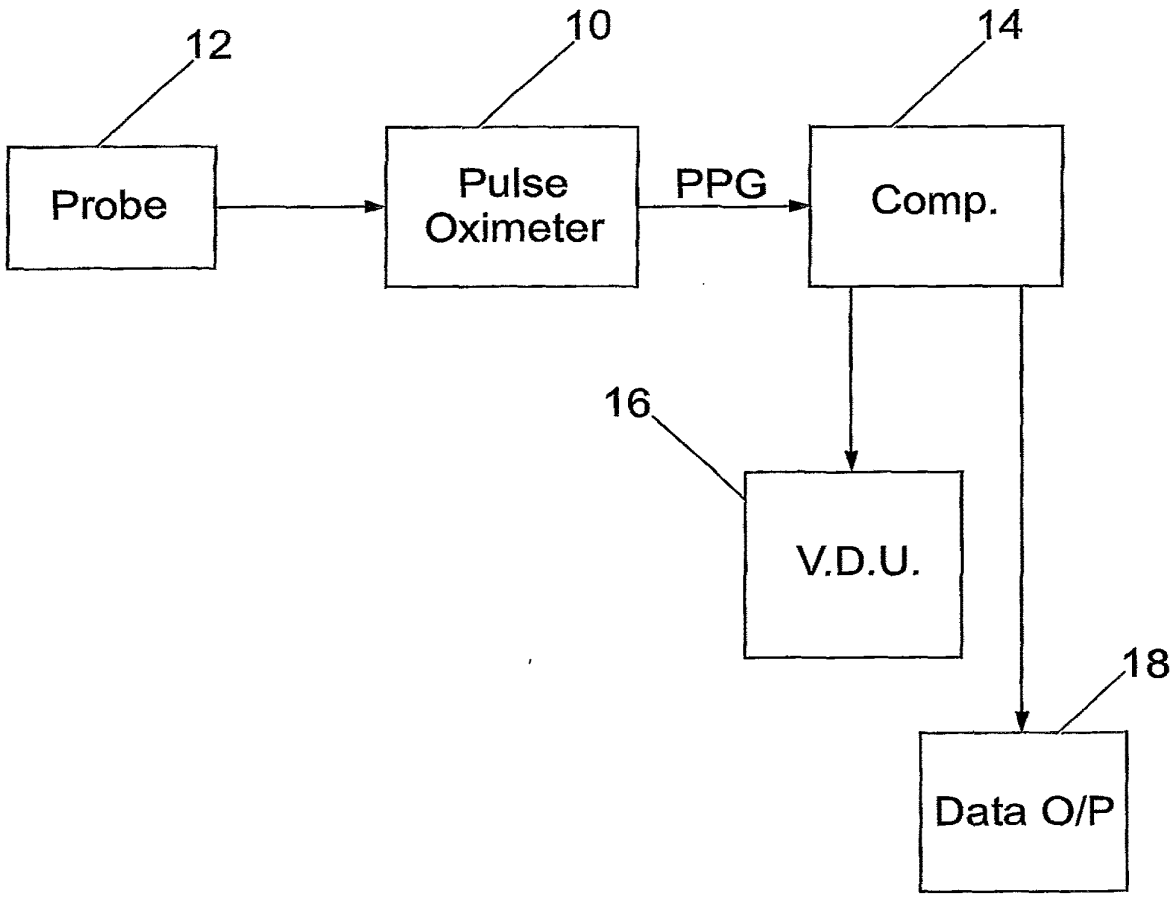


Fig. 17

Petitioner Ex-1004, 0244

BNSDOCID: <WO_____03000125A1_I_>

INTERNATIONAL SEARCH REPORT

Internati	Application No
PCT/GB	02/02843

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 G06F17/00

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)
IPC 7 A61B G06F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 25802 A (NTC TECHNOLOGY INC) 12 April 2001 (2001-04-12) page 8, line 7 - line 30 page 10, line 17 - line 30 page 12, line 8 -page 13, line 3 page 17, line 30 -page 18, line 16 page 23, line 24 -page 24, line 31	2,3, 8-10,12, 17,22,23
X	US 6 011 985 A (ATHAN STEPHAN PETER ET AL) 4 January 2000 (2000-01-04) column 5, line 48 -column 11, line 39; figure 2A	2,3,8,9, 12,22,23

-/--

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

[X] Patent family members are listed in 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
11 October 2002	21/10/2002

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Artikis, T

Form PCT/ISA/210 (second sheet) (July 1992)

BNSDOCID: <WO_____03000125A1_I_>

INTERNATIONAL SEARCH REPORT

Internat application No
PCT/GB 02/02843

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 117 075 A (BARNEA OFER) 12 September 2000 (2000-09-12) column 4, line 38 -column 7, line 20; figure 4	2,3, 8-11, 22-24
A	US 6 208 951 B1 (DIXIT NARENDRA MADHUKAR ET AL) 27 March 2001 (2001-03-27) column 2, line 1 -column 6, line 37 column 7, line 30 -column 9, line 33	2-4, 6-11,17, 18,22-24
A	US 6 135 966 A (KO GARY KAM-YUEN) 24 October 2000 (2000-10-24) abstract; figures 3,8A,8B	2-4, 6-10,12, 22,23
P,A	WO 01 82099 A (WATSON JAMES NICHOLAS ;ADDISON PAUL STANLEY (GB); COURT OF NAPIER) 1 November 2001 (2001-11-01) the whole document	1-24

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

BNSDOCID: <WO_____03000125A1_I_>

INTERNATIONAL SEARCH REPORT

Inte nal application No.
PCT/GB 02/02843

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1 and its dependent claims
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Diagnostic method practised on the human or animal body.
Claim 2 and all claims dependent on it (except claim 21) have been searched.

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

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

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

BNSDOCID: <WO_____03000125A1_I_>

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat Application No
PCT/GB 02/02843

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 1173813 A1	23-01-2002
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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 724 684 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
22.11.2006 Bulletin 2006/47

(51) Int Cl.:
G06F 9/46 *(2006.01)*

(21) Application number: **05291064.3**

(22) Date of filing: **17.05.2005**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR
Designated Extension States:
AL BA HR LV MK YU

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(54) System and method for task scheduling, signal analysis and remote sensor

(57) The present invention concerns a real-time operating system, associated network transmission protocol implementation, a method of analysis of an ECG signal, and a wireless sensor network device integrating all of said, wherein the method comprises :

acquiring one or more ECG signals over a period of time;
filtering said one or more ECG signals with at least one filter selected from the group consisting of a low pass filter, a high pass filter, and an adaptive filter; and
extracting one or more features from said filtered signal.

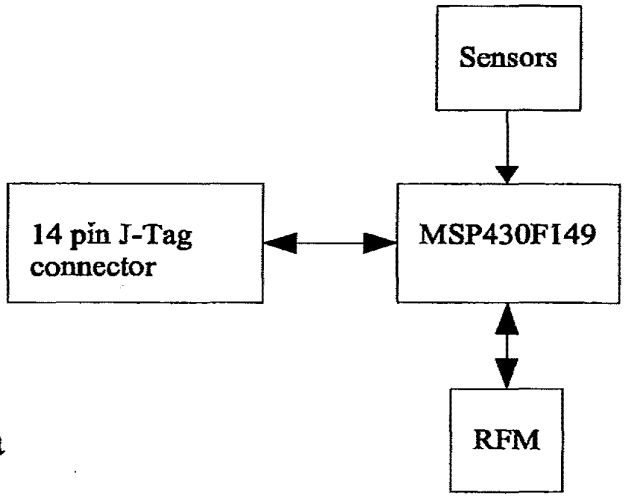


Fig. 1a

EP 1 724 684 A1

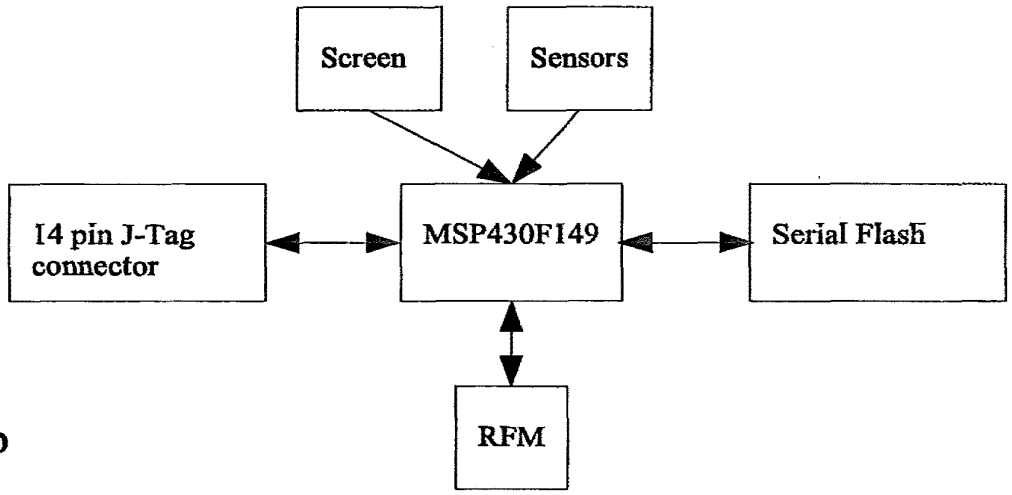


Fig. 1b

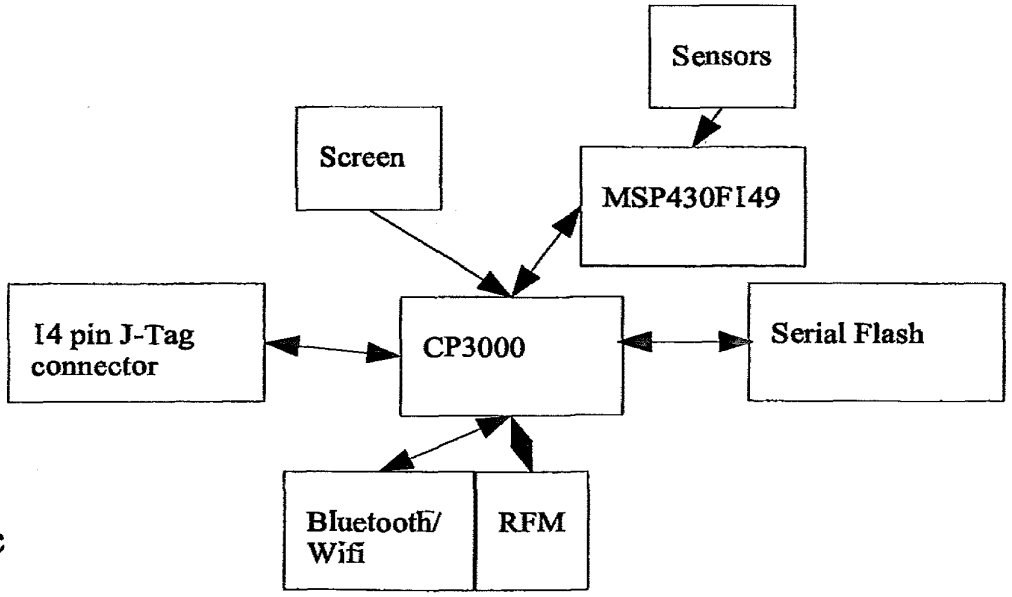


Fig. 1c

Petitioner Ex-1004, 0250

BNSDOCID: <EP_____1724684A1_I_>

Description

[0001] Wireless sensor networks (WSN) technology is a powerful technology that is currently shaping science and engineering in the twenty-first century. Revolutionary changes are already underway in a broad range of monitoring and control fields: transportation, manufacturing, health care, environmental surveillance, virtual reality, safety and security, to name just a few. Each of these areas has developed corresponding technologies, with their own hardware, algorithms, mathematics and specialized techniques. Advances in networking and integration have enabled small, flexible and low-cost nodes that interact with their environment through sensors, actuators and communication mediums. Single-chip systems are now merging that integrate low-power CPU and memory, radio or optical communication device and substantial Micro-ElectroMechanical-based Sensors (MEMS). Target costs for single-chip nodes are very cheap per unit, which enables networks with potentially tens of thousands of nodes. Target power consumption means that nodes can last years with low-bandwidth communication or even be battery-free when fuelled by ambient power, e.g. heat, light or vibration from the environment. The combination of sensing, computation and wireless communication into a single tiny node is termed a WSN node, also known as a "mote" or smart dust. WSN nodes are tiny wireless MEMS that can detect everything from light to vibrations. Due to recent breakthroughs in silicon and manufacturing techniques, these "motes" could eventually be the size of a grain of sand, and yet each would still contain sensors, computing circuits, bidirectional wireless communications technology and a power supply. Motes can gather a large number of data, run computations and communicate the information obtained using for example two-way band radio between motes. The emergence of WSN has created a new way of thinking about the computer and greatly extends the range of potential sensor applications. In general, traditional wireless devices, such as cell phones, personal digital assistants (PDA) or laptops equipped with IEEE 802.11 wireless network interfaces, cost hundreds of dollars, target specialized applications and reply on the pre-deployment of extensive infrastructure support. In contrast, a WSN system uses small, low-cost embedded devices for a wide range of applications and does not depend on any existent infrastructure. The fundamental feature of a WSN node is its tiny size and associated tiny cost. The core of a WSN node is a small, low-cost, low-power microcontroller that performs both application and protocol-level processing. By monitoring one or more sensors, a WSN node can obtain various exterior information including signals for temperature, light, sound, position, acceleration, vibration, stress, weight, pressure, humidity, etc. A WSN node can connect with other nodes or access points through a small and low-power radio at a distance of approximately 100 meters. The real-time monitoring capability is the fundamental feature of a WSN system. The most straightforward application of WSN technology is to monitor in real time remote environments for low frequency data trends. Typical usage scenarios for a WSN system range from real time tracking, environment monitoring, real time patient care, structural monitoring, or even battlefield monitoring, etc.

[0002] Telemedicine is defined as the delivery of healthcare and sharing of medical knowledge over a distance using telecommunications systems. The term telemedicine is usually applied to interactive televideo "store-and-forward" image and medical record transmission via personal computers, and to remote monitoring. Currently, there are over 450 telemedicine programs worldwide. There are programs in virtually every medical speciality, and the patients they most commonly serve include those who live in rural areas, the elderly and etc. With the growing ability of modern computer and communication technologies, key clinical data, such as ECG (electrocardiograph), images, etc, can be captured and immediately transmitted to remote servers. In this way, clinical data are used to improve the health care of all the patients who live in areas where medical personnel are not readily available. Telemedicine also allows remote monitoring of patients anywhere and at anytime, and provides a new approach to health care. Despite the widespread use of telemedicine in all areas of health care delivery, this area is still considered unacceptable or unavailable for most people. One of the three main reasons currently impeding the growth of telemedicine is uncertainty about its efficacy, which has resulted in a certain unwillingness to implement telemedicine programs. A number of systematic reviews noted that although telemedicine technology shows promise in certain areas, the overall methodological quality of the evaluative studies was low. There is only a small amount of evidence that interventions provided by telemedicine result in clinical outcomes that are comparable to or better than face-to-face care. The low cost-effectiveness of telemedicine is another of the main obstacles to its current development. The costs of home-based telemedicine devices, remote network connection and services for clinical review are much more expensive than face-to-face care in many telemedicine applications. There is still a lack of a plan for the most appropriate and cost-effective use of telemedicine. Finally, conventional telemedicine is a "store-and-forward" operation mode, where clinical data is collected and forwarded for review later in a completely asynchronous manner. This mode is effective for patients with chronic diseases, but does not work for those sudden diseases, such as the heart attack which often results in a sudden cardiac death if the patient does not receive a treatment in time.

[0003] The emergence of WSN technology thus brings great opportunity to the traditional health care field. The combination of WSN technology and telemedicine technology allows patients to receive 24 hours per day real time care with time and space decoupled. The sensors of a WSN node capture patients' biomedical information, e.g. temperature, blood pressure, electrocardiograph (ECG) etc, over a long period ranging from a few days to several months. The wireless delivery mode of a WSN node allows patient daily activities when receiving a health care service without motion

Petitioner Ex-1004, 0251

BNSDOCID: <EP_____1724684A1_I_>

limitation. The computation capability of a WSN node makes it possible for real-time analysis and diagnosis of clinical information. It should be noted however, that technical problems still remain to be solved in this application field including providing a suitable biomedical wireless sensor device dedicated to the applications of health care or other biological signal processing.

[0004] The object of the invention is therefore to provide such a wireless sensor device or remote sensor system, and an embedded real-time multi-tasking operating system dedicated to said WSN device. Other objects of the invention are an embedded wireless communication protocol stack and a real-time method of biological signal analysis that is particularly suited to applications in the field of health care, and most notably in the detection and prevention of cardiac arrhythmia.

[0005] Insofar as some of these objects are concerned, it is possible, and the inventors have demonstrated, that the implementation can be software or hardware driven. In particular, the present applicants have developed a super-small distributed real-time micro kernel, hereafter designated SDREAM, a minimal real-time embedded TCP/IP stack, herein identified as μRET, a real-time automated ECG diagnostic (AED) algorithm used for analysing and processing the biological signals that are captured by the sensor device or system, and a telemedicine platform system for multi-user remote real-time ECG detection and diagnosis, all of which work together with the device to perform the necessary signal processing and handling.

[0006] Consequently, one object of the present invention is a Super-small Distributed REAl-time Micro Kernel, hereinafter known as SDREAM. Realizing a WSN system presents very significant challenges, especially at the architectural, operation system and protocol, software or hardware level. Major steps forward are required in the field of operating systems, communications protocols, data processing, and application support. One of these challenges is the design of an Embedded Operating System (EOS) on a WSN device having limited resources and yet still meeting real-time requirements. Comparing to conventional embedded devices, a WSN device has far stricter resource constraints and requires the ability to communicate wirelessly, which means that most popular EOSs can not be migrated directly onto a WSN device. In addition, WSN applications often contain real-time concurrent activities, e.g. simultaneous data acquisition, data processing and data transmission, which means that a WSN OS must also be a Real-Time Operating System (RTOS) that supports real-time multitasking operations. A WSN OS is therefore effectively an embedded real-time OS that is tuned to strictly constrained resources such as limited power, processing, storage, and bandwidth, and which supports wireless communication and real-time distributed activities. The present applicants have succeeded in creating a Super-small Distributed REAl-time Micro kernel (SDREAM) that is primarily aimed for such a WSN system. The SDREAM of the present invention is a tuple-based message-driven real-time operating system dedicated to resource constrained wireless devices. It has been designed to run on general purpose architectures where a single CPU is shared between application and system processing. The SDREAM of the present invention also provides a highly efficient communication mechanism and a fine-grained concurrency mechanism to real-time applications. It enables the development and implementation of multi-tasking real-time applications by providing a "priority-based preemptive scheduling" scheduling strategy. The tuple concept of LINDA parallel programming is preferably used for inter-task communication and task synchronization. The SDREAM of the invention has a flexible hardware abstraction capability which enables it to be rapidly migrated onto different WSN platforms and tiny embedded devices. Preferred microcontrollers for the implementation of the SDREAM and that may be used alone or combined in accordance with the invention are any 8 bit to 32 or even 64 bit multichannel microcontrollers, such as the 16 bit TMS320C541 0 microcontroller available from Texas Instruments, the 16 bit MSP430F149 microcontroller available from Texas Instruments, and the 16 bit CP3000 microcontroller available from Texas Instruments. In a most preferred embodiment, the MSP430F149 microcontroller is used for signal acquisition and the CP3000 microcontroller is used for system management.

[0007] All WSN nodes comprise four basic subsystems :

- a power subsystem: in order to monitor an environment for any length of time, the WSN node ought to have enough energy to survive anywhere from a few hours to months at a time. The energy can be provided by any well known means, for example, direct electrical current, batteries or accumulators, magnetic field induction, radio frequency induction, solar energy and the like, but obviously small and compact energy provider solutions are preferred in view of the intended application of the WSN node;
- a computation subsystem: since the WSN node is expected to communicate and process sensor data, it will generally have computational requirements that range anywhere from an 8 bit microcontroller to a 16, 32 or 64 bit microprocessor;
- a sensor subsystem: the interface between the environment and the WSN node is the sensor. The WSN nodes usually have at least one sensor, which may include temperature, pressure, humidity, light, sound, acceleration, magnetic fields, etc;
- communication: communication must be possible in standard outside environments. WSN nodes usually have the ability to communicate with one another at ranges from a few meters to several kilometers.

Petitioner Ex-1004, 0252

BNSDOCID: <EP_____1724684A1_I_>

[0008] "Commercial Off-The-Shelf" (COTS) motes are well known WSN platforms per se and serve as the "de facto" WSN platform standard due to their flexibility and availability of components for a great many applications. The COTS motes provide a practical method to test basic WSN functionality. A survey of the three generations of quickly developed WSN prototypes that have been built to date using COTS components is presented hereafter.

[0009] The COTS mote is also named COTS Dust, the platform architecture of which originated from the research of Seth Hollar. All COTS motes have a similar architecture, but differ in sensor medley and communication type. The COTS mote architecture was defined in detail in the master's thesis of Seth Hollar. An Atmel AVR microcontroller served as the brain, and depending on the flavour of the device, either optical or RF communication was used. Most COTS devices were powered by a 3V lithium battery. Finally, each device had its own sensor suite chosen according to the demonstration it was to present.

[0010] A representative implementation of the first generation COTS mote is the Radio Frequency (RF) mote. The RF Mote consists of the Atmel AT90LS8535, an RF Monolithics 916MHz transceiver set, and 7 sensors (temperature, light, barometric pressure, 2-axis acceleration, and 2-axis magnetometers). The RF Mote system clock of the Atmel MicroController Unit (MCU) runs at 149.475 KHz with a single instruction performed per clock cycle. Nineteen instructions are required to send and receive raw data bits through the RF system. The raw data rate of the RF system is 149.475 KHz / 19 Cycles / bit = 7.867 Kbps, but with the implementation of Manchester encoding, the data rate is cut in half to 3.934 Kbps. The weC mote is basically a smaller version of its predecessor, the RF mote. The weC Mote consists of an RFM TR1000 RF transceiver, an integrated Printed Circuit Board (PCB) antenna, temperature and light sensors, and an additional MCU, an Atmel AVR AT90S2313, which is a smaller version of the AT90S8535. The original intent of the weC mote was to test out amorphous computing style algorithms specifically for distributed sensor networks based on pheromone messaging.

[0011] The René mote is the mote of Crossbow resulting from collaboration with the University of California Berkeley. The René mote is based on a modular design concept. The main processor-radio board contains the same components as the weC Mote. The modular design introduces two 51 pin connectors (male and female) for interfacing to sensor and programming boards. Lastly, the sensor board emphasizes the modularity of the René mote. A sensor board has the same dimensions as the main processor-radio board and also has two connectors. The first sensor board, known as the "Basic Sensor Board", contains a light and a temperature sensor and a prototyping area. Thus, a sensor can be connected to the sensor board. Moreover, any number of sensor boards can be attached to the main board by stacking them. The René2 mote replaces the main MCU of the Rene Mote, the AT90S8535, with the ATMEGA163. This MCU has 1 KBytes RAM and l6Kbytes flash memory. The Dot Mote is a circular platform (diameter = 1 inch or 2.54 cm). The Dot Mote consists of the same components as the René2 Mote. Without a 51-pin sensor board interface, the Dot Mote has a temperature and light sensor. The Dot Mote was used at the August 2001 Intel Developers Forum (IDF). The demonstration consisted of wirelessly reprogramming the 800 Dot Motes with a Simple Voting Demo. The entire demo demonstrated Network Discovery, Routing, and Aggregation.

[0012] The Mica Mote consists of a RFM TR1000 RF transceiver, 4 Mbit external flash memory (AT45DB041 B), 6 ADC channels available for different sensors, and an 8-bit MCU with a CPU clock of 4MHz consisting of an Atmel ATMEGA103 microcontroller (later versions are an ATMEGA128 in 103 Mode). The original intent of Mica Mote is to overcome the shortcomings of René2 mote. Compared to the René2 mote, the Mica Mote has more storage, more communication bandwidth, stabilized board voltage and more board capability. The Mica Mote has more flexibility for communication protocols, time synchronization, and other algorithms. The Mica2 Mote is the second generation of the Mica Mote. The main improvements of the Mica2 over the Mica are: 1) main MCU with a CPU clock of 7.3827 MHz: ATMEGA128 in 128 Mode, 2) New Chipcon CC1000 RF transceiver with 916/433 MHz bands, 3) Coax antenna connector for external antenna, 4) Streaming ADC data to ATMEGA128 at max rate: 20KHz at 10-bits, 50KHz at 8-bits, etc. Like the Dot mote of the René series, Mica2 also has a circular simplified platform (diameter=1 inch or 2.54 cm). The Mica2Dot consists of the same components as the Mica2 Mote with only the difference in CPU crystal: 4MHz in Mica2Dot vs 7.3827 MHz in Mica2.

[0013] Despite the fact that COTS motes have been used predominantly in previous WSN systems research and development, other WSN platforms have been developed and are in use. The EYES project, for example, of the European Research Consortium (ERC) which initiated in 2002 is one such other non COTS mote system. The EYES project represents another approach to WSN development by presenting a different platform from the COTS motes. The EYES project focuses on the architecture, protocol and software issues of their WSN system, and on self-organizing and collaborative energy-efficient sensor networks. It addresses the convergence of distributed information processing, wireless communications, and mobile computing. In the EYES architecture, applications rely on a two-level structure. The lower layer deals with sensors and networking, whereas the upper layer provides distributed services to the application by using the networking and transport capabilities offered by the lower layer. The EYES mote consists of a RFM TR1001 RF transceiver with OOK/ASKS modulation, 1Mbits external flash memory, and a 16-bit MCU: TI MSP430F149 with 2KBytes RAM and 60KBytes program memory.

[0014] The WSN project that is one of the objects of the present invention is also different to the known COTS mote

Petitioner Ex-1004, 0253

BNSDOCID: <EP_____1724684A1_I_>

systems, and is particularly suited to real-time cardiac arrhythmia detection and diagnosis. The present invention is exemplified with regard to applications of the WSN in real-time ECG detection and diagnostics. Preferably, a Texas Instruments MSP430F149 microcontroller serves as the brain which has a CPU clock of 8MHz and a maximum of 8 channels available for sensors, for example, ECG electrodes, while different wireless communication models can be used, for example and preferably, IEEE802.11 b, or even the Bluetooth wireless transmission protocol. In a still yet even more preferred embodiment, the microcontroller used is a CP3000, to manage the system, while a MCU MSP430F149 is preferably dedicated to signal acquisition. System block diagrams of three types of SDREAM architectures as described above are illustrated in Figure 1.

[0015] The operating system is viewed as a layer of software that multiplexes, as well as abstracts, hardware resources, such as memory, processor cycles, I/O devices, etc, for applications, and acts as an interface between applications and the hardware platform. The application programs rely on facilities provided by the operating system to gain access to hardware resources. There are a number of existing RTOSs that are potential candidates for use on a WSN node. A number of RTOSs adopt a form of "Modularity" through the use of microkernel architecture, for example, VxWorks, QNX, WinCE, PalmOS, RTLinux. The TinyOS is a well-known system software platform used by a WSN node. TinyOS is dedicated to providing a software solution based upon severe resource constraints.

[0016] An "embedded system" for the purposes of the present specification and claims, is generally any computer system or computing device that performs a dedicated function or is designed for use with a specific embedded software application. An embedded system usually involves a microcontroller with limited computational power and a simplified architecture. A good embedded OS should desirably be configurable and scalable with a modular architecture. It generally has a small footprint and low CPU requirement in terms of low system resource constraints compared to those of a general purpose processor.

[0017] A "real-time system", for the purposes of the present application, is one in which the correctness of the computation not only depends upon the logical correctness of the computation but also upon the time at which the result is produced. If the timing constraints of the system are not met, system failure is said to have occurred. The ability of a real-time operating system is to provide a required level of service in a bounded response time. A real-time operating system provides an infrastructure for running software on an embedded hardware platform. It abstracts the hardware wherever possible and provides access to the hardware wherever needed. The key difference between general-computing operating systems and RTOS is the need for "deterministic" timing behaviour in the real-time operating systems. The RTOS must guarantee Interrupt Server Routine, or ISR, latency and context switch time in order to achieve deterministic performance. A Real-time system is generally classified into two categories: a hard real-time system and a soft real-time system. The former must keep to very strict timing constraints. Missing timing constraints in a hard real-time system will cause the result to be totally useless, and thus regarded as a system failure even it is correctly computed. In contrast, in a soft real-time system, missing timing constraints occasionally is not fatal, although it might indicate a flaw in the design.

[0018] A kernel is the smallest portion of the operating system that provides an abstraction layer upon which the application software will run. The kernel hides the hardware details of the processor, or set of processors, for application software. A RTOS kernel normally consists of four main categories of basic services: task management, intertask communication & synchronization, timer & I/O interrupts, and memory management. The task management is the core of the RTOS kernel, which contains a task scheduling scheme and context switches. A scheduling scheme is mandatory in all microkernel instances, which is a set of rules, procedures, or criteria used in making processor scheduling decisions. The typical scheduling scheme for RTOS has two aspects: priority-based scheduling and pre-emptive scheduling. Cooperating processes need to exchange information, as well as to synchronize with each other, to perform their collective task(s). Methods for effective sharing of information among cooperating processes are collectively known as intertask communication & synchronization. Two basic models are used: message passing and shared memory. The main mechanisms of intertask communication & synchronization include mutex, pipe, semaphore, message queue, and monitor, etc. In an embedded system, a RTOS normally adopts a shared memory model for huge data exchange to decrease the overhead of data-copying and to reduce the storage consumption. The timer is an essential unit of any microkernel. It is normally configurable to show the time consumption by the changes of time-tick variables. With regard to the differences in applications and hardware platforms, there are different I/O interrupts in a RTOS. They provide interactive interfaces between embedded devices and the external environments. The RTOS must be carefully designed to meet timing constraints of real-time applications. Several key time factors in a RTOS include interrupt action latency, interrupt dispatch latency, and task scheduling time, or context switch time. The memory management of a RTOS is normally simple due to the bounded memory resources. There are generally two different management models: dynamic and static memory allocation.

[0019] There are lots of commercial and academic real-time operating systems, ranging from small real-time kernels with the size of several kilo-bytes to huge packages with full support for a file system, networking systems, graphics, etc. A brief overview on the designs of some well-known real-time kernels is provided hereafter.

[0020] μC/OS-II is a fully pre-emptive kernel written in ANSI C by Jean J. Labrosse. It can manage up to 64 tasks,

Petitioner Ex-1004, 0254

BNSDOCID: <EP_____1724684A1_I_>

eight are reserved for system use and the remaining 56 tasks are available for user applications. As each task has a unique priority assigned to it, thus there are 64 priority levels in μC/OS-II. The priorities are dynamic and alterable during execution. μC/OS-II is a configurable kernel so only the required kernel features are selected to reduce memory consumption. μC/OS-II can behave as a non-pre-emptive system by disabling the scheduler. μC/OS-II is a multi-tasking operating system and provides a protection mechanism for shared resources. It provides multiple IPC and synchronization services like mailboxes, message queues, semaphores, fixed-sized memory partitions, time-related functions, etc.

[0021] VxWorks5.x from Wind River Systems, Inc. is a priority real-time operating system and supports a wide range of industry standards including POSIX 1003.1 b Real-Time Extensions, ANSI C and TCP/IP networking. Both a pre-emptive priority and a round-robin scheduling mechanism are available in VxWorks5.x. There are 256 priority levels and the maximum number of tasks is only limited by the amount of the memory available. All tasks share the same address space, but an optional component (VxVMI) can allow each task to have its private virtual memory and provide memory protection. Interrupt Service Routines (ISRs) in VxWorks5.x run in a special context outside of any task's context, so that there are no additional context switches involved. The intertask communication mechanisms include shared memory, semaphores, message queues, pipes and signals, etc. VxWorks5.x adopts a modular framework and is thus scalable. By selecting various modules, VxWorks5.x can be configured for the use in a small embedded system having tough memory constraints up to complex systems. Furthermore, individual modules themselves are scalable. Individual functions may be removed from the library, or specific kernel synchronization objects may be omitted if they are not required by the application.

[0022] QNX Neutrino from QNX Software Systems Ltd. has a client-server architecture consisting of a lean microkernel that implements only core services and optional cooperating processes, such as signals, timers, and scheduling. All other components: file systems, drivers, protocol stacks and applications, run in the safety of memory-protected user space. QNX Neutrino is a message-based multi-process operating system. Message passing is the fundamental means of IPC. This message passing forms a virtual "software bus" and messages can flow transparently across processor boundaries, providing seamless access to any resource, anywhere on the network. QNX Neutrino is a self-healing system and has powerful fault resilience ability. In QNX Neutrino, every process has its own virtual memory, code and data segment. QNX Neutrino provides full MMU (memory management unit) support for memory protection. An interrupt handler execution can be pre-empted by interrupt handlers from a higher priority interrupt source. QNX Neutrino complies with POSIX 1003.1-2001 and features an extensive POSIX feature set, including real-time extensions and threads. As a result, it's very easy to port Linux, Unix, and other POSIX-based open source programs. Moreover, the QNX Neutrino is the only commercial RTOS to support true symmetric multiprocessing (SMP): it allows any thread in any process to be scheduled to run on any processor of an SMP system.

[0023] pSOSystem3 from Wind River Systems, Inc. is a modular, high-performance, memory protected, highly reliable real-time operating system, designed specifically for embedded microprocessors. It includes a kernel pSOS+ and the integrated development environment pRISM+. The configurability and extensibility is achieved by highly modularized design; there are separate modules that support single and multiple processors, file management and TCP/IP, streams communication, graphics, and JAVA. pSOS+ is a variant of the client-server architecture and uses a software bus to communicate between the different modules. pSOS+m is a multiprocessor version of the pSOS+ kernel. It requires one node to be a master and the rest are slaves. The nodes can be connected in different ways: shared memory, message-based buses or custom links, etc. Priority FIFO scheduling and round-robin scheduling schemes are adopted in pSOSystem3. pSoSystem3 has a flat memory space and the memory protection function is optional. It offers two sets of memory handling functions: Regions, i.e. non-fixed block size pools and Partitions, i.e. fixed-size block partitions.

[0024] LynxOS4.0 from LynuxWorks is a hard real-time operating system. Each OS component of LynxOS 4.0 is designed for absolute determinism. It performs a complex series of tasks respecting the time constraints (predictable response). LynxOS4.0 is a multi-tasking RTOS and has four scheduling schemes (FIFO, Priority Quantum, Round-Robin and Non-pre-emptive). It offers comprehensive intertask communication facilities: message queues, semaphores, shared memory, sockets, signals, pipes, mutexes and condition variables. LynxOS4.0 provides address spaces protection for tasks through MMU, and is linearly scalable to an unlimited number of tasks. Lynx4.0 conforms to open system standards: Linux, UNIX and POSIX. It can offer true Linux binary-compatibility which means that applications written for Linux run on LynuxOS 4.0 with no loss of functionality. Moreover, LynxOS gives access to a full state of the art TCP/IP stack derived from FreeBSD4.2.

[0025] RTLinux from New Mexico Tech. is a hard real-time operating system that handles timecritical tasks. It runs Linux as its lowest priority execution thread. RTLinux uses a virtual machine layer to make the standard non-real-time kernel be fully pre-emptive, so that real-time threads and interrupt handlers are never delayed by non-real-time operations. Interrupt off/on operations are emulated by a lower level kernel. It allows the system to run accurate time constraint applications to perform data acquisition, system control, etc, while serving as a standard Linux workstation. Real-time threads in RTLinux can communicate with Linux processes via shared memory or a file-like interface, so real-time applications can make use of all the powerful, non-real-time services of Linux. The results of interrupt latency measurement indicate that a great improvement over the Linux operating system is achieved; the interrupt latency of Real-Time

Petitioner Ex-1004, 0255

BNSDOCID: <EP_____1724684A1_I_>

Linux is about one third that of the Linux operating system on 33MHz Intel 80486 machines, while one eighth on 120MHz Intel Pentium machines.

[0026] Windows CE.NET is a hard real-time embedded operating system of Microsoft Corporation. Lots of processors have been validated to support Window CE.NET and its main application areas are: PDAs (Personal Digital Assistants), industrial embedded systems, and game consoles. Windows CE .NET is a "componentized" operating system. It includes a comprehensive set of more than 350 technology components. It provides a graphical integrated development environment (IDE) listing a comprehensive and extensible catalog of all operating system components. Through its extensible and robust componentization, Windows CE .NET offers a scalable operating system for a wide range of device types. Windows CE.NET supports true real-time behaviors. It provides 256 levels of thread priority. Nested interrupts are supported to ensure that a high priority level interrupt is serviced immediately. The per-thread quantum feature means users can adapt the scheduler according to the current need of application. Priority inversion technology enables the lower-priority thread to inherit the more critical thread's priority and to run at the higher priority until it releases the critical resource. Moreover, Windows CE .NET provides networking and communications capabilities, i.e. a full TCP/IP stack, that enable devices to connect and communicate more securely with other devices and people over both wireless and wired networks.

[0027] DREAM is a software real-time pre-emptive microkernel written in ANSI C by C. de Vaulx. DREAM is dedicated to intelligent biomedical sensors. It performs sets of tasks within predictable time. DREAM is a multi-tasking RTOS and provides three classes of tasks: periodic, aperiodic and daemon. It offers two inter-task communication facilities: semaphore and tuple, a concept of LINDA. DREAM does not manage virtual memory and does not provide address space protection for tasks. DREAM is a fault-tolerant system which gives an abstract definition for system behaviours and primitives by Meta language. It is also a distributed system that can run over a set of processors. DREAM supports dynamic memory configurations. It does not conform to any open system interface standard.

[0028] All the RTOSs support multi-tasking pre-emptive scheduling. Each task has a unique priority level which is a static or dynamic configuration according to the needs of applications. The response time for interrupt handlers and context switches are predictable so as to guarantee deterministic timing behaviours. Virtual memory and memory protection capability are provided in most RTOSs to avoid race conditions and to enhance the reliability of the system. Moreover, most RTOSs comply with a wide range of industry standards including POSIX, ANSI C, or Win32 API, etc, which makes programming on different platforms similar, and ports across these platforms easier.

[0029] Since a WSN operating system is dedicated to tiny WSN hardware platforms, it ought to be small and efficient in terms of highly constrained resources - limited power, processing, storage, and bandwidth. It must also be agile enough to allow multiple applications to simultaneously use system resources such as communication, computation and memory. Moreover, a WSN OS should be flexible for the rapid release of hardware and the variety of sensors. The extreme constraints of WSN hardware make it impractical to use traditional OSs. A well-known and widely-used WSN OS is TinyOS. TinyOS is a component-based, event-driven operating system for sensor network nodes developed as part of the Berkeley WEBS project. The TinyOS design follows two basic criteria:

extremely simple and extremely efficient. It focuses on three high-level goals in sensor network system architectures:

take account of current and likely future designs for sensor networks and sensor network nodes;
allow diverse implementations of both operating system services and applications, in varying mixes of hardware (in different mote generations) and software;
address the specific and unusual challenges of sensor networks: limited resources, concurrency-intensive operation, a need for robustness, and application-specific requirements.

[0030] In order to provide a comparison with TinyOS, some micro-operating systems (Micro-OSs) dedicated to microcontrollers are also presented.

[0031] TinyOS provides an efficient architecture of an event-driven concurrency model for modularity and resource-constraints. The modular architecture allows the OS to adapt to hardware diversity while still allowing applications to reuse common software services and abstractions. The design of the TinyOS Kernel is based on a two level scheduling structure: events and tasks. Events are divided into two classes: hardware events and software events. Software events signal completion of the requested action. Hardware events are interrupts, caused by a timer, sensor, or communication device. Hardware events are intended to do a small amount of processing (e.g. timer interrupts, ADC interrupts) and can pre-empt, i.e. interrupt, longer running tasks. When no useful work is to be performed, the TinyOS system enters an ultra-low power state, causing shutdown of the WSN node except for the clock, to reduce power consumption. Tasks are a form of deferred procedure call that allows a hardware event or task to postpone processing. They are intended to do a larger amount of processing and are not time critical e.g. computing an average on an array. Tasks can be scheduled at any time but will not execute until current pending events are completed. Tasks always run to completion with respect to other tasks, which implies that a TinyOS system application only needs a single stack. System modularity

Petitioner Ex-1004, 0256

BNSDOCID: <EP_____1724684A1_I_>

is based on a component model. A named component encapsulates a private data frame of some fixed-size state and a number of tasks. Components interact with each other strictly via function call interfaces, which are related groups of commands and events. The set of interfaces that a component uses and provides define its external namespace. Commands typically represent requests to initiate some action; events represent the completion of a request or something triggered by the environment, e.g., message reception. A specific set of events are bound to hardware interrupts. An application is assembled by specifying a set of components and "wiring" their interfaces together. The TinyOS concurrency model intentionally does not support blocking or spin loops. As a result, many operations are split-phase : the request is a command that completes immediately, and an event signals the completion of the requested action. This approach is natural for reactive processing and for interfacing with hardware, but complicates sequencing high-level operations, as a logically blocking sequence must be written in a state-machine style. TinyOS allows many concurrent activities to be serviced on a single stack, reflecting the very limited memory on modern microcontrollers. It also makes handling of error conditions explicit. TinyOS intentionally defines neither a particular system/user boundary nor a specific set of system services. Instead, it provides a framework for defining such boundaries and allows applications to select services and their implementations. Nonetheless, a common set of services has emerged and is present on most platforms and used by most applications. This includes timers, data acquisition, power management, and networking. This general decomposition is not unique to TinyOS; it can be found in other sensor network platforms. It covers the basic requirements of a sensor network: use little power, periodically collect data, perform some simple processing on it, and if needed, send it to a neighboring node.

[0032] Some Micro-OSs have been written for microcontrollers with commercial or academic intentions. The Micro-OS provides a software platform over the limited resources of microcontrollers. In general, it addresses itself to a set of particular applications or a series of particular processors.

[0033] RTOSs focus on the real-time requirements of embedded applications. The "priority-based pre-emptive multi-tasking scheduling" scheme guarantees the predictable responses and deterministic behaviours. However, despite RTOSs having reduced function "bloat" to meet large scale deeply embedded devices, they still appear too "huge" for some ultra-small WSN nodes. For example, most RTOSs provide virtual memory for each task or interrupt handler. A private memory space of each task can improve the reliability of RTOS, but may cause high system overhead due to large memory consumption and more context switch. In addition, as general embedded devices have an unlimited power source, the designs of RTOSs are normally unconcerned or not tuned particularly to the strict power constraints of WSN nodes. Hence, conventional RTOSs can not be utilized directly for strict resource constrained devices, i.e. WSN nodes. In fact, in terms of the application scenarios of WSN system, many unnecessary and overkill functionalities can be omitted from RTOS, e.g. address space isolation, complex I/O subsystem, and UI/GUI, etc.

[0034] On the other hand, TinyOS focuses on the wireless sensor application over the extremely strict resource constraints of embedded devices. TinyOS is a naturally single-tasking-model event-driven system, which provides a two-level scheduling scheme (event and task) to handle interrupts. As a result of limited system resources, TinyOS can not support large numbers of real-time interrupts tasks. Moreover, traditional network protocols, i.e. TCP/IP stack, are not supported because of their relative high memory requirements and "stop and wait" semantic model, since TinyOS does not support blocking or spin loops. Because traditional TCP/IP headers and sockets are not suited to a bounded TinyOS environment, the overhead per TCP/IP packet is rather expensive for any given WSN platform. It means a WSN node that uses TinyOS can not directly connect with the existing network infrastructures.

[0035] In order to provide real-time multi-tasks processing and traditional networks connection capabilities for WSN nodes, there was therefore a need to design a new WSN operating system. Accordingly, the present invention provides such an OS, which additionally and advantageously is small enough and efficient enough for the tiny resources and low power source of a WSN node. Secondly, the operating system according to the present invention is a true RTOS, supporting real-time multi-tasking operation and TCP/IP network connection capability. An efficient task scheduling scheme and a smart inter-task communication and synchronization mechanism have been developed by the applicants which has led to reduction in the consumption of resources and power, and reduced overhead of computation and communication.

[0036] One object of the present invention is therefore a Super-small Distributed REAl-time Micro Kernel (SDREAM). SDREAM is a microkernel and comprises four main components: task management, inter-task communication and synchronization, memory management, and interrupt handling and timer management. SDREAM has an abstract system definition and description through a Meta language, known as a Kernel Modeling Language : Meta, or KML:Meta. The four components of SDREAM and their Meta description are described hereafter.

[0037] As has been mentioned above, the motivation for designing SDREAM was to implement a distributed real-time kernel for a wireless sensor for use in intelligent biomedical applications. In SDREAM, tasks are classified into two categories: periodic and priority; system primitives and behaviours are defined using a Meta language. SDREAM adopts a real-time two-level scheduling scheme called "priority-based pre-emptive scheduling". SDREAM is a tuple-based message-driven system. It supports blocking and spin loop operation. The "tuple-based message" is the basis of task communication and synchronization. A shared data memory area, named tuple space, consists of a set of tuples each

Petitioner Ex-1004, 0257

BNSDOCID: <EP_____1724684A1_I_>

having a unique ID: KEY. In SDREAM, task communication is implemented by two system primitives: SND() and RCV (). The memory management of SDREAM adopts a static pre-allocation strategy for all system elements, including a set of tasks e.g. periodic and priority, a set of tuples, etc. There are two classes of interrupts in SDREAM: an I/O interrupt and a timer interrupt. A timer ISR (interrupt service routine) manages system time variables and triggers task scheduling; leaving I/O ISRs to be handled immediately to meet the strict time constraints. In order to tune to intelligent biomedical applications of a WSN node, SDREAM is small and efficient for tiny resource consumption and low power overhead. It also satisfies the requirements of multi-tasking real-time operation. The main advantages of SDREAM are that :

- it is ideally suited to distributed applications;
- it is highly reliable, in that it can support long-term no-fault operation;
- it contains two classes of tasks: periodic and priority;
- the periodic task being interruptible and non-pre-emptible;
- the priority task being interruptible and preemptible;
- each task is an automaton;
- it uses the IPC primitives SND() and RCV().

[0038] In accordance with the present invention, a task is defined as a couple, termed couple $(T, \wp)$, where T is a set of temporal TAGs, $T=\{tj;\ j=1,\ldots, n\}$ and $\wp$ is a set of actions, $\wp=\{ai;\ i=1,\ldots, n\}$. The $\wp$ can be an ordered sequence or a non-ordered sequence, correspondingly SDREAM supports precedence and concurrence operations. Each task is an automaton, as represented in Figures 2a and 2b. It communicates with each other through two basic system primitives, named SND() and RCV(). A task is interruptible by exceptions caused normally by interrupts.

[0039] In accordance with the present invention, an intelligent sensor has two classes of tasks: periodic and priority tasks, also called aperiodic or sporadic tasks. Periodic tasks are typically suitable to capture sensor signals, such as ECG, video image, temperature and the like, or to control actuators, which are interrupted at fixed-time intervals. Periodic tasks have a very short execution time and deterministic response time as well as the highest priority level, which is preferably 10, in SDREAM. They are interruptible but non--pre-emptible. Priority tasks are typically suitable for time constrained applications, which are interrupted at variant-time intervals. Priority tasks have predictable response times so as to conform to real-time constraints. They are interruptible and also pre-emptible, having priority levels comprised from 1 to 9, i.e. from low to high. The Daemon, the idle task of SDREAM, is a particular priority task with the lowest priority level, in this case priority 0. This task is executed only when no task is available in the task ready queue. It means that the system is in idle status. An application or job is composed of a set of tasks, including periodic and priority tasks. An application is also an automaton in SDREAM. Each application is interruptible by the timer and external peripheral interrupts.

[0040] Definitions of symbols:

- P: Periodic task
- A^x : Priority task with a priority level x
- A^y : Priority task with a priority level y
- <> : A set of tasks or actions
- Description of an application (3P, $2A^x$ and $3A^y$):

Job = $<< P_1, P_2, P_3>, <A^x{}_1, A^x{}_2>, <A^y{}_1, A^y{}_2, A^y{}_3>>$ (x >y)

[0041] In SDREAM, each task is assigned a priority, with higher priority values representing the need for quicker responsiveness. SDREAM provides a two-level scheduling scheme according to different task types. For periodic tasks, SDREAM adopts a "FIFO (First-In, First-Out)" scheduling scheme and tasks are selected according to their arrival order in the ready queue. Two tasks that run at the same priority, e.g. 10, can use FIFO scheduling to ensure mutual exclusion to a shared resource. Neither task will be pre-empted by the other while it is executing. For example, if they shared a memory segment, each of the two tasks could update the segment without resorting to some forms of semaphoring. A task selected to run continues executing until it voluntarily relinquishes control, i.e. it is completed. The response time and execution time of periodic task are very short and deterministic in SDREAM, so they are used to respond to I/O interrupts or to monitor actuators. Moreover, all periodic tasks share the system stack, thus there is no overhead of context switch when running periodic tasks. For priority tasks, SDREAM adopts a "priority-based pre-emptive" scheduling scheme and tasks are selected according to their priority level. The scheduler always allows the higher-priority tasks to run first. The low-priority tasks will run when the higher-priority tasks have finished. When the scheduler determines a task needs to run immediately, the "pre-emptive" property enables it to stop any priority task at any execution point out of the critical section. Priority tasks are therefore suitable for strict time constrained applications. According to the same priority level tasks, the "round-robin" scheduling scheme is adopted. In round-robin scheduling, a time-slice is associated to a task, which means the lifetime of a task. Once it consumes its time-slice, a task is pre-empted and the next ready

Petitioner Ex-1004, 0258

BNSDOCID: <EP_____1724684A1_I_>

task at the same priority level will get the system control. A task selected to run continues executing until it voluntarily relinquishes control or consumes its time-slice. In fact, apart from time slicing, round-robin scheduling is identical to FIFO scheduling. Figure 3 illustrates the task scheduling scheme adopted in SDREAM corresponding to the application as defined in the expression above. The three periodic tasks have the highest priority values 10. They are run in sequence by "FIFO" scheduling. After the periodic tasks are completed, a higher-priority task (A^x_1) is selected to run. It has a time-slice. If it is not completed but consumes its time-slice, a next ready task (A^x_2) at same-priority level will pre-empt the CPU control. Until the tasks with higher-priority (x) are completed or voluntarily relinquish control, the low-priority tasks (y) are able to obtain the CPU control. Each time the scheduler is triggered by a timer interrupt, the following 5 steps are carried out. These 5 steps together are called "task switching" or "context switching":

determine whether a currently running task should continue to run. If not, suspend said current task and goto next step;
determine which task should run next;
save an environment of the task that was suspended, so it can continue later
set up a running environment of an other task that will run next;
allow this other task to run.

Meta Definitions and Descriptions
Definitions of symbols:

// : Concurrent or Parallelism operation

$\rightarrow$: Precedence operation
Description of task scheduling of an application:

$$P1 \rightarrow P2 \rightarrow P3 \rightarrow (A^x_1 \,//\, A^x_2) \rightarrow (A^y_1 \,//\, A^y_2 \,//\, A^y_3)$$

Rules:

$$(A^x_1 \,//\, A^x_2) = (A^x_2 \,//\, A^x_1)$$

$$(A^y_1 // A^y_2 // A^y_3) = (A^y_2 // A^y_3 // A^y_1) = (A^y_3 // A^y_2 // A^y_1)$$

[0042] Like task scheduling, SDREAM has different task states definitions according to the task types. Three states are defined for the periodic task to describe the task operations: Sleep, Ready and Execution. The "Execution" state is a transient state which is held only when the task is running. For an activated periodic task, it is held on the "Ready" state at most of time. The "Sleep" state shows that a task has been created but not been activated in present. The state transition diagram of a periodic task is shown in Figure 4a. When compared to the periodic task, the priority task has one more state named "Suspend". If a running condition is not available, the current priority task will be blocked and the task state will be changed to "Suspend". If a running condition is available, the suspended priority task will be woken up to resume running and the task state will be changed to "Ready". The state transition diagram of priority task is shown in Figure 4b.

[0043] The transition functions table below (Table 1) shows the operations of task state transitions.

Table 1

Transition Functions	
(1) :	Activate Task
(2) :	Deactivate Task
(3) :	Scheduler
(4) :	Suspend Task

Petitioner Ex-1004, 0259

BNSDOCID: <EP_____1724684A1_I_>

(continued)

Transition Functions	
(5) :	Resume Task

[0044] SDREAM does not support the dynamic creating or releasing a task. The number of tasks is pre-configured by the user at compile time. The "Sleep" state is the original and terminal state of a task. Each task is initialized to "Sleep" state when it is created. Four system functions and the scheduler together enable a task to transit over different states. The four transition functions are described as follows:

DeactivateTask is called to terminate a task when this task is completed (priority task) or an exception happens. The task's state is changed to "Sleep".

ActivateTask is called to activate a "Sleep" task when this task is assigned to an application. The task's state is changed to "Ready".

SuspendTask is called to block a task when the running condition of this task cannot be satisfied in present. The task's state is changed to "Suspend".

ResumeTask is called to resume a task when the running condition of this task is satisfied. The task's state is changed to "Ready".

Meta definitions and descriptions
Definitions of symbols:

c : Operation of inserting a task into a task queue
$\supset$: Operation of extracting a task from a task queue
M (A, Ss, Sd) : Change the state of task A from Ss to Sd

Ss : Task source state

Sd : Task destination state

rea : Task READY state

sus : Task SUSPEND state

slp : Task SLEEP state

‖...‖ : Critical section or Atomic Operation, disable interrupts
SC(A) : Save the context of task A
RC(A) : Restore the context of task A
SCHED : Call scheduler
| : 'Or' Operation

[0045] Descriptions of transition functions:

Petitioner Ex-1004, 0260

BNSDOCID: <EP_____1724684A1_I_>

DeactivateTask: || $M(A^x$, rea|sus, slp) ||;

ActivateTask: || $M(A^x$, slp, rea) ||;

SuspendTask: || $M(A^x$, rea, sus);

IF (A^x == runTask) THEN

SC(A^x) → RC(scheduler) → SCHED;

END IF||;

ResumeTask: || M(Ax , sus, rea);

SC(runTask) → RC(scheduler) → SCHED ||;

[0046] The inter-task communication and synchronization models of the conventional embedded operating systems are space couple or time couple. They use classical concepts such as: message passing, mailbox, port (Inter-task communication) and semaphore, mutex (task synchronization). These models were originally developed for general purpose multi-user applications, but are not adapted to the tiny resource embedded real-time applications. The key idea of the inter-task communication and synchronization service provided in SDREAM is named "Tuple". The "tuple" model originates from the LINDA concept. LINDA is a parallel programming language which supplies a number of operations or primitives that provide the ability for tasks to communicate. It uses a shared structure, called a tuple space, which is an unordered collection of tuples. A tuple is an ordered collection of elements, with each element having a value and an associated type. Tasks insert tuples into the tuple spaces, and other tasks can then retrieve those tuples using a related matching process. LINDA provides asynchronous communication between tasks via tuple. The only way that two tasks can communicate with each other is to do so through tuple spaces using tuples and the LINDA primitives. The basic LINDA primitives of posting and reading a tuple are: OUT() and IN(). When a task wants to send a message, it calls the IN() primitive by posting a tuple in the tuple space. When a task wants to read a message from a related tuple, it calls the OUT() primitive: if this tuple template matches (message is available), a message will be extracted from the tuple space; Otherwise, this task is suspended. The message is extracted based upon matching of contents, thus the inter-task is not space couple. The inter-task communication in LINDA is asynchronous, thus it is not time couple. The tuple model used in the present invention therefore enables asynchronous communication between tasks, and is extensible to support a multi-process parallel programming model and suitable for distributed multiple application processing. However, the original LINDA concept is not adequate for distributed hard real-time parallel processing, because the time of inter-process communication (IPC) is not deterministic and increases dramatically when the numbers of processes and processors are important, for example, more than 100. To overcome these problems, SDREAM provides two very light IPC primitives: Snd() and Rcv(), which are simplified implementations of IN() and OUT () of LINDA. Instead of using all the message content to match and to extract a tuple, only one numeric value (KEY) is used to identify a tuple. Thus, the numeric identifier and the type of tuples may be assigned to local, shared or distributed memory, which are statically configured by the user in SDREAM. All the message buffers are mapped into an array of bytes associated to a table of tuple which realizes the tuple space (input/output buffer table). Thus, the content of a message may be accessed immediately when a tuple is not empty, and the operation time of tuple template matching is very short and deterministic in spite of the number of tasks or processors. The SDREAM is a tuple-based message-driven system. Each message, no matter network data, sensor acquisition or task data, must associate with a unique tuple. When a message received from the network, sensors, or other tasks arrives at its associated tuple, it will drive a task scheduling and subsequently wakeup the tasks suspended on the tuple.

Meta definitions and descriptions

Definitions of symbols:

[0047]

T(key) : A tuple with an ID: key

Petitioner Ex-1004, 0261

BNSDOCID: <EP_____1724684A1_I_>

B(key) : A used data buffer associated to the tuple(key)
M : A message
N : A waiting time
E(err) : Operation of error report, err is error code
+ : Operation of inserting a message into a tuple
- : Operation of extracting a message from a tuple
-- : Operation of decrement instruction
: Length of an object :

#B(key) : length of a used data buffer B in the tuple(key)
#T(key) : Maximum length of the tuple(key)
#M : Length of a message
#Q(key) : Number of suspended tasks in the tuple (key)

Descriptions of system primitives: SND() and RCV()

```
SND:
|| WHILE (#B(key) > (#T(key) - #M) && N >0 ) DO ||
N--;
ENDWHILE
|| IF (#B(key) ≤ (#T(key) - #M)) THEN
        B(key)+m;
IF (#Q(key) >0) THEN
        ResumeTask;
ENDIF
        ELSE E(err);
ENDIF ||

RCV:
|| IF (#B(key) ≥ #M) THEN
        B(key)-m;
ELSE SuspendTask;
END IF ||
```

[0048] SDREAM according to the present invention has tiny memory requirements and can reside in the internal memory of a microcontroller, for example, residing in a static 60KBytes program memory and a 2KBytes dynamic RAM of a Texas Instruments MSP430F149 microcontroller. Most microprocessors and microcontrollers have only one execution mode, i.e. there is no supervisor mode, and do not have a MMU to allow memory protection or virtual memory management. SDREAM also has a unique physical memory address space (user and kernel). The same address space enables memory sharing between system kernel and tasks. Therefore, SDREAM reduces greatly the overhead of memory usage and avoids buffer copying. There are three major memory usage areas in SDREAM: stack space, tuple space, and code and data space. The memory map of SDREAM is shown in Figure 5 :

Petitioner Ex-1004, 0262

BNSDOCID: <EP_____1724684A1_I_>

Code and Data space: the executable codes and program constants are invariable, which are normally stored in the program memory of processor. The global variables are stored in the public area of RAM and the private variables (priority task) are stored in the private stack of each task;

Stack space: each priority task has a private stack on which the accesses of other tasks are refused. The stack space contains task context, function pointers and parameters as well as functions' private variables. Since there is no MMU for memory protection, the function calls in SDREAM are not recursive, thereby minimizing system stack size and avoiding stack overflow. Each stack size is predetermined by the application developer according to the application;

Tuple space: All tasks and interrupt service routines in SDREAM share a tuple space which consists of a set of non-ordered tuples. A task has a right to read and write data in a tuple if it gets a tuple access key. Hence, tuple space is a data exchange area for kernel and tasks while the related KEY provides the memory protection. Each tuple allows simultaneously unique task writing and multi-task reading operations at the same time. Each tuple memory is a circular buffer, thus the reading operation will generally be faster than the writing operation.

[0049] The SDREAM of the present invention only supports static memory allocation. The allocation of memory with fixed position and fixed size is controlled by the compiler in a predetermined fashion. Neither dynamic memory i.e. no malloc, nor heap memory is provided in the SDREAM of the present invention. The static memory allocation mechanism avoids memory fragmentation caused by continuous dynamic allocation and de-allocation and also reduces the overhead of memory management. The main memory allocations are :

Task table i.e. fixed numbers of periodic and priority tasks;
Stacks for system and priority tasks, i.e. fixed sizes;
Tuple table, i.e. fixed sizes.

[0050] The interrupt handling in a kernel is normally closely tied to the hardware on which it is intended to run. Interrupts can be caused by a variety of conditions, both internal and external to the processor. An interrupt forces an interrupt service routine (ISR) to a predefined address in the interrupt vector. Many portable RTOSs rely on a compiler-provided mechanism for interrupt handling where C functions can be used as interrupt service routines. In this general approach, all registers are saved and restored while handling interrupts, which thus has an overhead of interrupt-oriented context switching. The compilers of the two preferred SDREAM hardware platforms, i.e. TMS320C5410 and MSP430F149 microcontrollers, adopt this approach. The external interrupts in SDREAM are normally the hardware events from the sensors and the network devices. They can be periodic events, e.g. data sampling from sensors, or aperiodic events, e.g. uncertain network connection requirements. SDREAM uses a small footprint method for handling external interrupts. Instead of function calling or task scheduling to handle interrupts, SDREAM places directly the related actions into interrupt service routines. The most important action of external interrupts in SDREAM is to copy data, preferably one or two bytes at a time, between the interrupt registers and associated tuples. The actions of ISRs are straightforward and can be performed in a very short and deterministic time. Moreover, since there are no task scheduling and no complex internal actions in external ISRs, SDREAM only needs to save and restore only parts of the general registers. The "part of registers" feature enables SDREAM to speed interrupt handling and to reduce the overhead of interrupt-oriented context switching. SDREAM internal interrupt is normally a periodic timer interrupt caused by system clock. In general, a processor contains one or multiple programmable interval timers that generate periodic timer interrupts. The time interval of the timer interrupt, i.e. the clock tick, is configurable and may vary from platform to platform. All program timer-variables used in system kernel and applications are managed by the ISR of timer interrupt. Each time a timer interrupt happens, the timer-variables will be changed. When the value of the scheduling timer-variable reaches the threshold, a task scheduling occurs. In this condition, all general registers will be saved into the stack of current running task, and then the scheduler is called in ISR to select a next task.

[0051] In one particularly preferred embodiment of the present invention, SDREAM is substantially implemented in the C programming language, except for a few hardware-related elements which are preferably implemented in assembly language. Since SDREAM is intended for wireless sensor network applications, the preferred microcontrollers of choice are the TI MSP430F149 16-bit microcontrollers, available from Texas Instruments, USA. In addition, in another preferred embodiment, it is also possible to implemented SDREAM on the TMS320C5410 16-bit digital signal processor. The implementation of the SDREAM architecture will now be described in detail. The main data structures of SDREAM are presented as is an overview of kernel initialization during system startup, and a description is made of the SDREAM scheduler, which comprises a two-level scheduling scheme for periodic and priority tasks. The task state transition functions: InitializeTask, ActivateTask, DeactivateTask, SuspendTask and ResumeTask, are also described in detail. In addition, the preferred implementations of two task communication primitives: RCV and SND are also given.

[0052] The kernel initializes itself before the applications run. The task and tuple are preconfigured by the user and initialized by the system startup program, i.e. normally by the main() function, in which hardware initialization operations

Petitioner Ex-1004, 0263

BNSDOCID: <EP_____1724684A1_I_>

are also performed.

Data structures

[0053] To simplify system implementation, a simple buffer structure such as a table or a queue is used in SDREAM. SDREAM has one periodic task descriptor table (PrdtskTable), one priority task descriptor table (PritskTable) and one tuple table (TupleTable). The members of these tables are Prdtsk, PriTsk, and Tpl respectively. Table 2 illustrates the structure of the periodic task descriptor. The task address pointer is stored in the TskAdr field. The Tid is a task identifier and its value indicates the index of a task element in task descriptor table. The value of Prd field indicates the time period of a periodic task, and the value of CurClk filed indicates the residual time interval for next task execution. The CurClk value is initialized to the task period (Prd) at the beginning of task execution, and is decremented by one at each task scheduling. A period task will keep to perform until the value of CurClk is equal to zero or the completion of task. The value Pri field indicates the task's priority. The periodic task has the highest priority value, i.e. 10 in SDREAM. This Pri value is unchangeable while the system is running. The Sta describes the task state. The periodic task has three task states: Sleep, Ready and Execution.

Table 2 : Structure of Periodic Task Descriptor

PrdTsk	
Struct PrdTsk {	
short TskAdr;	/* Task Address pointer*/
char Tid;	/* Task Identifier */
char Prd;	/* Task Period */
char CurClk;	/* Task Running Time */
char Pri;	/* Task Priority */
char Sta;	/* Task State */
};	

[0054] The structure of the priority task descriptor is shown below in Table 3:

Table 3 : Structure of Priority Task Descriptor

PriTsk	
Struct PriTsk {	
PriTsk	
short TskAdr;	/* Task Address Pointer*/
char Tid;	/* Task Identifier */
char Prd;	/* Task Period */
char CurClk;	/* Task Running Time */
char Pri;	/* Task Priority */
char Sta;	/* Task State */
short IniSp;	/* Start Address Pointer of Task Stack */
short CurSp;	/* Current Address Pointer of Task Stack*/
};	

[0055] PriTsk has two additional elements compared to PrdTsk: IniSP and CurSP. The identically named elements of the priority task have the same significance as for those of the periodic task. The Prd and CurClk indicate the maximal and residual lifetimes of a priority task. These two variables are useful for time sharing between same-level priority tasks. There are four states for priority tasks: Sleep, Ready, Suspend, and Execution. The priority tasks are arranged in the

Petitioner Ex-1004, 0264

BNSDOCID: <EP_____1724684A1_I_>

task descriptor table according to the sequence of task priority, i.e. from high to low priority. Each priority task has its private stack space. The value of IniSP indicates the start address of a task stack and the value of CurSP points to the address position of the current execution point in a task stack.

[0056] The Tpl structure defines a tuple, shown in Table 4. The Sta filed shows the tuple state. If a message is unavailable in a tuple, the wait tasks in this tuple will be blocked and the Sta value is set to NOREADY; whereas, if a message is available in this tuple, the Sta value is set to READY and the suspended task will thus be woken up. The Key is the access identifier of a tuple which also implies the type of a tuple. The MsgNb indicates message numbers in a tuple buffer. The WrMsgPtr and RdMsgPtr are the reading and writing pointers of the tuple buffer which point to the current reading and writing buffer addresses. The StaBfrAdr and EndBfrAdr indicate the start and end address of this tuple buffer respectively. The tuple buffer is a circular buffer space. If the WrMsgPtr or RdMsgPtr is equal to the EndBfrAdr, it will automatically jump to the StaBfrAdr. Hence, in order to ensure reliability of SDREAM, reading operations must be faster than writing operations.

Table 4 : Structure of Tuple Descriptor

Struct Tpl {	
char Sta;	/* Tuple State */
char Key;	/* Tuple Key */
unsigned char *WrMsgPtr;	/* Current Write pointer */
unsigned char *RdMsgPtr;	/* Current Read pointer */
short StaBfrAdr;	/* Start address of Tuple Buffer*/
short EndBfrAdr;	/* End address of Tuple Buffer */
short MsgNb;	/* Message Number */
};	

[0057] The SDREAM system startup program contains two main steps: system initialization and task scheduling. When a processor is reset, it obtains the address of the system startup program, the main() function is called and the kernel is running, as shown below.

System startup routine :

Main

```
main ()
{
        /*Initialisation of software: variables, tasks, tuples, etc... */
        Init_Software()

        /*Initialisation of hardware platform: IO interrupts, timer, clock, etc... */
        Init_Hardware()

        /*Start Scheduler*/
        While(1) {
                /*Goto the system stack IniSysSP*/
                SysSPPtr = IniSysSP;
                Set_SP();
```


Petitioner Ex-1004, 0265

BNSDOCID: <EP_____1724684A1_I_>

```
                    /*Call function Schedule()*/
                    SysTskPtr = (unsigned short)schedule;
                    Set_Tsk();

                    /*Run function schedule()*/
                    Run_Tsk();
                }
}
```

[0058] The definitions and the configurations of tasks and tuples are carried out by the developer in the system header file. The numbers of periodic tasks, priority tasks, and tuples are pre-configured, and the buffer size of stacks and tuples are pre-allocated. The *Init_software()* function initializes system variables, two classes of tasks and the tuples. It loads the tasks by calling the system function *ActivateTask().* An associated stack will be assigned to a priority task in this system function. The *Init_hardware()* function initializes all hardware-related information, such as system clock frequency, I/O interrupts, timer period, sample frequency of sensor, and system mode, etc. Subsequently, the scheduler is called, and the system enters an infinite loop. In a preferred example of SDREAM implementation in MSP430F149, there is one periodic task, four priority tasks, including the daemon, and five tuples. The four stacks are pre-allocated to priority tasks, which have different sizes according to the practical applications. In this preferred example, the first priority task is dedicated to network communication based on the point-to-point protocol (PPP), named *Net_PPP()* with a priority of 9; the second task aims to real-time transmit sensor signals, named *ECG_SER()* with a priority of 9; the third task is a minimal Web Server, named *WEB_SER()* with a priority of 8; and the fourth task is a daemon program with the lowest priority of 0. The stack sizes for the four priority tasks identified in this example are, in bytes : 100, 120, 120, and 30 respectively. This instance pre-allocates five tuples in the tuple space, including: USART (Universal Synchronous and Asynchronous Receiver and Transmitter) serial output tuple (OutUartBfr), USART serial input tuple (InUartBfr), sensor input tuple (McbSpBfr), UDP input tuple (UdpBfr), and TCP input tuple (TcpBfr), the tuple buffer sizes of which are, in bytes : 256, 128, 130, 4, and 6 respectively. In order to avoid a data race condition, SDREAM supports only a single UDP connection and a single TCP connection at a time.

[0059] SDREAM according to the present invention provides a two-level scheduling scheme in view of two classes of tasks. The periodic task adopts a "FIFO" scheduling scheme. All periodic tasks have the highest priority level 10, and they are executed sequentially according to their orders in the periodic task table. The priority tasks adopts a "priority-based pre-emptive" scheduling scheme. They have priority levels ranging from 9 to 0 (from high to low). A high priority task can pre-empt the CPU control of lower-priority task. This scheduling scheme supports time sharing between tasks of same priority. The priority task descriptor table ranks from highest to lowest priority and the index of each member of the table corresponds to the task identifier. The "priority-based pre-emptive" scheduler algorithm is implemented to elect a highest priority task and to allow sharing time between tasks as shown below:

Petitioner Ex-1004, 0266

BNSDOCID: <EP_____1724684A1_I_>

```
for(i=Next_Index;i<Maximum_Number_Of_Priority_Process; i++)
{
        if(Priority_Process[i].Status==READY) {
                The process having i identifier is elected,
                break;
        }
}
/*
        Set Index to next priority process having the same priority,
        it allows time sharing
*/
if(Priority_Process[i+1].Priority == Current_Process_Priority){
        Next_Index = i+1;
}
else {
        Next_Index = 0;
}
```

[0060] Like the priority task, periodic tasks are stored in the periodic task descriptor table, but they are non-ordered because all the periodic tasks have the same priority, i.e. 10. The index of the table corresponds to the periodic tasks identifier and all the elected periodic tasks must be executed and completed before the next task scheduling. The scheduling algorithm is shown below:

```
for(index=0;index<Maximum_Number_Of_Periodic_Process; index++)
{
        Update Periodic_Process[index].Period;
}
for(index=0;index<Maximum_Number_Of_Periodic_Process; index++)
{
        if (Periodic_Process[index].Period <= 0){
                /*
                periodic process is READY
                */
                Push The Periodic_Process[index].Address on the system
                stack;
                Update Periodic_Process[index].Period;
        }
}
```

[0061] SDREAM according to the present invention provides five system functions to manage task state transition for a periodic or priority task : InitializeTask, ActivateTask, DeactivateTask, SuspendTask, ResumeTask. In SDREAM implementations of the present invention, a task can be "sleep", "suspended" or "ready" by only changing its state variable without moving to task state queues. This approach is simple and efficient when few tasks are involved.

[0062] The Initialize Task function is called to initialize the periodic and priority tasks in the system startup program. The configurations of tasks are set manually and the fields of two task tables are filled by the developer during the compile time. The initial state of all tasks is "Sleep". An example of the InitializeTask function is presented below. It has six parameters:

Type : The type of the task (periodic task : 0, priority task: 1);
Tid : The index of the task in associated task queue;
TskAdr : The address of the task;

Petitioner Ex-1004, 0267

BNSDOCID: <EP_____1724684A1_I_>

Pri : The priority of the task (periodic task: 10, priority task: from 0 to 9);
Prd : The period of the task;
SP : The stack pointer of the priority task.

InitializeTask :

InitializeTask (char Type, char Tid, short TskAdr, char Pri, short Prd_SP)

```
{
        if (Type == 0) {
                /* Initialization of periodic task */
                PrdtskTable[ Tid ]. TskAdr = TskAdr ;
                PrdtskTable[ Tid ]. Tid = Tid ;
                PrdtskTable[ Tid ]. Pri = Pri ;
                PrdtskTable[ Tid ]. Sta = SLEEP ;
                PrdtskTable[ Tid ]. Prd = Prd_SP ;
                PrdtskTable[ Tid ]. CurClk = Prd_SP ;
        }
        else if (Type ==1 ){
                /* Initialization of priority task */
                PritskTable[ Tid ]. TskAdr = TskAdr ;
                PritskTable[ Tid ]. Tid = Tid ;
                PritskTable[ Tid ]. Pri = Pri ;
                PritskTable[ Tid ]. Sta = SLEEP ;
                PritskTable[ Tid ]. IniSP = Prd_SP ;
                PritskTable[ Tid ]. CurSP = Prd_SP ;
        }
}
```

[0063] The ActivateTask function activates a "sleep" task into a "ready" state. It is normally called during task initialization in the system startup program or when a user manages a task in an application. The algorithm description of this function is presented below and has two parameters: Type and Tid.

ActivateTask
DISABLE_ALL_INTERRUPTS:
IF current task is SLEEP THEN Modify the state of current task to READY;
ENDIF
ENABLE_ALL_INTERRUPTS;

[0064] The DeactivateTask function is called to terminate a task when this task is completed (priority task) or some abnormal exceptions happen. The task state is changed from "ready" or "suspend" to "sleep". The algorithm description of this function is presented below. It has the same parameters as those of ActivateTask.

DeActivateTask

```
DISABLE_ALL_INTERRUPTS;
```


Petitioner Ex-1004, 0268

BNSDOCID: <EP_____1724684A1_I_>

```
IF current task is READY or SUSPEND THEN Modify the state of current task to SLEEP;
ENDIF
ENABLE_ALL_INTERRUPTS;
```

[0065] In SDREAM, only the priority task can be suspended and resumed. When the running condition of a task is not satisfied, such as a receive message is not available, this task will be suspended by calling SuspendTask, and the task's state is set to "suspend". If the task in question is the current running task, context switching will occur, and the scheduler is thus called. The algorithm description of the SuspendTask function is given below. It has one parameter: the index identifier Tid on the priority queue.

SuspendTask

```
DISABLE_ALL_INTERRUPTS;
IF current task is READY THEN Modify the state of current task to SUSPEND;
IF current task is the running task THEN Save current context;
Restore system context;
Run Scheduler ;
ENDIF ENDIF ENABLE_ALL_INTERRUPTS;
```

[0066] When the running condition of a suspended task is satisfied, the ResumeTask function is called to resume the execution of this task, and the task's state is set to "ready". If the priority of this suspended task is greater than the one of current running task, context switching will occur, and the scheduler is called. The algorithm description of this function is given hereafter. It has the same parameters as the SuspendTask function.

ResumeTask

```
DISABLE_ALL_INTERRUPTS;
IF current task is SUSPEND THEN Modify the state of current task to READY;
IF the_priority_of_current_task > the_priority_of_the_running_task THEN Save the context of the running
task;
Restore system context;
Run Scheduler ;
ENDIF
ENDIF
ENABLE_ALL_INTERRUPTS;
```

[0067] The service of inter-task communication and synchronization consists of a tuple space, or a collection of tuples, and two system primitives, RCV and SND. These two basic primitives are not only responsible for the task-to-task communications, but also for task-to-device communications, such as the sensors and network mediums. By calling RCV and SND primitives, a task posts a message into a tuple or reads a message from a tuple The messages stored in tuples conform to the format of AHDLC (Adaptive High Level Data Link Control).

[0068] When a task wants to extract data from a related tuple, identified by a key, a RCV primitive is called. If a message is available in a tuple, RCV translates the original data from the message in AHDLC format, and then stores the data into the task buffer. Consequently, the RCV primitive returns and this task continues. However, if no message is ready, the task will be suspended until its running condition is satisfied. The algorithm description of RCV primitive is shown below. It has three parameters:

Key : a tuple access identifier;
MsgPtr : the task buffer pointer to store the message;

Petitioner Ex-1004, 0269

BNSDOCID: <EP_____1724684A1_I_>

SP : the maximum message size that the task can receive.

RCV

```
DISABLE_ALL_INTERRUPTS;
IF (message is NOREADY in the tuple) THEN SuspendTask;
ELSE Extract and store data into task buffer from a message with AHDLC format;
ENDIF
ENABLE_ALL_INTERRUPTS;
```

[0069] When a task wants to write data to a related tuple, a SND primitive is called. If the tuple has enough empty space for current data, the SND encapsulates the data into a message in the AHDLC format, and then stores the message into the tuple buffer. The AHDLC format thus allows better utilization of network bandwidth with word-oriented communication. Consequently, the SND returns and the task continues. If a data size is greater than the free space size of the tuple, the task will wait a special waiting time. After a waiting time, if there is still not enough memory, an error will be reported. The algorithm description of the SND primitive is shown below. It has the same parameters as those of RCV. The MsgPtr and Msglen indicate the task's data buffer pointer and data size respectively.

SND

```
DISABLE_ALL_INTERRUPTS
DO
N--;
WHILE (data_size > free_buffer_size_of_tuple && N > 0)
IF (data_size > free_buffer_size_of_tuple) THEN Err(errocode) ;
ELSE
Encapsulate data into a message with AHDLC format and store it in the tuple;
ENDIF
ENABLE_ALL_INTERRUPTS;
```

[0070] The implementation with the SDREAM architecture was ported to two kinds of processor architectures: microcontroller MSP430F149 and digital signal processor TMS320C5410. The memory and power consumption of SDREAM on these two processor architectures was measured, execution times of system primitives and functions calculated, system latencies determined, thereby enabling comparison of the SDREAM architecture with those of other RTOSs and TinyOS.

[0071] The SDREAM architecture was implemented and evaluated on two hardware platforms: TMS320C541 0 and MSP430F149. The TMS320C5410 is a 16-bit fixed point digital signal processor having a 100 MHz clock frequency. The TMS320C541 0 has 80KWs (W 'word' = 16 bits) of internal memory (16KWs of RAM and 64KWs of ROM) and three serial ports.

[0072] The MSP430F149 is a 16-bit RISC microcontroller having a 8MHz clock frequency. The MSP430F149 has 62KB (1 B=8bits) of internal memory (60KB of flash memory and 2KB of RAM), two serial communication interfaces (USART) and a fast 12-bit Analogic-to-Digital Converter (ADC) (8 channels).

[0073] The following Table 5 presents the respective sizes of memory consumption of two SDREAM implementations on the two different processors. The first is a minimal kernel containing the essential components of a real-time kernel: task primitives, scheduler and tuple space. The second is a complete kernel which integrates an embedded TCP/IP protocol stack (PPP, IP/ICMP, TCP/UDP, and HTTP/SNMP) and several applications, including sensor signal acquisition and transmission application, SNMP agent and Web server. It has one periodic task, four priority tasks, including a daemon, and five tuples. The memory consumption of SDREAM is very low, and is ideally suited for tiny embedded devices, especially for a WSN node, which has very severe resource constraints.

Petitioner Ex-1004, 0270

BNSDOCID: <EP_____1724684A1_I_>

Table 5 : comparative memory consumption across processors

Processor	Code size	Data size
Minimal implementation		
TMS320V5410 (W, 'word'=16 bits)	4,393	606
MSP430F149 (B, 'Byte'=8bits)	4,762	327
Complete implementation		
TMS320V5410 (W, 'word'=16 bits)	18,398	7,191
MSP430F149 (B, 'Byte'=8bits)	19,120	1,972

[0074] SDREAM can be configured to operate in low-power mode, thereby supporting the ultra-low power applications of WSN. Table 6 shows the power consumption of different operating modes on a WSN system according to the present invention. The MSP430F149 provides different levels of operation modes to support various requirements for ultra low power consumption. The low-power modes can enable or disable the CPU and the clocks. In addition, specific peripherals can be enabled or disabled to further reduce power consumption. In the general operating mode of MSP430F149, the operating current is on average 2.24 mA at 8 MHz clock frequency and 3V supply voltage. However, in the low-power mode 3 (LPM3), there is only 2 pA power consumption under the same conditions. When the SDREAM system is in the idle state, i.e. running the daemon task, LPM3 is selected by setting several bits in the status register of MSP430F149. Immediately after the bits are set, the CPU and some clocks halt and all internal activated buses stop until an interrupt request or reset occurs. Peripherals that operate with these inactive clocks are also inactive. A WSN system according to the present invention adopts the Bluetooth wireless communication access medium. The BlueWAVE, a Bluetooth serial wireless cable used in a WSN according to the invention, provides different operating modes to reduce power consumption. In the general connected mode, the average power consumption of a wireless connection is 92.5 mA at 3V; while in sleep mode, the average power consumption is only 6.25mA. When there is no data transmission in SDREAM, Bluetooth can be set to sleep mode until a data transmission request occurs. If there is no transmission request in a long-term or the peer is unreachable, the power supply for the Bluetooth can be cut off manually by the user. The Bluetooth is reset until the user requests a new Bluetooth connection.

[0075] For most WSN applications, such as environmental data collection, security monitoring, and sensor node tracking, the sensor data sampling frequency is low and SDREAM is in the idle state most of time. SDREAM can thus operate in low-power mode most of the time to reduce overall power consumption. In one preferred device of the invention, the default power source is a Lithium-Ion video battery with the capacity of 700mAH at 3V. A SDREAM application system, implementing 500Hz four-channel data sampling and real-time wireless connection, can run 7.4 hours in the general operating mode, whereas in low-power mode, the runtime is extended to 112 hours or more.

Table 6 : Power Consumption of different Operating modes in a WSN device according to the invention

Voltage = 3V, Capacity =700mAH	Normal Mode	Low-Power Mode
MSP430F149 (8Mhz)	2.24mA	2μA (LPM3)
BlueWAVE	92.5mA	6.25mA
Lifetime	7.4h	> 112h

[0076] The numbers of instruction cycles of the system primitives and functions on two different processors were evaluated respectively. The runtime of each primitive or function was calculated in view of the different clock frequencies on the MSP430F149 (8MHz) and the TMS320C541 0 (100MHz). Table 7 presents the results of the performance evaluation of system primitives and functions. The evaluation version of SDREAM is a complete implementation which is configured with one periodic task, four priority task and five tuples.

Petitioner Ex-1004, 0271

BNSDOCID: <EP_____1724684A1_I_>

Table 7 : Performance Evaluation of system primitives and system functions in SDREAM

Primitives	Conditions	MSP430F149				TMS320C5410			
		Cost (cycles)		Time (μs)		Cost (cycles)		Time (μs)	
		Min	Max	Min	Max	Min	Max	Min	Max
IntializeTask		121	156	15.125	19.5	60	79	0.6	0.79
ActiveTask		43	74	5.375	9.25	43	47	0.43	0.47
DeactiveTask		53	83	6.625	10.375	49	58	0.49	0.58
SuspendTask	Min : suspend a task in Ready state Max: suspend a running task	106	231	13.25	28.875	75	331	0.75	3.31
ResumeTask	Min : a task having lower priority Max : a task having higher priority than current running task	77	203	9.625	25.375	57	318	0.57	3.18
InitTuple		114	134	14.25	16.75	134	160	1.34	1.6
SND	Send a message with a length of 8 bytes	405		50.625		542		5.42	
RCV	Receive a message with a length of 8 bytes	411		51.375		548		5.48	

BNSDOCID: <EP_____1724684A1_1_>

Petitioner Ex-1004, 0272

[0077] In this static configurable SDREAM system, the execution time of system functions are determinate, which is between the minimal and maximal times. Moreover, because the size of a tuple message is limited and predefined, the execution times of SND and RCV primitives are thus predictable. The deterministic and predictable behavior of system primitives and functions is the most important property of a real-time operating system.

[0078] For a real-time operating system, the task scheduling scheme and the interrupt handling mechanism ought to be efficient and time predictable. Several system latencies are used to rate the performances of SDREAM task scheduling and interrupt handling, as shown in Figure 6. The time it takes for the system to switch from one task to another is called the task switch latency, or context switch latency. It is important that this latency is as short as possible to keep the task-switching overhead in the application to a minimum. In SDREAM, since two classes of tasks are defined, i.e. periodic and priority tasks, there are three latencies that can be used to evaluate the task scheduling scheme:

Periodic-to-periodic task switch latency: the time it takes for the system to switch from one periodic task to another periodic task. As periodic tasks don't have a local stack, there is no overhead for a context-switch between periodic task-switching. Moreover, the scheduling sequence of periodic tasks is determined in one-time scheduling. Thus, the periodic-to-periodic task switch latency is virtually equal zero;
Periodic-to-priority task switch latency: the time it takes for the system to switch from a periodic task to a priority task. There is one context-switch between the system and the priority task;
Priority-to-priority task switch latency: the time it takes for the system to switch from one priority task to another priority task. There is one context-switch between the system and the current running task and one context-switch between the system and the next priority task.

[0079] Real-time applications need the interrupt events to be handled as soon as possible. The interrupt latencies will be expected to be finite, and never exceed a predefined maximum. Two latencies are used to rate the performance of the interrupt handling mechanism:

Interrupt Response Latency: the time elapsed between the execution of the last instruction of the interrupted task and the first instruction in the interrupt handler. This is an indication of how fast the system reacts to an external event;
Interrupt Dispatch Latency: the time interval to go from the last instruction in the interrupt handler to the next task scheduled to run. This indicates the time needed to go from an interrupt level to a task level.

[0080] In order to evaluate system latencies, an SDREAM implementation according to the invention was configured with five periodic tasks, five priority tasks running at different priority levels and five tuples. The evaluation results of task switch latencies and interrupt latencies are presented in Table 8 and Table 9 respectively.

Petitioner Ex-1004, 0273

BNSDOCID: <EP_____1724684A1_I_>

Table 8 : Performance Evaluation of Task Switch Latencies

	MSP430F149				***TMS320C5410***			
	Cost (cycles)	Time (μs)	Cost (cycles)	Time (μs)	Cost (cycles)	Time (μs)	Cost (cycles)	Time (μs)
	Min	Max	Min	Max	Min	Max	Min	Max
Periodic-to-periodic task switch latency	0(285)[1]	0(481)	0(35.625)	0(60.125)	0(98)	0(238)	0(0.98)	0(2.38)
Periodic-to-priority task switch latency	284	519	35.5	64.875	146	299	1.46	2.99
Priority-to-priority task switch latency	482	645	60.25	80.625	930	1015	9.3	10.15
1 : the value in parentheses indicates the time of periodic task scheduling								

BNSDOCID: <EP 1724684A1_I_>

Petitioner Ex-1004, 0274

Table 9 : Performance Evaluation of Interrupt Latencies

	MSP430F149 Time μs			*TMS320C5410 Time μs*		
	Min	Avg	Max	Min	Avg	Max
Interrupt response latency	47.72	61.25	93.75[1]	2.82	2.873	4.133[1]
Interrupt dispatch latency	60.25	68.25	86.5	2.56	3.2	3.68
[1] : The max value of Interrupt response latency indicates the case were SDREAM runs in a critical area, especially in RCV or SND primitives.						

[0081] In order to entirely evaluate the performances of SDREAM, we compared it with other real-time operating systems and the WSN operating system TinyOS. The performance data of some popular RTOSs were obtained from evaluation reports of Dedicated System Experts. The evaluation reports for the following commercial operating systems are currently available:

RTX 4.2 from VenturCom, Inc.
Hyperkernel 4.3 from Imagination Systems, Inc.
VxWorks/x86 5.3.1 from WindRiver Systems Inc.
pSOSystem/x86 2.2.6 from Integrated Systems Inc.
QNX 4.25 from QNX Software Systems Ltd.
QNX/Neutrino1.0 from QNX Software Systems Ltd.

[0082] The evaluation platform adopted by Dedicated Systems Experts is an Intel Pentium 200MHz MMX based PC with a Chaintech motherboard. Time intervals are measured using external equipment: the PCI bus analyzer; and system peripherals are simulated by means of another external device: the PCI bus exerciser. The evaluation RTOSs are running with ten different priority-level tasks. In order to compare with the evaluation results of the SDREAM implementation on TMS320C5410, the inventors considered that the P200MMX has at least 300 MIPS (millions instructions per second) and the TMS320C541 0 has no more than 100 MIPS. Hence, the intrinsic execution time of P200MMX is 3 times faster than the TMS320C5410. The comparisons of two interrupt latencies between other RTOSs and SDREAM are shown in Figure 7a and 7b. In the two histograms, we can see that SDREAM has the smallest average interrupt response latency and the smallest average interrupt dispatch latency.

[0083] The TinyOS is a naturally multi-tasking event-driven system dedicated to wireless sensor applications. It has been tested on ATmega128 (4MHz clock frequency). The evaluation results are currently available. The minimal SDREAM implementation on MSP430F149 (8MHz clock frequency) was used to compare with the TinyOS. Since SDREAM was tested on a different platform to that on which TinyOS runs, the inventors only compared three system operations: schedule a task, context switch and hardware interrupt. The SDREAM is pre-configured with one periodic task and one priority task for this evaluation. The higher cost of task scheduling in SDREAM compared to TinyOS indicated the overhead of the scheduler function in SDREAM. The operation of context switching happens only between the system scheduler and a priority task. A hardware interrupt includes the hardware (hw) part and the software (sw) part. It was shown that in order to support true real-time multi-tasking operations, SDREAM had a greater system overhead when than TinyOS.

[0084] The SDREAM is a true real-time multi-tasking micro-kernel dedicated to embedded wireless sensor devices. A meta language is used to define and to describe the abstract manners of system primitives and operations. In SDREAM, tasks are classified into two categories: periodic and priority. The periodic task has the highest priority level and is responsible for capturing sensor signals or actuating control signals; the priority task has various priority levels and is suitable for time-constrained applications. The two-level task scheduling policy scheme, named "priority-based pre-emptive scheduling", is used for electing a task. SDREAM is a tuple-based message-driven system. The "tuple" is the foundation of task communication and synchronization. A shared data memory, named "tuple space", consists of a set of tuples each having a unique ID: key. All task and tuple members are static pre-allocation by the user at compile time. The interrupt handling mechanism of SDREAM is small and efficient, and has very short and determinate latencies for external events. The SDREAM has two fundamental features: it is both small and efficient. The minimal SDREAM version uses only 5 Kbytes of memory. The optional low-power operation mode enables an application of SDREAM, e.g. a 500Hz four-channel data sampling and real-time wireless connection, to run more than 120h on a wireless sensor device integrating the MSP430F149 microcontroller with a battery of 700mAH and a supply voltage of 3V. The evaluation results of the execution times of system primitives and system functions, task switch latencies and interrupt latencies demonstrate

Petitioner Ex-1004, 0275

BNSDOCID: <EP_____1724684A1_I_>

that the SDREAM architecture supports determinate and predictable system behavior, and the maximum response time for external events is under all system loads circumstantial. The SDREAM architecture integrates the advantages of both conventional RTOSes and the TinyOS operating system. Compared to the popular RTOSes, SDREAM has minimum resource consumption (memory and power) and minimum response time for interrupt events. It is thus ideally suited to migration into tiny-resource embedded devices, typically a wireless sensor network node. Even when compared to TinyOS, SDREAM is a true real-time multi-task system and has better scalability and flexibility for different hardware platforms and various applications requirements. SDREAM can run on platforms as diverse as tiny-resource devices to complex distributed systems and can support applications ranging from simple single tasks to real-time multi-tasks.

μRET: Minimal Real-time and Embedded TCP/IP implementation

[0085] Over the last few years, the interest for connecting embedded devices to wireless networks has steadily increased. Computers are becoming more and more seamlessly integrated with everyday equipments and prices are dropping. At the same time new wireless networking technologies, such as Bluetooth and IEEE 802.11 b WLAN, are emerging and maturing. Small devices such as sensors can be connected to an existing network infrastructure for example the global Internet, and be monitored from anywhere. With the success of Internet, the TCP/IP protocol stack has become a global standard of network communication. The widespread adoption of the TCP/IP stack in software applications has led to it being implemented in wireless or portable devices that can connect directly to an intranet or even the Internet. While originally developed for low speed networks such as ARPANET, traditional TCP/IP implementations run over a large spectrum of link technologies with vastly different characteristics in terms of bandwidth and bit error rate. Traditional technologies have often paid more attention to providing a solution for the flexibility of network communication in different network environments and traditional implementations, normally Berkeley stacks, are the basis of most of the commercial TCP/IP stacks for embedded systems. However, because real-time and embedded systems face many issues that are unique, a straight port of the traditional stack is not the best solution for the particular needs of an embedded and real-time system. Moreover, traditional TCP/IP implementations consume both CPU and memory resources that are scarce on such embedded devices. To run the full TCP/IP stack a few hundred kilobytes of code and data are necessary. Thus, in practical terms, the full TCP/IP stacks are not adapted to embedded systems because the on-chip memory of most microcontrollers devices is smaller than 100KB. Since embedded devices are often required to be physically small and inexpensive, there is thus a need to provide a minimal implementation of the TCP/IP stack that will be capable of matching the limited resources available. Despite the fact that there are numerous TCP/IP implementations for embedded systems, many of the existing implementations lack research into the simplification mechanisms of the TCP/IP stack. The present inventors have thus conceived and developed a minimal version of a TCP/IP stack, named μRET (Minimal Real-time and Embedded TCP/IP implementation). The μRET according to the present invention was initially implemented for an intelligent wireless ECG sensor that also forms one of the objects of the present invention.

[0086] In accordance with a further object of the invention, the design and implementation of μRET are also presented herein, as are the data structures, algorithms and mechanisms, and the general control flows used. The performance of μRET was also evaluated.

[0087] The TCP/IP (Transmission Control Protocol/Internet Protocol) protocol stack is probably the most well known communication protocol for the Internet and networks worldwide. Its simplicity and power has lead to its becoming the de facto standard for computer communications in today's networked world. The main design goal of TCP/IP was to build an interconnection of networks, referred to as an internet, or internetwork, that provided universal communication services over heterogeneous physical networks. TCP/IP provides communication services that run between the programming interface of a physical network and user applications. It contains a common interface for these applications, independent of the underlying physical network. The architecture of the physical network is therefore hidden from the user and from the developer of the application. The applications only need code to the standardized communication abstraction to be able to function under any type of physical network and operating platform.

[0088] TCP/IP is modeled in layers. By dividing the communication software into layers, the protocol stack allows for division of labor, ease of implementation and code testing, and the ability to develop alternative layer implementations. Layers communicate with those above and below via concise interfaces. In this view, a layer provides a service for the layer directly above it and makes use of services provided by the layer directly below it. However, the layering of TCP/IP is not kept as strict as in other protocol stacks, and it is possible for, e.g. application layer functions to access the internet layer directly. The functionality provided by each layer is :

The network interface layer, also called the data-link layer, is the interface to the actual network hardware. This interface may or may not provide reliable delivery, and may be packet or stream oriented. It takes care of low-level addressing and address mapping.

The main protocols of the network interface layer are PPP, and Ethernet, etc;

The Internet layer, also called the network layer, provides the "virtual network" image of an internet. It provides abstract

Petitioner Ex-1004, 0276

BNSDOCID: <EP_____1724684A1_I_>

addressing and routing of datagram between different physical networks. The Internet Protocol (IP) is a connectionless protocol that doesn't provide reliability, flow control and error recovery.

The transport layer provides the end-to-end data transfer by delivering data from an application to its remote peer. The Transmission Control Protocol (TCP) provides connection-oriented reliable stream delivery, data suppression, congestion control and flow control. The User Datagram Protocol (UDP) provides connectionless, unreliable, best-effort datagram delivery service.

The application layer is provided by the programs that use TCP/IP for communication.

The interface between the application and transport layers is defined by port numbers and sockets.

[0089] The de facto standard for TCP/IP implementations is the one from the CSRG (Computer Systems Research Group) at the University of California at Berkeley. Historically this has been distributed with the 4.x BSD system (Berkeley Software Distribution), and with the "BSD Networking Releases." This source code has been the starting point for many other implementations. Many vendors or free implementations, such as SunOS 4.x, SVR4, AIX 3.2 and Linux were originally developed from the Berkeley sources. These implementations have much in common, often including the same bugs. Since the first widely available release was published in 1983, the BSD TCP/IP implementation has evolved and many versions have been released. Many important TCP/IP features have been incorporated into these new releases. The 4.3BSD release (1986) improved TCP performance, the 4.4BSD Tahoe release (1988) incorporated RTT estimation, congestion control mechanisms and a fast retransmit algorithm, the 4.4 BSD Reno release (1990) then implemented a fast recovery algorithm as well as many other performance related optimizations, such as TCP header prediction, SLIP head compression and routing table change technologies. The last distributed release is 4.4 BSD (1993), which incorporated multicasting and long fat pipe modifications technologies.

[0090] As part of the open source movement, the Linux operating system is freely available to everyone and becoming more and more popular. Thousands of programmers are constantly working on the code to implement new features, improve existing ones, and fix bugs and inefficiencies in the code. Detailed sources are obtained for learning more about Linux, from the source code itself to books to "HOW-TOs" and message boards maintained on many different subjects. The kernel of network codes in a Linux operating system is a TCP/IP implementation which originates from the BSD releases. The well documented implementation and the free design mode, study and modification of the TCP/IP implementation under Linux has made this implementation one of the most frequently examined when setting out to develop a new TCP/IP implementation.

[0091] The networking function of embedded systems brings has greatly enchanced development of embedded applications and the maturity and progress in networking and VLSI technologies have also contributed to the network ability of embedded systems. However, embedded systems still require small TCP/IP implementations to meet with their constrained hardware resources. Currently, a lot of small TCP/IP implementations have been developed for commercial purposes or in various studies relating to microprocessors and microcontrollers. Some of these implementations are directed to particular hardware materials and system kernels and provide certain network functions, whereas others provide a complete protocols implementation for the common platforms. A. Dunkles implements two small generic and portable TCP/IP implementations, μIP (micro IP) and lwIP (lightweight IP). The lwIP is a full-scale, but simplified TCP/IP implementation that includes IP, ICMP, UDP and TCP. It is modular enough to be easily extended with additional protocols. The μIP is designed to contain only the absolute minimal set of features needed for a TCP/IP stack. The source code is available for both lwIP and μIP. The two implementations have been ported to various 8 bit and 16 bit platforms such as the AVR, H8S/300, 8051, Z80, ARM, M16c, and the x86 CPUs. InterNiche Technologies has designed two commercial TCP/IP implementations for an embedded system: NicheStack and NicheLite. The NicheStack is a small, portable, and RFC compliant implementation of the TCP/IP protocol suite. NicheStack has a small memory requirement. A full featured TCP/IP stack adding the sockets API brings the total ROM and RAM requirements to 51.5 KB on an ARM 32 bit processor. NicheLite is a full featured subset of NicheStack TCP/IP, and was designed for small memory targets and requires only 12 KB of ROM. There are also numerous TCP/IP implementations for embedded systems. Other known implementations are the embedded web servers of Atmel Corporation and A. Dannenberg, the TCP/IP stack of Kadak KwikNET, and the implementations of NexGen, etc.

[0092] TCP/IP breaks the data down into a series of packets or frames. Buffers are created to hold the data frames. Because of the inherent asynchronous nature of a network, buffers must be allocated and de-allocated dynamically. They can be deployed from a pre-allocated series of buffer pools or be allocated from the global memory pool when needed. Buffers have variable lifetimes depending on many numbers of factors, such as network throughput, whether the included frame is part of a stream transmission, or whether the packet is a datagram. An understanding of buffer management is therefore fundamental to an understanding of the protocol implementation.

[0093] The basic buffering mechanism used in Berkeley-based TCP/IP is called mbufs (memory buffers). Mbufs can be expanded to allow for variable length frames used often in IP-based communications. Small amounts of data can be placed directly in the data area of the mbuf. Larger amounts of data require the mbufs to be extended with clusters. A cluster is a data structure that holds heterogeneous data for extending the data-carrying capability of an individual mbuf. Mbufs can be chained to allow easy implementation of packet queues. The basic mbuf contains some header information

Petitioner Ex-1004, 0277

BNSDOCID: <EP_____1724684A1_I_>

with a data area which can be extended with a cluster if the frame can't fit into the data area. Mbufs are also convenient places to put control information or other temporary data used within the protocols. The mbuf supports four data types defined in the m_flags field in the mbuf structure :

0 flags : Mbuf contains only data which can be up to 108 bytes.
M_PKTHDR : Mbuf contains a packet header and up to 100 bytes of data.
M_EXT : Mbuf is extended with a cluster allowing up to 2,048 bytes of data.
M_PKTHDR | M_EXT : Mbuf contains the packet header and a pointer to a cluster, allowing it to contain up to 2,048 bytes of data.

[0094] In the Linux kernel, the key to maintaining the strict layering of protocols is the common packet structure, named sk_buff (socket buffer).The primary goal of the sk_buff routines is to provide a consistent and efficient buffer handling method for all of the network layers, and by being consistent, to make it possible to provide higher level sk_buff and socket handling faculties to all the protocols. A sk_buff is a control structure with a block of memory attached. There are two primary sets of functions provided in the sk_buff library:

routines to manipulate doubly linked lists of sk_buffs;
functions for controlling the attached memory.

[0095] The buffers are held on linked lists optimized for the common network operations of append to end and remove from start. As so much of the networking functionality occurs during interrupts these routines are written to be atomic. The list operations are used to manage groups of packets as they arrive from the network, and as they are sent to the physical interfaces. The memory manipulation routines are used for handling the contents of packets in a standardized and efficient manner.

[0096] The Application Program Interface (API) defines the way the application program interacts with the TCP/IP stack. Two popular APIs for applications using the TCP/IP protocols are called sockets and TLI (Transport Layer Interface). The former is sometimes called "Berkeley sockets" or BSD sockets, indicating where it was originally developed. The latter, originally developed by AT&T, is sometimes called XTI (X/Open Transport Interface). The BSD socket is the most popular and commonly used API for TCP/IP which is implemented in most Unix systems and has heavily influenced the Microsoft Windows WinSock API. It abstracts the network communication so that sending or receiving data from the network is no different from writing or reading from an ordinary file. From the application's point of view, for example, a TCP connection is just a continuous stream of bytes rather than segmented. Even though the BSD socket API is not formally defined as a standard API, the success of BSD has resulted in a large number of applications written for the BSD socket API.

[0097] The BSD TCP/IP implementation is a complex incorporation of multi-layer network protocols, which integrates various network standards and network technologies. This feature of BSD stack makes it flexible for the network communication between different network environments. However, this complicated implementation is resource hungry, which is obviously unacceptable for embedded system. The key issue of small implementations is therefore to reduce the bloat in the BSD stack and to behave in accordance with the actual circumstances of application. Although numerous small TCP/IP implementations have various simplified models, there are still certain simplification rules that can be followed. These rules are based on the several assumptions about the communication environments.

[0098] Firstly, the most common assumption is that the remote peer of embedded system, such as PC, runs a full-scale and standards compliant of TCP/IP implementation. By relying on the standards compliance implementation of the remote host, even an extremely simplified and standards non-compliant TCP/IP implementation will enable embedded system communicate with remote host. The usual simplifications are to tailor the TCP/IP stack and to remove certain communication mechanisms. One of the notable implementations is the IPic web server, which implements a web server on a chip PIC 12C509A with the code size of 256 bytes (12 bit). The files for the web server are stored on an EEPROM chip. In such an implementation, UDP is not necessary for a web server and the retransmission mechanism can not be made by the TCP module in the embedded system because nothing is known about the active connection. Another example is the Atmel TCP/IP implementation which removes TCP's congestion control mechanism. This implementation can work well when connected within a single network connection at a time. By removing certain protocol and several mechanisms, the complexity of an implementation is reduced, and the memory requirement is thus decreased. Secondly, another common simplification is to support embedded systems that handle one network connection at a time. This is a sensible simplification for many applications which dedicate to one special network transaction. This assumption will also greatly decrease the usage of RAM. Texas Instrument's MSP430 TCP/IP stack provides a TCP connection each time for a web server. This assumption has proven to be effective for an embedded system with scarce resources. The third common simplification is to pre-allocate frame buffers statically rather than to allocate them dynamically from the global heap at run time (via malloc). The header length of protocols, including IP, UDP and even TCP, is fixed if the

Petitioner Ex-1004, 0278

BNSDOCID: <EP_____1724684A1_I_>

implementation removes the options of protocols' headers. The data length of a frame is predictable, which is no more than the MTU (Maximum Transfer Unit) or MRU (Maximum Receive Unit). This method is useful to simplify the memory management of the implementation and enhance its effectiveness, particularly for the network transaction of constant data length. The μIP implementation of A. Dunkles gives an example of statically configuring a frame buffer at compile time, in which the number of the TCP listening port, the TCP connection and ARP table entries are pre-configured. In a fourth modification, the IP fragment reassembly module is optional and can be removed for many applications. TCP/IP implementations that are able to correctly reassemble fragmented IP packets are usually too large in terms of program memory and RAM requirements. The fragment and reassembly module is also the most complex part of the buffering and memory management mechanism. If particular applications can guarantee that no fragmented IP packets will occur in embedded systems, the reassembly function can be removed. Moreover, if the length of transmitted data is constrained to be no more than the MTU, the fragment function can also be removed. Finally, as the cost of data copying is expensive in a real-time embedded system, one simplification is to copy data as few times as possible and thus minimize the overhead of copying data. The data within each frame can be maintained in the same buffer so it doesn't need to be copied and re-copied by the CPU at each stage of the protocol. The networking chip's DMA places the packets directly in the managed buffer pool where the packet is passed up through the stack by manipulating pointers and not by copying data. Also, some vendors have extended the MBUF mechanism of BSD to allow data sharing between kernel space and user space where STREAMS protocols are also present in the system. For example, the NicheStack and NicheLite implementations are declared by InterNiche Technologies to support ZERO data copy for ultra fast performance.

[0099] TCP/IP implementations are designed and modularized in a layered fashion as a hierarchy architecture described in Figure 8, where each protocol layer solves a separate part of the network communication problem and each protocol is separately encapsulated as a unique communication module. This modularization approach can simplify the TCP/IP implementation in which it one can add or remove protocol modules. Since each protocol is implemented as a module, every protocol layer module is thus composed of some functions and can provide uniform entry points for other modules, applications, and network interfaces. Traditional TCP/IP implementations keep a strict division between the protocol layers. Implementing the protocols in a strictly layered way can bring additional communication overhead between the protocol layers. This overhead degrades the overall performance of TCP/IP implementation, especially for the low-resource embedded devices. Moreover, in most implementations, the application layer and the lower protocol layers are strictly divided. The low protocol layers are implemented as a part of the operating system with entry points for communication with the application layer process. From the application program's point of view, there is no difference between network communication and inter-process communication. It implies that the application program is unaware of buffer mechanisms used by the lower layers and the memory spaces between application and system kernel are completely separated. Hence, when an application sends data, this data only has to be copied once from the application space into the system kernel space before being processed by network code. To overcome the problems caused by the strictly layered approach, most embedded TCP/IP implementations adopt relaxed layered schemes for the communication between the applications and the lower layer protocols. There is no strict protection barrier between the kernel and the application tasks. Therefore, an application task can directly read and write to the buffers of kernel space and share memory with networking code. By accessing shared memory, applications can more efficiently reuse buffers, and thus save the overhead of data copying. Moreover, some TCP/IP implementations violate the separate rule of protocol module and provide "wickets" for protocol modules. In this situation, a protocol module can directly extract information from other modules by not only the entry points but also the "wickets". By adopting the "wickets", the implementation can reduce function calls and more efficiently reuse buffers.

[0100] One object of the present invention is therefore a μRET implementation that can provide network function for a intelligent wireless ECG sensor, also an object of the invention. This particular application has a certain number of network connections, i.e. one TCP connection and one UDP connection at a time, and has a unique network medium, i.e. a wired or wireless serial link. The data sizes of sent and received IP packets are determined to be no more than the MTU and MRU, and the remote peer is a standard machine which runs a full-scale and standards compliant TCP/IP implementation. These application conditions distinctly satisfy with the simplification assumptions of the TCP/IP stacks. The layered protocol design idea is adopted for the design of the μRET implementation. Each protocol is implemented as a single module, with a few functions acting as entry point of each protocol. In order to improve performance in terms of processing speed and memory usage, the μRET implementation adopts a relaxed layered scheme for communication between the application and the lower layer protocols, and provides "wickets" for data exchanges among the lower layer protocols modules. The μRET implementation consists of several protocol modules - PPP, IP, ICMP, UDP, and TCP - which are illustrated in Figure 8.

[0101] The buffering and messaging subsystems are an important component of protocol implementation, which directly influence the efficiency of network communication. The key point of the buffering subsystem is the definition of packet structure. The design of the packet buffer adheres to two criteria: firstly, the packet buffer should be accommodated to different protocol formats and very varying data sizes; secondly, the buffering subsystem should be able to simply and effectively reuse the buffer and avoid data copying. Due to the pre-configured application features of wireless device

Petitioner Ex-1004, 0279

BNSDOCID: <EP_____1724684A1_I_>

according to the invention, and in order to improve efficiency and reduce memory usage, a simple buffering mechanism was designed for the μRET. The mechanism supports only static pre-allocated memory. The packet buffers, sockets, network interface tables, and route tables are all allocated before run-time. Since there is no need for dynamically handling memory allocation and de-allocation, memory management is thus extremely simple. The messaging subsystem presents the message handling functions of the protocol modules. In some particular situations, certain network functions of the TCP/IP stack can be removed. For example, TCP congestion and flow control mechanism is not indispensable if the network link can guarantee a reliable connection; and IP fragment reassembly function is not necessary if the data size can be controlled by the application programs of the peer-pairs. As a protocol implementation for the present invention, μRET has a sensitive application environment that can satisfy various assumptions of simplification. In this way, all the unnecessary network functions are not implemented in μRET, thus μRET may be considered as having a very simple and effective message subsystem.

[0102] The μRET implementation according to the present invention provides a simple packet structure, named ippacket, to handle IP packet buffers (see Figure 3.3) [27].

IPPACKET

```
STRUCTIPPACKET
{
struct IPHDR I ph; /*IP head*/
union{
struct UDPHDR udph; /*UDP head*/
struct ICMPHDR icmph; /*ICMP head*/
struct TCPHDR tcph; /*TCP head*/
}trah;
unsigned char * dat_ptr; /*Data pointer*/
short dat_len; /*data size*/
short ipp_len; /*ip packet size*/
unsigned char flag;
/*0000 /*relative socket index*/
0 /*unused*/
1 /*transport layer head flag.
1: used; 0: unused*/
0 /*ippbuf unit use flag.
1: used; 0: unused*/
1*/ /*packet type flag.
1: in; 0: out */
};
```

[0103] The ippacket is a rather simple structure and supports only static memory pre-allocation. In view of the fact that it is only intended to handle 2 or 3 simultaneous network connections and short message sizes in the μRET, there are four ippacket buffers pre-allocated for network communication. These four ippackets constitute an ippacket queue and the index is used to indicate a ippacket member. The ippacket structure consists of an IP header structure, a variable transport layer header, a data pointer, two length fields, and a flag field. The IP header (iph) has a fixed length of 20 bytes (8bits/byte), and the IP options are not implemented in μRET. The transport layer header structure (trah) encapsulates three protocol headers: TCP, UDP and ICMP. The TCP header (tcph) has a fixed length of 20 bytes. In μRET, the TCP options only exist in the TCP SYN segment, which are stored into the TCP data buffer, as described further. The UDP header (udph) has a fixed length of 8 bytes. The ICMP is an Internet layer protocol, but in terms of the encapsulation sequence, it acts more like a transport layer protocol. Depending on the message types, the ICMP header (icmph) can have varying lengths. μRET only provides one ICMP service ("Ping") which has a fixed length of 8 bytes. The dat_ptr pointer points to the associated data buffer of an IP packet. The data buffer exists in either user space or kernel space. The dat_len field contains the length of data buffer. The ipp_len field contains the total length of an IP packet, which is the sum of the dat_len, and the length of iph and trah. In the flag field, the first four bits contain an index value of relative socket of the IP packet. The sixth bit indicates whether or not there is a transport layer protocol in the IP packet. The seventh bit is used to mark if current IP packet buffer is used or not. The last bit of flag field describes the type of IP packet: '0' indicates input packet and '1' represents output packet.

[0104] The relaxed layered scheme and the "wickets" technique are used in μRET of the present invention to avoid data copying and reuse shared memory. The message traffic flows of μRET describing how data is copied and memory usage are shown in Figure 9. There is only one data copying operation for outgoing messages in μRET. Data is copied

Petitioner Ex-1004, 0280

BNSDOCID: <EP_____1724684A1_I_>

directly from the application program into the network output queue. While for incoming messages, in view of the different message types, there are one or two data copying operations. If an incoming message is a PPP negotiation frame or ICMP datagram or IP forwarding packet, it means that this packet is for a "handshake" or testing ("ping" service) or forwarding. Data is therefore copied directly into the network output queue. Whereas, if the incoming message is a UDP datagram or TCP segment, data is first copied from the network input queue into the socket queue to wake up a suspended application process, and then the invoked application process will copy data once more into its application buffer for subsequent processing. Typical network applications included in μRET comprise a web server (TCP) and a SNMP agent (UDP).

[0105] An outgoing message flow begins with an application process to write data to a socket. A socket is allocated from the pre-allocated socket queue for a network connection. The socket output function verifies the status of the socket, examines its protocol type, and sends the data to the transport layer routine (such as TCP or UDP). Subsequently, this transport protocol allocates an ippacket buffer from the pre-allocated ippacket queue for the outgoing packet, records the address pointer and the size of the application data, and fills in its header information (such as port number, data length and checksum) before passing the ippacket to the internet layer (usually IP). The IP output functions fill in more of the buffer with its own protocol headers (such as the IP address, lengths, and checksum). It may also fragment the packet if required. Next IP route function searches a matching route and network interface. Then the IP layer passes the packet to the related network interface layer. The network layer interface protocol, PPP in μRET, encapsulates IP packet to PPP frame with the AHDLC format and copies the frame onto the network output queue. At this time, the application process will return and the device driver of the physical medium undertakes the subsequent communication job, which includes reading data from the network output queue onto the physical device or writing data from the medium onto the network input queue. The send message modules are shown in Figure 10.

[0106] An incoming message flow begins when a message is ready in the network input queue. The PPP module verifies and extracts a message from the received frame, and identifies the message type. If the received message is a PPP negotiation frame, i.e. LCP and IPCP, the PPP negotiation automaton is called to establish, configure or terminate a PPP connection. Otherwise, if the received message is an IP packet, a free ippacket member is allocated from the ippacket queue to store this IP packet, and then the PPP protocol passes it to the IP layer. The IP layer examines the packet for errors and routes it; the packet will be sent up to the transport layer (such as TCP or UDP), or to the ICMP protocol module for the "Ping" service, or (down) to network interface layer for IP forwarding packets. The transport layer again checks for errors, looks up a socket pair associated with the port specified in the packet, and stores the packet in the socket queue. Once the packet is in the socket queue, the kernel will wake up the corresponding application process. As a consequence, the application process may make or return from a read system call that copies data from the socket queue into its own buffer. The message receiving modules are shown in Figure 11.

[0107] The purpose of the network interface layer in the TCP/IP protocol stack is to send and receive IP datagrams for the IP module. TCP/IP supports different network interface layer protocols, depending on the type of network access medium being used (physical layer). A common network interface structure has been defined for different protocols adapted to physical devices in μRET. The IP module does not concern the practical network interface protocol or the physical device. The transmission and reception of IP datagrams are implemented by the output and input functions of the network interfaces. These input and output functions have uniform encapsulation formats for all network interfaces. The Point-to-Point Protocol (PPP) is a network layer protocol used to control the delivery of IP datagrams between two hosts interconnected by a point-to-point link. It is described in IETF document (Internet Engineering Task Force) RFC 1661 and RFC 1662 (Request For Comments). In embedded systems, the point-to-point line, also named serial line, is the most widely used to connect an embedded device with remote hosts. The wireless serial connections, for example, 802.11 x and Bluetooth, and the wired serial connections, for exampel, classical modem or ADSL, can be implemented by PPP. The purpose of designing PPP into μRET was to provide an ability of point-to-point link connection for embedded systems. Since a remote machine that acts as a PPP server runs a full-scale and standards compliant of PPP protocol, a simplified and standards incompliant PPP protocol will be able to run in the embedded device.

[0108] In μRET, physical medium are presented by a network interface structure similar to that of BSD, shown below. There are two network interfaces supported by μRET: a serial link interface and a loopback interface. Since there is no Ethernet device in the systems according to the present invention, the most common Ethernet network layer protocol is not implemented in μRET.

Petitioner Ex-1004, 0281

BNSDOCID: <EP_____1724684A1_I_>

New_ndevice

```
struct new_ndevice
{
unsigned char i n dex;
unsigned char n ame[2];
struct ip_addr if_addr;
struct ip_addr if_broadaddr;
struct ip_addr if_mask;
int (*if_output)(struct ppp_state *state,int ipp);
void (*if_input)(unsigned char *buf, int len);
};
```

[0109] Two network interface structure buffers are pre-allocated in SRAM (static RAM) to store the interface information. The index field is used to indicate the position of the interface in a network interface array. Each network interface has an abbreviation name to identify the type of physical access medium, which is stored in the name field, e.g. bl(Bluetooth), wf(IEEE 802.11 b), sl (serial line), md(modem) and lb (loopback). The three IP addresses ip_addr, ip_broadaddr and ip_mask are used by the IP layer when sending and receiving packets. Each network interface must have a unique IP address as the identified flag. The IP address of the loopback interface is always "127.0.0.1". The IP address of the serial link interface is allocated automatically by the remote PPP server or set manually by the user. The if_output and if_input pointers point to the output and input function addresses of network interface. A network interface is connected to a physical access medium through the if_output and if_input functions. When a data frame has been received, the function pointed by if_input is called. The two arguments are respectively the address pointer and size of receive data buffer. For the serial link interface, the input function unwraps the incoming PPP frame, and then calls the PPP input function which is used to handle the PPP frame. For the loopback interface, since it is a virtual interface, the input function of the IP layer is called directly. When an IP packet is to be transmitted, the output function of the network interface is called by the IP layer. The first argument to the output function, its state, is the pointer of the PPP state structure data. It contains the status information of the PPP connection and the address pointers information of network input/output queues. The second argument, ipp, is the index of this IP packet in the ippacket array. For the serial link interface, the output function encapsulates the IP packet into a PPP frame in the AHDLC format, and simultaneously copies it onto the network output queue. For the loopback interface, the first argument (state) is NULL, and its output function copies the IP packet directly onto the network input queue.

[0110] PPP has three main components:

A method for encapsulating datagrams over serial links
A Link Control Protocol (LCP) for establishing, configuring, and testing the data-link connection;
A family of Network Control Protocols (NCPs) for establishing and configuring different internet layer protocols.

[0111] In μRET, only IPCP (IP control protocol) is implemented to support IP layer interconnection. RFC 1661 specifies the encapsulation method and the link control protocol. RFC 1662 describes the use of HDLC-like framing for PPP encapsulated packets. RFC 1332 specifies the network control protocol for IP.

[0112] PPP encapsulation provides for multiplexing of different network-layer protocols simultaneously over the same link. The format of the PPP frames was chosen to look like the ISO HDLC standard, named AHDLC (Adaptive High-Level Data Link Control). Figure 12a shows the format of PPP frames. Each frame begins and ends with a flag byte whose value is 0x7e, which is used for frame synchronization. The address byte 0xff and control byte 0x03 are always constant. A protocol field is used to identify the type of PPP frame. Three types of PPP frames are supported in μRET: a value of 0x0021 means the information field is an IP datagram, a value of 0xc021 means the information field is link control data, and a value of 0x8021 is for network control data. The CRC field (or FCS: Frame Check Sequence) is used for cyclic redundancy check, to detect errors in the frame. A fast FCS implementation and computation method is provided in RFC 1662. In μRET, fast FCS calculation mode is supported, which improves performance by using additional 512 bytes of memory for a FCS lookup table.

[0113] The Link Control Protocol (LCP) is used to negotiate the configuration of the connection link. A LCP packet is encapsulated into the PPP information field, where the PPP Protocol field indicates type Oxc021. A summary of the Link Control Protocol packet format is shown in Figure 12b.

[0114] The Code field identifies the type of LCP packet. The LCP packet types defined in RFC 1661 include the following LCP codes: Configure-Request(1), Configure-Ack(2), Configure-Nak(3), Configure-Reject(4), Terminate-Request(5), Terminate-Ack(6), Code-Reject(7), Protocol-Reject(8), Echo-Request(9), Echo-Reply(10), and Discard-Re-

Petitioner Ex-1004, 0282

BNSDOCID: <EP_____1724684A1_I_>

quest(1). LCP packets are classified into 3 classes:

Link configuration packet used to establish and configure a link (code 1 ~ 4);
Link Termination packets used to terminate a link (code 5, 6); and
Link Maintenance packets used to manage and debug a link (code 7 to 11).

[0115] The identifier field is used to match requests and replies of the LCP packet. The length field indicates the length of the LCP packet, including the Code, Identifier, Length and Data fields. The Data field has zero or more bytes. In most LCP packets, the data field is filled with LCP Configuration Options which allow negotiation of modifications to the default characteristics of a point-to-point link. The format of configuration options is shown in Figure 12b. For example, for a given LCP configuration option, e.g. MRU, the value of its type field is 1, which indicates the type of configuration options. The length field of MRU is 4, which indicates length of this configuration option including the Type, Length and Data fields. The data field of MRU is two bytes, and specifies the maximum number of bytes in the Information and Padding fields.

[0116] The IP Control Protocol (IPCP), described in RFC1332, defines the manner in which IP datagrams are delivered over the link established by PPP. An IPCP packet is encapsulated into the PPP information field, where the PPP Protocol field indicates type 0x8021. The IPCP is responsible for configuring, enabling, and disabling the IP protocol modules on both ends of the point-to-point link. The IPCP packet format and packet exchange mechanism are exactly the same as the Link Control Protocol. IPCP Configuration Options allow negotiation of desirable Internet Protocol parameters. IPCP uses the same Configuration Option format defined for LCP. The most well known IPCP Configuration Option is the IP-address which provides a way to negotiate the IP address to be used on the local end of the link.

[0117] In order to establish communications over a point-to-point link, each end of the serial link must first send LCP packets to configure and test the data link. After the link has been established, the peer may be optionally authenticated.Then, PPP sends NCP packets to choose and configure one or more network-layer protocols. Once the IP layer protocol has been configured, IP datagrams can be delivered over the point-to-point link. RFC 1661 proposes the standard for PPP finite-state automaton. Based upon the standard automaton, μRET implements a simplified finite-state automaton to negotiate, configure and manage a point-to-point link, which is defined by events, actions and state transitions.

[0118] In the process of configuring, maintaining and terminating the point-to-point link, the PPP link goes through several distinct phases which are specified in the simplified phase diagram of Figure 13.

[0119] The point-to-point link begins and ends necessarily with a Dead phase. When an external UP event (such as carrier detection or user configuration) indicates that the physical-layer is ready to be used, PPP will proceed to the Establishment phase. In the Establish phase, LCP is used to establish a connection through an exchange of LCP Configuration options. The Authenticate phase which is in advance of the Network phase can provide authentication from the peer. The Authentication phase is optional. If link establishment is completed, LCP enters the Opened state and PPP proceeds to the Network phase directly. In the Network phase, IPCP is used to negotiate the network configurations. After IPCP has reached the Opened state, PPP will deliver IP datagrams. PPP can terminate the link at any time. In the Terminate phase, LCP is used to close the link through an exchange of Terminate packets. PPP then returns to the initial phase: Dead.

[0120] The finite-state automaton is defined by events, actions and state transitions. Events include reception of external commands such as Open and Close, expiration of the restart timer, and reception of packets from a peer. Actions include the starting of the restart timer and transmission of packets to the peer. States indicate the different connection status of LCP and IPCP. μRET contains a simplified PPP automaton, the events, actions and states of which is a subset of the standard automaton of RFC 1661. These events, actions and states are specified in Figure 14.

[0121] The state transition table of the PPP automaton of μRET is shown in Figure 15. States are indicated horizontally, and events are read vertically. State transitions and actions are represented in the form action/new-state. Multiple actions are separated by commas; multiple actions may be implemented in any convenient order. The dash ('-') indicates an illegal transition.

[0122] Figure 16 shows how to configure the LCP and IPCP options, and how to establish and terminate a PPP link in active mode. The active mode is the most common operation mode in the device according to the present invention, here given the designation "STAR" for convenience, in which a point-to-point link is opened and closed by a STAR user. The interrelation of phases, events, actions and state transitions are illustrated as the description of the state transition table. The initial phase of the PPP link is Dead, and the LCP and IPCP states are Initial. After LCP negotiation, the LCP connection has been established. The phase of the PPP link proceeds to Establish, and the LCP state is changed to Opened. Subsequently, exactly the same operations are carried out to establish the IPCP connection. The PPP phase then proceeds to Network, and IPCP enters Opened state. From now on, IP datagrams can be delivered in the established PPP link. In the active mode, a STAR user requests the termination of the PPP connection by sending a Term_Req LCP packet. The PPP phase proceeds to Terminate, the IPCP returns to its initial state and the LCP state is changed

Petitioner Ex-1004, 0283

BNSDOCID: <EP_____1724684A1_I_>

to Closing. If Term_Ack packet is acknowledged by the peer or a timeout event is happened, the PPP connection will be completely closed, and the whole PPP link returns to the initial point.

[0123] IP is the workhorse protocol of the TCP/IP protocol suite. All TCP, UDP and ICMP data will be transmitted as a formatted IP packet. The IP protocol hides the underlying physical network by creating a virtual network view. It provides an unreliable, best-effort and connectionless packet delivery service which means that the packets sent by IP may be lost, arrive out of order, or even be duplicated. The IP module assumes that higher layer protocols will address these anomalies. RFC 791 is the official specification of IP. IP provides three important definitions. First, the IP protocol defines the format of header encapsulation and data delivery mechanism. Second, IP performs the routing function, choosing a path over which data will be sent. Third, IP includes a set of rules that embody the idea of unreliable packet delivery. The μRET of the present invention implements only the most basic functionality of IP, which provides packet sending, receiving and forwarding ability.

[0124] For incoming IP packets, the input function of the IP layer, new_ip_input(), is called by the PPP input function. Here, the initial sanity check of the IP version field and the header length is done, as well as computing and checking the header checksum which uses standard techniques. Next, the function checks the destination address to see if there is a match the IP addresses of the network interfaces to determine if the packet is intended for the host. As mentioned in a previous section of this patent specification, there are only two network interfaces supported by μRET: serial link interface and loopback interface, which are stored in the pre-allocated network interface array. If the incoming packet is found to be destined for this host, the protocol field of the IP header is used to decide to which higher level protocol or transport layer, control should be passed. The μRET supports three types of transport layer: UDP, TCP, and ICMP, since in μRET, ICMP is implemented as a transport protocol.

[0125] An outgoing data generated by applications and wrapped by a transport layer protocol will be sent to physical media over the IP layer. The outgoing data is handled by the output function of IP layer, new_ip_output(). Here, all IP header fields are filled in and the IP header checksum is computed. Then, it uses the function new_ip_route() to find the appropriate network interface to transmit the packet on. When the outgoing network interface is found, the packet is passed to the output function of the network interface, which takes two arguments as described in the network interface structure. In μRET, the size of outgoing data is limited to be no more than MTU, which thus avoids the overhead of IP packet fragmented operation.

NEW_ROUTE

```
struct new_route{
unsigned long ro_dst; /*destination host adress or net address*/
unsigned long ro_src; /*interface addr*/
unsigned long ro_mask; /*destination net and subnet mask*/
unsigned long ro_gate; /*gateway address*/
unsigned short ro_flag; /*route flags*/
Int r o _ifdex; /*the index of interface device*/
#define NEW_RU 0x01 /*route can be used*/
#define NEW_RG 0x02 /*route to gateway, if no ,route to host*/
#define NEW_RH 0x04 /*ro_dest is a host address, if no, a net address*/
#define NEW_RS 0x08 /*route static*/
#define NEW_RC 0x10 /*route can be cloned*/
#define NEW_RL 0x20 /*route include datalink lay data*/
#define NEW_RR 0x40 /*route loopback*/
};
```

[0126] The route information is stored on a route table structure buffer shown above. A route table array that has five route table members is pre-allocated in μRET. In the route table, the ro_dst, ro_src, ro_mask and ro_gate fields describe respectively the destination host address, the network interface address (source host address), the destination address netmask and the gateway address. The ro_flag field indicates the characteristics of route table defined in table structure. The ro_ifdex field is the index pointer of the network interface. Each route table is associated with a unique network interface. The IP module can add, delete or modify a route table member. As the number of route table members is small, the route algorithm is thus fairly simple: if the masked destination address of IP packet is equal to the masked interface address of a route table member, a network interface is chosen; whereas if no match is found, a default network interface, i.e. point-to-point link, is used.

[0127] if an incoming packet is not for this host, it means that no network interface matches the destination address of the incoming packet. Hence this packet should be forwarded by new_ip_forward(). The IP header is changed, the

Petitioner Ex-1004, 0284

BNSDOCID: <EP_____1724684A1_I_>

TTL is decreased to indicate one more incidence of IP forwarding, and the IP header checksum is recomputed. Then, the new_ip_output() is called to transmit the forwarding packet to the remote peer via the default network interface.

[0128] The ICMP protocol described in RFC 792 is used for reporting error conditions and for querying host parameters. The most frequent scenario for ICMP is to probe the remote host or network, if reachable, by using ping program. The ping program is the simplest of all TCP/IP applications which uses ICMP echo mechanism. It sends ICMP datagrams to a specified destination host and measures the RTT (Round Trip Time) to receive a response. The ICMP implementation in μRET is very simple in that it only supports the ICMP echo message, i.e. the ping program. Figure 17 shows the format of the ICMP message in the present invention for echo request and echo reply. The value of the type field is 8 for an echo request (ping request), and 0 for an echo reply (ping reply). The code field contains the error code for the datagram reported, and for an echo message, the value of this field is always 0. The checksum field contains the checksum for the ICMP message starting with the type field. The identifier field is set to be an identifier of the ping process, for the case where multiple instances of the ping program might be running at the same time on the same host. The sequence number starts at 0 and is incremented every time when a new echo request is sent. These two values are used to identify an ICMP echo datagram and they are returned in the echo reply. The data field for the ping program is normally the timestamp of this ping request in sender.

[0129] ICMP is an internet layer protocol, but in the present invention it acts more like a protocol of the transport layer. As the ICMP module of μRET according to the invention does not deliver ICMP error messages generated in IP, TCP or UDP, it means that the transport layer protocols have no need to call ICMP functions. An input function of ICMP, new_icmp_input(), is activated by when an ICMP echo request message is received from remote hosts. This function automatically generates an ICMP echo-reply message in response to the echo-request. Replies to echo messages are constructed by simply swapping the source and destination IP addresses of echo request message and rewriting the ICMP header with the Echo-Reply message type. The ICMP checksum is adjusted using the same method as described for the IP header checksum. Finally, the constructed echo reply message is passed into the IP layer and transmitted by new_ip_output().

[0130] UDP is a simple, datagram-oriented transport layer protocol: each output operation of a process produces exactly one UDP datagram, which causes one IP packet to be sent. UDP provides an unreliable datagram delivery service and the application function is responsible for the reliability of data exchange. RFC 768 is the official specification of UDP. The encapsulation of UDP is fairly simple. The UDP header is composed of the port numbers of the source host and the destination host, the length of the UDP header and the UDP data in bytes, and the UDP checksum. The basics for calculating the UDP checksum are similar to the one for the IP header checksum, but some differences are worthy of mention. First, the UDP checksum covers the UDP header and the UDP data, which is unlike the IP checksum that covers only the IP header. Second, the length of the UDP datagram can be an odd number of bytes, while the checksum algorithm adds 16-bit words. The solution is to append a pad byte of 0 to the end, if necessary, just for the checksum computation. Third, both UDP and TCP include a 12-bytes pseudo-header with the UDP datagram (or TCP segment) just for the checksum computation.

[0131] The input and output processing of UDP is straightforward in μRET. When applications generate outgoing data, the output function of UDP new_udp_sendmsg()is called. This function immediately calls another output function new_udp_output()(in order to have a uniform style with TCP, we define two UDP output functions). Here, an ippacket buffer is allocated to accommodate the UDP datagram. The UDP checksum is computed and UDP header fields are filled. UDP pseudo header can be stored into the IP header field of the ippacket structure buffer. If the application program does not specify the IP address or the port number of the sender, the default IP address and the port number will be designated to this packet and be attached to the socket-pair. Finally, the UDP datagram is turned over to new_ip_output () to transmit. When a UDP datagram arrives, the input function of UDP new_udp_input() is called. Here, the UDP checksum is checked and the datagram is de-multiplexed. The new_udp_lookup() is used to lookup an associated sock-pair for the received datagram in socket queue. When a socket-pair is found, the UDP data is copied to the related socket buffer. In next task scheduling, the UDP function new_udp_recvmsg() copies data from the socket buffer to the receiving buffer of the application. Consequently, the suspended application is returned and continues with the next operation. If no socket-pair is found, the UDP datagram is discarded silently.

[0132] TCP provides a connection-oriented, reliable, flow-controlled and ordered byte-stream service between the two end points of an application. TCP is the most complex protocol in the TCP/IP protocol stack. It uses the unreliable IP mechanism for communication and uses time with a retransmission mechanism to achieve reliability. The original specification for TCP is RFC 793. In view of the actual application circumstances of the system according to the invention, the TCP implementation has been greatly simplified in μRET. First, the TCP module in μRET acts as a TCP server, which responds to a TCP request from a TCP client and gives TCP acknowledgement. Since the remote peer runs a full-scale and standards compliant of TCP/IP implementation, only part of the functions needs to be implemented for TCP establishment and termination. Next, because there is only one TCP service i.e. a web server in a STAR system according to the present invention and only one TCP connection at a time in any current TCP application, some complex TCP communication mechanisms, such as retransmission, flow control, congestion control, and sliding window, can

Petitioner Ex-1004, 0285

BNSDOCID: <EP_____1724684A1_I_>

thus be simplified or removed.

[0133] The unit of transfer between two machines using TCP software is called a segment. Segments are exchanged to establish connections, to transfer data, to send acknowledgements, to advertise window sizes and to close connections. Each segment is divided into two parts, a TCP header followed by data. The TCP header carries the expected identification and control information. The way TCP achieves reliability is in the format of the TCP header. Figure 18 shows the TCP segment format used in the present invention.

[0134] The Fields, source port and destination port contain the TCP port numbers that identify application programs at the ends of the connection. The sequence number field identifies the sender's byte stream of data in the segment. The acknowledgement number specifies the number of bytes that the source expects to receive next. The header length field contains an integer value that specifies the length of the segment header in 32-bits. The header length covers the 20 bytes common TCP header and the varied TCP options. In the TCP implementation of the invention, only one TCP option, MSS (Maximum Segment Size) is defined for the TCP SYN segment. The TCP options are stored into a data buffer in μRET, so that the TCP header has a fixed-length which satisfies the transport layer header format of the ippacket structure. The 6 bits reserved field is reserved for future use and is filled with zero.

[0135] Six flag bits are used to determine the purpose and the contents of the TCP segment. These six bits tell how to interpret other fields in the header as illustrated in Figure 19. The TCP implementation of the present invention responds to the ACK, RST, SYN, FIN, and PSH segments. Since there is only one TCP application and one TCP connection at a time, the URG flag is meaningless for the identification of urgent data and the urgent pointer field is thus of no use. TCP software advertises how much data it is willing to accept every time it sends a segment by specifying its buffer size in the Window size field. The window size of the TCP segments in the present invention is fixed and equals the MSS minus the size of the general TCP header (MSS-20). The checksum covers the TCP segment: the TCP header and the TCP data. The TCP checksum is calculated similarly to the UDP checksum, using a pseudo-header as described above. The urgent pointer field is insignificant in our implement, which is ignored for the incoming segments and is filled with zero for the outgoing segments.

[0136] The lifetime of a TCP connection is divided into three phases: (1) opening the connection to create a full-duplex byte stream; (2) transferring data in one or both directions over this connection; and (3) closing the connection. A three-way handshake mechanism is utilized to facilitate the set up and closure of the TCP connection. Many of TCP's actions, in response to different types of segments arriving on a connection, can be summarized in a state transition diagram. The TCP implementation in μRET is a subset of the TCP standard, which implements the basic functions of a TCP server: passive opening TCP connection, transferring TCP segments, and active or passive closing TCP connection. Figure 20 shows the various state transitions of the TCP server according to the present invention. The CLOSED state is the begin and end point of a TCP connection. Before estimating a TCP connection, socket function new_socket() is called to create a socket, and then new_bind() is called to bind this socket with a specific port:

TCP server passive open: the application process calls socket function new_listen() to listen for connection requests from TCP clients, the connection state is changed to LISTEN. Then, socket function new_accept() is called to accept connection requests from TCP clients. If the opening request segment, with seq number of J, from a TCP client is received, a SYN segment, with a seq number of K and ack number of J+1 is sent back to the TCP client to actively set an active opening of the TCP client. The connection state changes to SYN_RCVD. When an ACK segment, with the ack number of K+1, is received, the TCP connection is established and the state is changed to ESTABLISHED. From now on, TCP data segments can be exchanged between TCP client and server.

TCP server passive close: when a FIN segment, with seq number of M, is received, it means that the client has begun to close the TCP connection. An ACK segment, with ack number of M+1, is sent to the TCP client. The connection state is changed to CLOSE_WAIT. Then, socket function new_close() is called to terminate the connection, which sends a FIN segment, with seq number of N, to activate the active closure of the TCP client. The connection state is changed to LAST_ACK. If last ACK segment, with ack of N+1, is received from the TCP client, the TCP connection is completely terminated and the connection state is returned to CLOSED.

TCP server active close: The application process calls the socket function new_close() to terminate a TCP connection. A FIN segment, with seq number of N, is thus sent to notify the client of a request to close the TCP connection. The TCP connection state is changed to FIN_WAIT_1 and the TCP client begins a passive closure. After one of the three following phases, the TCP server enters the TIME_WAIT state. Then, after waiting a time interval of 2MSL (2 times the Maximal Segment Lifetime), the TCP connection is completely terminated and the connection state is returned to CLOSED.

If a FIN segment is received first, with seq number of M, from the TCP client, the TCP server responds with an ACK segment, with seq number of M+1, and the TCP connection changes state to CLOSING. Then a received ACK segment, with ack number of N+1, will change the TCP connection state to TIME_WAIT.

If an ACK segment, with ack number of N+1, is received first, the TCP connection will change to FIN_WAIT_2. This is a half-closed state, in which the TCP server can still receive the data segments from the TCP client. When a FIN

Petitioner Ex-1004, 0286

BNSDOCID: <EP_____1724684A1_I_>

segment, with seq number of M, from a TCP client is received, the TCP server will send back an ACK segment (with ack number of M+1) and the TCP connection processes to TIME_WAIT.
If an ACK+FIN segment, with ack number of N+1 and seq number of M, is received, the TCP server responds with an ACK segment, with ack number of M+1, and the TCP connection directly proceeds to TIME_WAIT.

[0137] The function new_tcp_sendmsg() is called by the socket function to handle TCP data sending. Here, the data is divided into appropriate sized chunks, of a size less than MTU-28, and is attributed ordered sequence numbers. Next, in a control loop, new_tcp_output() is called to send each data chunk. In new_tcp_output(), an ippacket member is allocated to accommodate the TCP segment. The TCP header fields are filled and the checksum is computed. The SYN segment is handled differently. The SYN segment does not contain TCP data, but has TCP options, for example MSS. As the TCP header defined in the ippacket structure has a fixed length, TCP header options thus have to be stored in the data buffer, but are processed as the part of header. Like the process of the UDP output function, the IP address and port number of the sender must be attached to the socket-pair before calling the new_ip_output() function to transmit a TCP segment.

[0138] When a TCP segment arrives, the IP layer calls the new_tcp_input() function. The TCP checksum is checked and the segment is de-multiplexed. The new_tcp_lookup() function is used to lookup a socket-pair for the received segment in the socket queue. When a socket-pair is found, and depending on the segment type, different processes are performed. If the received segment is a SYN segment, FIN segment or an ACK segment for SYN and FIN requests, the passive mode of the TCP server for opening and closing a TCP connection is applied. If the received segment is a data segment, the data is copied to the corresponding socket buffer. The suspend function new_tcp_recvmsg() will be returned until the TCP connection is terminated, which means that all of the TCP segments of this TCP connection have been received. Then, the corresponding application program is invoked.

[0139] Most TCP implementations use the sliding window mechanism for sending data. In the STAR system of the present invention, there is only one TCP application and only one TCP connection at a time. In the web server application, the HTML page is stored in a pre-allocated data buffer. A TCP connection will be established when the user requests the HTML page through an Internet browser program, such as Internet Explorer or Netscape Navigator. The new_tcp_sendmsg() function is called to divide the HTML page buffer into several appropriated data chunks. There are thus several data segments that need to be transmitted for this service. These data segments are sent successively without waiting for an acknowledgement for each segment. The μRET implements the sliding window mechanism for TCP segments, and only needs a few lines of code to manage the data pointers of the TCP segments, avoiding increased complexity of the μRET implementation.

[0140] Since only the functions of a TCP server are implemented in μRET, the TCP implementation therein maintains three timers for each connection: a retransmission timer, a delayed timer and a 2MSL timer. The three timers are driven by a periodic system timer. Every time the periodic timer is invoked, these three TCP timers' values are decremented. If a timer's value reaches zero, the timer is considered to have expired and actions are invoked. The retransmission timer is set to the timeout each time the TCP sends data. If the segment is not acknowledged by the other end when the retransmission timer has expired, the TCP module retransmits the segment. The default retransmission timeout is set to 2.84s or 200 time-ticks for the Texas Instruments Digital Signal Processor TMS320C5410. Moreover, each time that the timer expires, its retransmission timeout is increased by 10 time-ticks. If the retransmission times arrive at the maximum threshold value, in this case 3 times, a FIN segment is sent to the other end, the TCP connection is terminated abruptly and the connection state is set to CLOSED. The delayed timer is set when the TCP server sends data segments which should have been acknowledged by the TCP client, and normally caused by the sliding window. The delayed timer has a longer timeout than, but its expired action is the same as, that of the retransmission timer. The default delayed timeout is set to 5.68s. The 2MSL (Maximum Segment Lifetime) timer is set when the the TCP connection state is TIME_WAIT. The TCP server has to wait an interval time of 2MSL in order to make sure that all data segments on the link will be received. When this timer has expired, the connection state is changed to CLOSED to terminate the connection. The default 2MSL timeout is set to 30s. The actual retransmission operation is fairly simple in μRET because the data buffer of the TCP application is pre-configured and always kept alive. Hence there are no additional buffer allocation/de-allocation operations for retransmission and no need to build a new segment. In fact, segment retransmission is similar to a normal segment transmission which further reduces complexity of the TCP implementation in μRET.

[0141] The Round-Trip time (RTT) is normally used to determine the retransmission timeout and to evaluate network communication capacity in most TCP/IP implementations. In μRET, the ping program (ICMP echo message) can be used to estimate RTT. In an exemplified STAR system of the present specification, the TCP application is extremely simple (single-user web server) and its physical network medium is a unique point-to-point link, the default timeouts of the three TCP timers and the network traffics are thus predictable and predefined during compile time, so that there is no need to estimate the retransmission timeout using RTT.

[0142] The purpose of TCP flow control mechanism is to allow communication between hosts with widely varying memory size. The flow control mechanism can be implemented by altering the window size field of the TCP header.

Petitioner Ex-1004, 0287

BNSDOCID: <EP_____1724684A1_I_>

The value of this field indicates the available buffer space of the sender. In the present invention, μRET does not integrate a flow control mechanism and the value of window size field remains constant. The sizes of the network input/output buffer determine the maximum size of the TCP segment. Additionally, the current TCP application of the STAR system in accordance with the invention only has a few segment exchanges, and each time only one TCP connection is allowed. There is thus no advantage to be gained from implementing window size control. By limiting the numbers of simultaneous TCP segments, the congestion control mechanism changes the data rates of the sender and the receiver to meet network capacity and to avoid potential congestion. Since the TCP application of the STAR system according to the invention only supports one TCP connection at a time, there is in essence no possibility for a potential congestion situation.

[0143] The standard BSD socket API adopts "stop and wait" semantics. It requests a data copy between the application program buffer and the system protocol buffers. The reason for data copy is that the application program and the TCP/IP stack usually reside in different protection domains. In most cases, the application program is a user process and the TCP/IP stack is the part of the system kernel. The user buffer space and the kernel buffer space are usually strictly protected and can not be shared with each other in most systems. It is for this very reason that the BSD socket API provides a high-level abstraction layer to manipulate the data exchanges between applications and network protocols. Therefore, the standard BSD socket API is not suitable for the purposes of the present invention. However, the BSD socket API is a well-known API, and has become a de facto industry standard. Lots of applications have been developed based on BSD socket API. It was thus considered appropriate to implement an API in the present invention which is compatible with the BSD socket API. In most small embedded systems, system kernels are designed to support direct data exchanges between applications and kernel by avoiding extra data copy operations and reducing memory usage. This is also an important advantage of the real-time embedded system SDREAM described above and one of the objects of the present invention. This feature makes it possible to implement an API which supports direct data exchanges between applications and network protocols. A simplified variation of the BSD socket API is thus implemented in μRET. It adopts completely compliant interfaces and call modes with the BSD socket API, but can also directly support data read and write operations among different data spaces.

[0144] Each network connection must have a unique socket-pair. The socket structure of μRET is shown below.

Socket structure

```
struct new_socket
{
int skfd;                          /* socket index in sock queue*/
int used;                          /* used flag. 0: unused; 1 used*/
struct new_skaddr srcskaddr;       /* source socket-address*/
struct new_skaddr dstskaddr;       /* destination socket-address*/
unsigned char * dbuf;      /* data buffer pointer*/
int d len;                         /* data length*/
int t ype;                         /* socket type: DGRAM,STREAM,RAW*/
int p r ot;                /* transport protocol: udp, tcp, raw*/
int dev_if;                /* device interface index*/
struct new_route * ro;     /* route table pointer*/
unsigned char state;               /* tcp socket state*/
};
```

[0145] This smart structure contains all the information of a network connection. The socket-address structure (new_skaddr) is composed of an IP address and a port number. The two socket-addresses of the source and the destination hosts, i.e. the srcskaddr and dstskaddr fields in socket structure, are combined as a socket-pair which is used to exclusively identify a network connection. The socket-pair is important to de-multiplex the incoming TCP segments or UDP datagrams for their corresponding applications. It is also useful to lookup a suitable route table and a network interface for outgoing packets. The values of dbuf and dlen fields are the address pointer and the size of the data buffer of the application, respectively. These two values are passed to an allocated ippacket member, which means that the protocol layers can directly manipulate the data buffer of applications and no data copying is needed here. There are three different types of socket interfaces which are identified in the type field: The stream socket interface (SOCK_STREAM), the datagram socket interface (SOCK_DGRAM) and the raw socket interface (SOCK_RAW). The protocol field is used to indicate the types of lower layer protocols: TCP for SOCK_STREAM, UDP for SOCK_DGRAM and ICMP for SOCK_RAW. The value of the dev_if field points to the index of the related network interface. The ro pointer points to the index of the related route table. The state field is only reserved for the SOCK_STREAM interface and the TCP protocol, which indicates the TCP connection state. The skfd field is the index of the socket in the socket queue. The

Petitioner Ex-1004, 0288

BNSDOCID: <EP_____1724684A1_I_>

used field then indicates the status of a socket. The skfd and used values are useful for designating a new socket or to search a related socket from socket queue.

[0146] The simplified variation of the BSD socket API is composed of seven basic socket calls, which allow application programs to communicate with any available transport layer protocol and underlying network service. In view of the functions of the socket calls, they can be classified into 3 classes: 1) socket allocation: new_socket(); 2) connection management: new_close(), new_bin(), new_listen(), new_accept(); 3) data delivery: new_sendto(), and new_recvfrom().

[0147] Socket system calls are frequently used for the connect-oriented TCP protocol and the connectionless UDP protocol. The TCP implementation of the present invention is designed to support applications of the TCP server, and thus the connection request call of a TCP client, i.e. new_connect(), is not implemented. Connectionless socket calls are simpler, in that the listen/accept/connect stages can be avoided.

[0148] In a application protocol layer, a SNMP agent and a minimum web server are implemented as the instances of UDP and TCP applications respectively. The SNMP agent and the web server run in the SDREAM system configured as two system priority tasks.

[0149] The Web (WorldWide Web, or WWW) is probably the most important network application of Internet. A web application is based on a typical client/server model and adopts HTTP (Hypertext Transfer Protocol) for web communications. The web client is normally an Internet browser program, such as Internet Explorer, Netscape Navigator, Opera, Konqueror, Mozilla, Mozilla Firefox, Lynx, etc. The web server listens to the well-known TCP port 80 and returns a HTML page to the client. HTTP is the application-level protocol which specifies the communication mechanism between web server and web client and runs over the TCP protocol. First, the client requests a web service. Through the TCP negotiation mechanism, the client establishes a TCP connection with the web server. The browser of the client sends a "GET" request automatically to and then reads the responses from the web server. The web server closes the TCP connection to indicate the end of the HTML page transfers. The most frequently used response data of web server is the HTML (Hypertext Markup Language) document which is described in RFC 1866. The minimum web server of the present invention implements only part of the functions of HTTP version 1.0. It responds only to "GET" requests from the client. The web data that includes the status information and the configuration parameters of the STAR system according to the invention are displayed in client's browser interface. The source code of the web server used in the implementation according to the present invention, in which the socket system calls of the TCP connection are presented, is shown hereunder for illustrative purposes.

Petitioner Ex-1004, 0289

BNSDOCID: <EP_____1724684A1_I_>

Web server implementation code

```
/*****************************************************************
*
* Web Server
*
*****************************************************************/
const unsigned char WebHead[] =  /*HTML page header*/
{
        "HTTP/1.0 200 OK\r\n"
        "Content-Type: text/html\r\n""\r\n"
};
const unsigned char WebBody[] =  /*HTML page body*/
{
        "<html><head><title>Hello, world!!</title></head>
        <body><center>Welcome, this is my first page!!!</center></body>
        </html>\r\n""\r\n"
};
void HttpServer(void)
{
        int                                     err, requst_id, tcpdatlen, tcpcurnum;
        unsigned char *         tcpdatptr;
        struct new_sockaddr                     my_addr, client_addr;

        while(!IS_PPP_OPEN());          /*Verify if the PPP connection link is opened*/
        while (1)
        {
                if (tcpskfd == -1){
                tcpskfd = new_socket(NEW_AF_INET,NEW_SOCK_STREAM ,0);
                /*Allocate SOCK_STREAM socket*/
                if (tcpskfd == -1) {
                        ErrTyp = ERR_SO_SOCK;
                        ErrMnm(); goto fini;
                }
                new_aton("10.0.0.2",&my_addr.sin_addr);
                my_addr.sin_port = HTTP_PORT;
                err=new_bind(tcpskfd, &my_addr);                /*Bind Well-known HTTP port*/
                if (err == -1){
                        ErrTyp = ERR_SO_BIND;
                        ErrMnm(); goto fini;
                }
        }
        while (1){
                err= new_listen(tcpskfd, 1);            /*Listening*/
                if (err == -1){
                        ErrTyp = ERR_SO_LISTEN;
                        ErrMnm(); goto fini;
                }
                err = new_accept(tcpskfd, &client_addr); /*Establish Connection*/
```


Petitioner Ex-1004, 0290

BNSDOCID: <EP_____1724684A1_I_>

```
                    if (err == -1){
                                ErrTyp = ERR_SO_ACCEPT;
                                ErrMnm(); goto fini;
                    }
                    err = new_recvfrom(tcpskfd, requst_id, 1, &client_addr);
                     /*Wait client's 'GET' request*/
                    if (err == -1){E rrTyp = ERR_SO_RECV;
                                ErrMnm(); goto fini;
                    }
                    if (request_id != HTTP_GET_REQUST){
                                ErrTyp = ERR_HTTP_TYPE;
                                ErrMnm(); goto reset;
                    }
                    tcpdatptr = (unsigned char *)&WebHead[0];
                    tcpdatlen = sizeof(WebSite1);
                    err = new_sendto(tcpskfd,tcpdatptr,tcpdatlen,&client_addr);
                                /*Send HTML page head*/
                    if (err == -1){
                                ErrTyp = ERR_SO_SEND;
                                ErrMnm(); goto fini;
                    }
                    tcpcurnum = 0;
                    while (tcpcurnum <= TCPNUM){
                     /*Send HTML page body: fragment in application layer*/
                                if (tcpcurnum == TCPNUM){
                                tcpdatptr = (unsigned char *)&WebBody
                                [tcpcurnum*TCPMSS];
                                tcpdatlen = sizeof(WebSite2) -tcpcurnum*TCPMSS;
                    }
                    else{
                                tcpdatptr = (unsigned char *)&WebSite2
                                [tcpcurnum*TCPMSS];
                                tcpdatlen = TCPMSS;
                    }
                    err = new_sendto(tcpskfd,tcpdatptr,tcpdatlen,&client_addr);
                    if (err == -1){
                                ErrTyp = ERR_SO_SEND;
                                ErrMnm(); goto fini;
                    }
                    tcpcurnum++;
          }
reset:              new_close(tcpskfd);          /*Close the TCP connection*/
          }
fini:     new_tcp_init();                  /*Initialization TCP */
          ]
}
```

[0150] The μRET implementation of the present invention integrates network management functions for small embedded devices. Network management of a TCP/IP implementation consists of network management stations, known as managers, communicating with network elements, known as agents. Network embedded systems act as SNMP agents to respond to managers' requests and to report the embedded system status. TCP/IP network management generally has three components:

A Management Information Base (MIB) that specifies what variables the network elements maintain. RFC 1213 defines the second version of this, called MIB-II.

A Structure of Management Information (SMI), which is a set of common structures and an identification scheme used to reference the variables in the MIB, is specified in RFC 1155.

The Simple Network Management Protocol (SNMP) details the format of the SNMP messages and defines the exchange mechanism between the managers and the agents. RFC 1157 specifies the protocol of SNMP version 1 and RFC 1901 defines the SNMP version 2. SNMP messages are normally encapsulated in UDP datagrams to be transported over the network.

[0151] The SNMP agent used in the present invention implements the SNMP protocol of version 1 and version 2c. It

Petitioner Ex-1004, 0291

BNSDOCID: <EP_____1724684A1_I_>

supports five basic SNMP operators, i.e. GET, GETNEXT, SET, GETRESPONSE and TRAP, shown in Figure 21. The manager sends its three classes of requests to the agent (UDP port 161), while the agent sends traps to the manager (UDP port 162). The SNMP agent contains two MIB groups: a public system group and a private STAR group. The system group is a basic MIB-II group which provides the vendor's information, while the STAR group is a private MIB group which includes the status information of the STAR system according to the invention. The two MIB group variables and their SMI definitions are shown in Figure 22. Figure 23 shows the tree structure of the two MIB groups.

[0152] The SNMP manager gets the MIB variables of the SNMP agent by the GET or GETNEXT command and modifies these variables by the SET command. The SNMP agent also allows adding new MIB group or variables by the SET command from the SNMP manager. If something has happened to the agent that the manager might want to know about, the SNMP agent voluntarily sends a TRAP message to the manager. The STAR system error codes, communication KEY/community, and other configuration/management information can be set as MIB variables. By getting and setting the MIB variables, the SNMP manager has the ability to remotely configure and manage the STAR system. The formal specification of SNMP uses Abstract Syntax Notation 1 (ASN.1) and the actual encoding of the bits in the SNMP messages uses the corresponding Basic Encoding Rules (BER). The format of the SNMP message is shown in Figure 24. In this figure, the version equals the SNMP version number minus one. The community is a character string that is a clear-text password between the manager and agent. In this SNMP agent, we have defined three community strings: public, private, and smir, each having different read and write privileges. The PDU indicates the type of SNMP message. For the GET, GETNEXT, and SET operators, the request ID is set by the manager, and returned by the agent in the GETRESPONSE message, which is used to identify the SNMP message. The error status and error index is used to indicate which type of error and which variable is in error, when an error occurred. A list of variable names and values follows in the GET, GETNEXT, and SET requests. The SNMP agent actively sends a trap message to the manager if something has happened on the agent that the manager might want to know about. The PDU of trap message is always 4 (trap). The enterprise field is the vendor's object identifier. The agent address is the IP address of the network device. The specific code indicates the trap type which identifies the specific trap events. The Time stamp represents the number of hundredths of a second since the agent initialized. The source code of the SNMP agent used in a STAR device according to the present invention, in which the socket system calls of the UDP connection are presented, is given below as an example :

```
/*********************************************************************
*
* SNMP Agent
*
*********************************************************************/
void SnmpAgent(void)
{
int err, nflg=0;
struct new_sockaddr my_addr, client_addr;
while(IIS_PPP_OPEN()); /*Verify if the PPP connection link is opened*/
new_snmp_init(&rcvpdu); /*Init Snmp Agent*/
err=new_snmp_trap(&rcvpdu,SNMP_TRAP_COLDSTART, 0); /*trap--CodeStart*/
if (err <= 0) goto fini;
while (1)
{
if (snmpskfd == -1)
{
snmpskfd = new_socket(NEW_AF_INET,NEW_SOCK_DGRAM ,0); /*allocate new socket*/
if (snmpskfd == -1) {
ErrTyp = ERR_SO_SOCK;
ErrMnm(); goto fini;
}
new_aton("10.0.0.2",&my_addr.sin_addr);
my_addr.sin_port = 161;
err=new_bind(snmpskfd, &my_addr); /*bind socket with SNMP_PORT
```


Petitioner Ex-1004, 0292

BNSDOCID: <EP_____1724684A1_I_>

```
if (err == -1){
ErrTyp = ERR_SO_BIND;
ErrMnm(); goto fini;
}
}
if (nflg == 1){
err=new_snmp_trap(&rcvpdu,SNMP_TRAP_WARMSTART, 0); /*trap--WarmStart*/
if (err <= 0) goto fini;
}
while (1)
{
err = new_recvfrom(snmpskfd, &SnmpSpace[0],MAX_SNMP_SPACE,&client_addr); /* Receive SNMP
message*/
if (err == -1){
ErrTyp = ERR_SO_RCVF;
ErrMnm(); goto fini;
}
err = new_snmp_parse(&rcvpdu,&SnmpSpace[0], err); /* Parse snmp packet*/
if (err <= 0){
if (err == -2)
err=new_snmp_trap(&rcvpdu,SNMP_TRAP_AUTHFAIL, 0); /*trap--Authfail*/
continue;
}
err = new_snmp_build(&rcvpdu); /*bind pdu according to the get/set request*/
if (err <= 0) continue;
err = new_sendto(snmpskfd,&SnmpSpace[0], err, &client_addr); /*send Get-Response*/
if (err == -1){
ErrTyp = ERR_SO_SEND;
ErrMnm(); goto fini;
}
}
fini:
new_close(snmpskfd); /*close the this SNMP socket connection */
snmpskfd = -1;
nflg =1;
err=new_snmp_trap(&rcvpdu,SNMP_TRAP_LINKDOWN, 0); /*trap--LinkDown*/
}
}
```

[0153] The complete function call flowchart of the µRET according to the present invention is shown in Figure 25. UDP, TCP and ICMP function calls are presented by three different applications: a SNMP agent (UDP), a web server (TCP) and a ping routine (ICMP).

[0154] The µRET of the present invention has been ported to two different processor architectures: microcontroller MSP430F149 and digital signal processor TMS320C5410. The following part of the description deals with measurement of the memory usage of µ RET in the two processor architectures, and compares µRET with other TCP/IP implementations with respect to code sizes and protocol functions. Then, the performance of µRET was evaluated.

[0155] The applicants analyzed the codes of µRET with respect to code size and data size of compiled objects. The code was compiled for two processor architectures: Texas Instruments (TI) digital signal processor TMS320C5410 and Texas Instruments microcontroller MSP430F149. The code for the first processor TMS320C5410 was compiled with the 'C5000 Code Composer Studio v1.20' IDE (integrated development environment) tool and the TMS 320C5410 EVM development motherboard, with compiler optimization option turned on. The codes for the second processor MSP430F149 was compiled with the 'MSP IAR C Compiler' development tool, with compiler optimization option turned on.

[0156] The TMS320C5410 is a 16-bit fixed point digital signal processor having a 100 MHz clock frequency. The TMS320C5410 has 80KW (W 'word' = 16 bits) internal memory (16KW of RAM and 64KW of ROM). The MSP430F149 is a 16-bit RISC microcontroller having a 8MHz clock frequency. The MSP430F149 has 62KB of internal memory (60KB of flash memory and 2KB of RAM). Analysis of compiled code size in the TMS320C5410 processor showed the SNMP

Petitioner Ex-1004, 0293

BNSDOCID: <EP_____1724684A1_I_>

module to have the greatest code size because this module requires the greatest memory space to be pre-allocated for the SNMP MIB variables. The PPP module represents approximately 40% of the total code size due to the complex PPP state automaton. An 11*6 two dimension data matrix was pre-allocated to store PPP state transition table and PPP two-way negotiation mechanism (LCP and IPCP), thereby increasing overhead of the PPP module. The TCP module represents approximately 20% of the total code size because of the complex mechanisms for the connection-oriented, reliable service. It has the largest size of all of the transport and internet layer modules of μRET. In view of the feature of 16-bit per word of the TMS320C5410, one way of reducing overhead for μRET is to use the first 8 bits of a word memory. For example, in TMS320C5410, a 'char' has 16 bits but only tail 8 bits are practically used and another 8 bits are thus wasted. Hence, using the idle 8 bits of each char is one significant way of decreasing memory usage.

[0157] Analysis of code and data sizes of each protocol module for the MSP430F149, was carried out. Due to the minimal system resources in this processor, the two application layer protocol modules, SNMP and HTTP, were not contained in the μRET when compiled for the MSP430F149. The code size for each protocol module was noticeably greater due to the fact that the MSP430F149 processor does not naturally support 32-bit operations and does not have an 8 bit idle space for a char, when compared to the TMS320C541 0 processor. Thus, any 32-bit operations will be expanded by the compiler into many more assembler lines in the MSP430F149 processor. Since the TCP module performs many 32-bit operations, it had the correspondingly greatest code size out of all of the protocol modules.

[0158] Performance of memory usage was analysed by comparing μRET with other TCP/IP implementations with respect to memory consumption and protocol functions,. Without the application layer SNMP and HTTP protocol modules, μRET only uses 13.7KB of memory for the MSP430F149 and 10.2KW of memory for the TMS320C5410. Compared to full-scale and generic TCP/IP implementations, such as KwikNet (158KB or 124.6KB), NicheStack (47KB) and NexGenIP (34.5KB), μRET of the invention therefore has far lower memory requirements. Additionally, when compared to known lightweight implementations, such as μIP (7.2KB), lwIP (13.8KB or 22.6KB), and Nichlite (10KB), μRET has far more protocol modules (PPP). In fact, if the PPP module is removed, μRET requires only 6.1 KB or 9.1 KW respectively, and can thus compete with any of the known lightweight TCP/IP implementations.

[0159] In order to meet different TCP applications and various hardware platforms, the μRET implementation can be further adapted to be able to meet the capacities of other processors. For example, in one preferred embodiment of the present application, the STAR device uses a MCU CP3000, providing more powerful computation capability and more internal memory. This MCU is designed to support different wireless sensor network applications. In view of variable network communication capacity and a large number of WSN nodes in the WSN applications envisaged by the invention, the μRET implementation for this processor provides RTT estimation ability and supports flow and congestion mechanisms. Again, the μRET implementation can be adapted to take into account network security and various authentication methods or encryption when connecting embedded systems to a WAN (wide area network) or even globally to the Internet. The μRET implementation is thus fully modular. Not only is it possible to add or remove each protocol module easily, but also each function component can simply be added to or removed from any particular protocol module. It is thus possible to modify the μRET implementation in such a way as to select those protocol modules and function components that provide efficient and reliable communication capability adapted to different platforms and applications.

[0160] In still yet a further object of the present invention, the applicants have devised embedded real-time diagnosis techniques for an Automated ECG Diagnosis (AED) system, and a corresponding system, known herein as the Star system.

[0161] Cardiovascular variables, such as heart rate, arterial blood pressure and the shape of the QRS complexes in the cardiac electrical signals, are almost "periodical", showing some variability on a beat to beat basis. This variability reflects the interaction between perturbations to the cardiovascular variables and the corresponding response of the cardiovascular regulatory systems. Therefore, the analysis of such variability can provide a quantitative and non-invasive method to assess the integrity of the cardiovascular system. The ECG (electrocardiogram), that is the body-surface manifestation of the cardiac electrical potentials, is the most prescribed diagnostic measure in medicine and is routinely used to diagnose heart disease, identify irregular cardiac rhythms (arrhythmias), evaluate the effects of drugs, and monitor surgical procedures. The magnitude, conduction, and duration of these potentials are detected by placing electrodes on the patient's skin. The ECG trace or plot is a series of waves that represent the electrical events in the heart. By examining the sequence of events on the ECG, it is possible to diagnose cardiac arrhythmias. Developments in computerized patient monitoring systems over the recent years have made remarkable demands on automatic ECG analysis systems. Many efforts have been focused on the enhancement of the efficacy and the accuracy of such AED systems and a variety of AED algorithms have been presented based upon different domains and/or techniques by researchers. The AED is one of real-world application of automated pattern recognition. The essential problem of pattern recognition is to identify an object as belonging to a particular group. In AED, it is to classify a cardiac cycle into a particular group of cardiac status by observing statistical features and morphological features of ECG signals. Assuming that each group of cardiac status has exclusive attributes, the problem of assigning an unlabelled cardiac cycle to a group can thus be accomplished by determining the attributes of this cardiac cycle (pattern) and identifying the group of which those attributes are most representative (recognition). Given the goal of classifying an object, i.e. the status of

Petitioner Ex-1004, 0294

BNSDOCID: <EP_____1724684A1_I_>

a cardiac cycle, based on their attributes, the functionality of an AED can be divided into two basic tasks: the description task generates attributes of an object using feature extraction techniques, and the classification task assigns a group label to the object based on those attributes with the rhythm classification. The description and classification task work together to determine the most accurate label for each unlabelled object analysed by an AED algorithm. This is accomplished with a training phase that configures the algorithm based on a collection of objects whose labels are known,i.e. a training set.

[0162] In terms of signal capture techniques, cardiac electrical signals are categorized into two classes: one from body-surface electrodes which is the most commonly performed cardiac test, named ECG (Electrocardiograph); another from implantable leads placed inside a patient's heart, which is therefore an invasive cardiac signal, called EG (Electrogram). The electrogram is mostly used in ICDs (implantable Cardioverter Defibrillators) that are implanted inside the body and can deliver pulses or shocks to treat rapid heart rhythms by continuously checking the heart's electrical signals. In contrast to ECG signals, the electrogram obtained from ICDs are generally of a higher quality and stability, and are free of disturbances originating from external situations, devices and patients, which include baseline drift, muscle tremor, electrical noise and motion artefacts. These external factors are mainly interferences attenuating and polluting the electrical signals. The ICDs, as a therapy for cardiac arrhythmias, are suitable for those patients having serious rapid heart rhythms such as VT and VF, but do not prevent and cure the underlying disease that causes cardiac arrhythmias. Moreover, the disturbance to daily movement, expensive fees, and even malfunctions, make ICDs generally unsuitable as a general cardiac care system for most people. The ECG signals are further classified into two types in view of the application environments: resting ECG (RECG) and ambulatory ECG (AECG). RECG is used for stationary hospital-bedside monitoring and diagnostics. It is a short-term (several hours) stable ECG record typically obtained from an ECG machine. AECG is generally used for long-term heart monitoring services normally acquired from sensors outside of laboratories or hospital care units. Compared to AECG, a resting ECG has a generally cleaner and more stable signal, and is free of the interferences caused by motion artefacts, which are the critical problem of AECG. Using RECG signals, AED algorithms have higher accuracy, but the counterpart thereto is that patients' motions are completely constrained. Moreover, cardiac arrhythmia events do not always occur in a limited clinical detection period and the decision-making rules of heart diseases are not entirely the same in a situation of movement when compared to a resting situation. RECG is thus suitable for monitoring in a clinical resting environment, but not illfitted to the requirements of daily real-time heart care. Since AECG signals are acquired outside of a laboratory, they are generally contaminated by environment factors, such as the electronic noises of nearby circumstances, the muscle tremor of patient and the unstable connections between electrodes and skin caused by patient movement. Compared to RECG, AECG signals show more non-stationarities, which are influenced by noises of transient phenomena or slow variance (trends). Noise causes significant problems in the identification of heart rhythms, so a signal preprocessing procedure is necessary to reduce the interferences of noise and to prepare clearer signals for the subsequent analysis tasks.

[0163] To date, there are three approaches to acquiring an AECG :

Holter monitoring generates a continuous recording of the ECG, usually for 24 hours. It does not constrain the daily motions of patients. The test is useful for detecting cardiac arrhythmias that may not appear during a resting ECG at the doctor's office. However, the short-term detection, say over 24h, may also miss some infrequent cardiac arrhythmias and the lack of real-time diagnosis prevents the implementation of real-time heart care.

The event recorder is carried over a period of days or weeks, and is used to record cardiac arrhythmias that occur infrequently. When symptoms occur, the patient activates the recorder which records and stores several minutes of ECG signals. Like Holter, this device lacks the ability to carry out real-time diagnosis and its performance depends only on the subjective interpretation of patients' feelings and is therefore unreliable.

The exercise ECG test, or treadmill test, allows cardiologists to record ECG signals during the stress of exercise. It can help bring on cardiac arrhythmias that may not occur during a resting ECG. The drawbacks of the device are its limitations in time and space because this test can practically only be done in hospital and can not run for long periods of time.

[0164] Due to the fact that severe noise pollution often occurs in AECG, the AED algorithms for AECG are different to those of RECG and EG. The traditional techniques of treating AECG signals are limited in time and / or space, and consequently most of them do not support real-time ECG detection and diagnosis and are unsuited to real-time long-term heart care.

[0165] ECG signals are acquired through electrode pads that are attached to the patient's chest, generally in a anterior-anterior placement. Since Ambulatory ECG takes place over a relatively long period and under the influence of the exterior environment, there is a higher probability of contamination by various interferences caused by noise. An artefact is an electrical signal caused by noise, and which is unrelated to cardiac behaviour. If artefacts cannot be effectively

Petitioner Ex-1004, 0295

BNSDOCID: <EP_____1724684A1_I_>

removed from or reduced in the ECG, they will cause incorrect detection of heart rhythms, and lead to inappropriate cardiac arrhythmia interpretations. For this reason, many AECG signals are digitized and processed to remove or reduce the effects of certain types of electrical interference before ECG detection and diagnosis is carried out on said signals. Sources of artefacts can be characterized as either controllable or uncontrollable. For example, direct manipulation of the electrode pads or the movements of the patient are examples of artefacts that can be controlled. Correspondingly, electrical interference and patient muscle tremors are sources of artefacts that are generally not within the control of the patient.

[0166] Baseline drift originates from high skin impedance caused by unstable electrode contact and poor skin preparation. This interference can be effectively eliminated by clinical means shown as follows:

de-greasing skin with alcohol and drying the skin with gauze, which lowers skin resistance;
employing the electrodes that are made of silver coated with silver chloride with stable impedances reducing slow drift;
attaching gel-impregnated foam pads that decrease movement artefact and lower skin impedance;
securely connecting electrode to skin and lead wire to electrode.

[0167] The technical solution is to employ a high-pass filter with cut-off frequency at 0.1 Hz to reduce low-frequency baseline drift.

[0168] Electrical interference caused by the electrical noise from nearby equipment may contaminate the ECG with a 50 Hz (France) or 60 Hz (America) signal. This interference is attenuated by a narrow stopband filter called a notch filter, which is tuned to remove the 50 or 60 Hz signals.

[0169] Muscle tremor present when a patient is tense, cold, or affected with muscle or nerve disorders may contaminate the ECG with high-frequency baseline noise. A low-pass filter can remove much of the noise. Unfortunately, the frequency spectrum overlaps the ECG frequency, so it is not possible to remove all of it without destroying ECG data. A 40 Hz low-pass filter is used in the present invention to minimize artefact from muscle tremor.

[0170] Electrodes on hairy chests and loose skin or acute motion can cause the electrodes to fall off or result in poor contact with the patient. Motion artefact commonly has an irregular rhythm and an irregular morphology that introduces increased difficulty in recognising QRS complexes. By monitoring the impedances between the electrodes and the patient, a procedure has been developed by the present applicants that can detect conditions that could compromise the algorithm results. For example, a pad that is not making good contact with the patient interferes with ECG data acquisition. The impedance data in this case suddenly changes to very high values and back again. Similarly, when a pad comes off completely, the impedance data suddenly changes to infinite. The procedure of the present invention monitors the impedance data for this type of change and alerts patient to reattach pads, if necessary. Moreover, the motion artefacts which have QRS-like waveforms will confuse the primary decision of the location of the QRS complex in the signal, and will require subsequent processing to confirmed and correct the detected QRS series. For the diagnosis algorithm in ambulatory ECG signals, one of the crucial problems is the discrimination of the QRS complex from motion artefacts. In fact, for each component of the present AED method, a solution is provided to eliminate the disturbance of motion artefacts.

[0171] Heart rhythms have certain attributes that can be used to recognize cardiac arrhythmias. These attributes are quantified by the measurements extracted from AECG signals. They are classified into two categories:

statistical features;
morphological features.

[0172] Statistical features reveal the quantitative changes of heart beat and are used to characterize heart rate variability (HRV), while morphological features describe the morphological interrelation between rhythms. The varieties of morphologies are related to the rhythm waveforms and their implications with respect to cardiac behaviour. These relationships are clearly understood by cardiologists and can be represented by foundational attributes, such as extreme amplitude, slope and duration, etc.

[0173] The time that elapses between consecutive heart beats, and is defined as that between two P waves, is named atrial heart rate when the P wave describes the atrial depolarization of cardiac behaviour. Considering the difficulty of locating the P wave in ambulatory data, it is ventricular beat-to-beat interval that is practically used to define the heart beat interval, named ventricular heart rate. The QRS complex represents ventricular depolarization. Compared to the P wave, the R wave has cleaner amplitude and a better frequency resolution, thus making it the signal of choice to detect the ventricular heart rate. As the time interval between the P and R waves can be assumed and has been shown to be constant, the atrial heart rate can be considered to be equal to the ventricular heart rate. The time intervals of consecutive heart beats are thus named RR interval time series or RR intervals. At the moment, the sequence of successive RR intervals is the simplest, but the most important time series that can be used to characterize HRV, either in time or frequency domain. In ECG signals, defining the positions of two consecutive R waves as s (t) and s(t+1),

Petitioner Ex-1004, 0296

BNSDOCID: <EP_____1724684A1_I_>

t=1...N, where t is the time parameter of a series and N is the length of this series. The expression RR(t) = s(t) - s(t+1) is represented for RR intervals. A heart rate time series [min^{-1}] is calculated by the expression HR(t) = 60 *(F_{sample}/RR (t)). The expression HRavg = (1/N)*$\Sigma_{i=1}^{N}$HR(t) shows the mean heart rate. These expressions reveal a non-linear relation of ECG time series and the results indicate the statistical features of AECG.

[0174] The morphology attributes of AECG are used to classify the QRS complexes of ECG signals. The different phases of a cardiac cycle in ECG are represented by their corresponding wave components. The P, QRS and T waves are represented respectively as atrial depolarization, ventricular depolarization and ventricular repolarization, as shown in Figure 26. The length of the QRS is defined as the time interval between the onset of Q wave (Qi) and the end of S wave (St), and is designated LQRS. It represents the duration of ventricular depolarization, and is usually used to measure the changes occurring with the ventricular depolarization and repolarization period. However, due to poor SNR (Single-to-Noise Rate) and the polymorphic nature of the QRS complex in AECG signals, it is nearly impossible to locate precisely the Qi and St points. In the AED method of the present invention, the time interval between the end of Q wave (Qt) and the onset of S wave (Si) is used to estimate LQRS.

[0175] In ECG signals, defining the positions of Qt and Si points of each QRS complex as Qt(t) and Si (t), t=1...N, the expression LQRS(t) = 1000 *(F_{sample}/(S, (t)-Q_t(t)) indicates the LQRS time interval in millisecond. The other morphological attributes, such as the amplitude of R wave (VR), the two slopes of QRS (SP, SN) then are extracted by studying the QRS complex.

[0176] The AED system according to the present invention replaces the cardiologist in the diagnosis of ECG signals. The diagnosis of cardiologists is rooted in their knowledge gained through experience of electrocardiographs obtained from long-term studying. In contrast to human diagnosis, the AED system of the present invention uses a dedicated algorithm to process ECG signals collected by sensors, resulting in a rhythm classification and arrhythmia interpretation. The AED algorithm of the present invention is commonly divided into two tasks: a description task and a classification task. The description task transforms the ECG signal into features, i.e. the characteristics that are derived from ECG and are representative of the heart rhythms. The description task can involve several different but interrelated activities:

signal preprocessing to modify the data to correct deficiencies in the ECG signals due to the limitations of the sensor and the interferences of noise, and/or to prepare the conditioning signals for subsequent activities later in the description task or in the classification task;

feature extraction is the process of generating features to be used in the classification task. According to diagnosis techniques, the features can either be derived from time domain data directly, and/or are generated by performing manipulations and /or transformation on the data.

[0177] Feature extraction is an important aspect because the features made available for discrimination directly influence the efficiency of the classification task: features which truly discriminate among groups will assist in identification, while the lack of such features can impede the classification task from arriving at an accurate identification. The end result of the feature extraction task is a set of features, commonly called a feature vector, which constitutes a representation of the data. In the AED system of the present invention, two classes of features, i.e. the statistical features and the morphological features, are extracted from the AECG signal. The classification task uses a classifier to map a feature vector to a group. Such a mapping is specified either by hand, or induced from a training set in a training phase. Once formulated, the mapping can be used to assign identification to each unlabelled feature vector subsequently presented to the classifier. In the AED system, the rhythm classifier identifies rhythms based on the heart rate and the morphological attributes of QRS complex, and consequently interprets corresponding cardiac behaviours.

[0178] The signal features of AECG determine the complexity of the diagnosis techniques that are incumbent in accurate diagnosis. Compared to RECG and EG, AECG has more disturbances caused by a variety of noises. Due to their irregularity and QRS-like features, motion artefacts reduce the performance of ECG diagnosis. In the past twenty years, automated ECG diagnosis techniques have improved vastly. Based on various pattern recognition techniques and distinctive theoretical foundations, a large set of feature extraction techniques and rhythm classification techniques have been developed. However, because most of the actual AECG devices do not provide the ability to carry out real-time long-term diagnosis, most of the diagnostic algorithms focus only on the reliability and accuracy of diagnosis, in which the efficiency and real-time requirement cannot be studied correctly. Thus, one of the objects of the present invention is to develop an AED algorithm suitable for real-time continuous cardiac arrhythmia detection and diagnosis in sensor devices and on remote telemedicine platforms. In order to overcome the shortcomings of conventional ECG monitoring methods, the present invention provides a diagnosis system that can support long-term, i.e. from a few days to weeks, real-time ECG monitoring and allows daily patient movements in exterior environments. The AED method of the present invention is thus free of the limitations in time and space that are known in current implementations. In addition, in order to provide a cardiac diagnosis function for a sensor system, the algorithm is both simple and efficient, and can be implemented in VLSI or integrated into an embedded system.

[0179] The architecture used in the present invention is shown in Figure 26. It consists of three components:

Petitioner Ex-1004, 0297

BNSDOCID: <EP_____1724684A1_I_>

Data acquisition and signal conditioning;
Feature extraction;
Cardiac arrhythmias classification and interpretation.

[0180] The signal preprocessing and conditioning component acquires the ECG signal from sensors and removes unwanted noises and artefacts. The "clean" ECG signals are prepared for the feature extraction component. In the feature extraction component, the algorithm yields feature sets from the measurements of AECG signals that are used to discriminate heart rhythms. Finally, in the rhythm classification component, the classifier uses the feature sets to classify rhythms and to interpret cardiac arrhythmia events.

[0181] The electrocardiograph, as a non-invasive and easy-acquired cardiac test, is routinely used to diagnose heart disease and monitor cardiac behaviours. The features of the ECG signals, including the variety of heart beat and morphologies, and their implications with respect to cardiac activities are well understood by cardiologists. The automated pattern recognition techniques have been widely used in ECG diagnosis in recent years. A variety of diagnostic techniques based upon the theories of pattern recognition have been proposed, and a lot of automated ECG diagnosis systems have been developed practically. A heart beat, or a cardiac cycle, consists of several phases that include atrial depolarization, AV conduction, ventricular depolarization and ventricular repolarization. In a ECG signal waveform, a cardiac cycle is divided into three main waveform components: P wave, QRS complex and T wave. The characteristics of a cardiac cycle are classed into two categories: statistical features and morphological features. Insofar as the pattern recognition concept is concerned, a cardiac cycle is defined as an object; the features extracted from ECG signals are named a feature vector; a group is a pattern template with respect to one class of cardiac behaviour. The feature vector of each group has exclusive feature values. Through the experience of cardiologists, or through training rules obtained by studying a training set, a cardiac cycle can be classified into a group of cardiac status via feature vector template mapping.

[0182] According to the classification methods of pattern recognition, there are two fundamental approaches to implementing an AED system: statistical and structural. Each approach employs different techniques within the description and classification tasks which constitute a whole algorithm for the AED system. Statistical pattern recognition draws from established concepts in statistical decision theory to discriminate among signals from different groups based upon quantitative features of the signals. There is a wide variety of statistical techniques that can be used within the description task for feature extraction, ranging from simple descriptive statistics to complex transformations. The typical techniques include mean and standard deviation computations, Fourier transformations, wavelet transformations, etc. The quantitative features extracted from each object for statistical pattern recognition are organized into a fixed length feature vector where the implication of each feature is determined by its position within the vector. The collections of feature vectors generated by the description task are then passed to the classification task. Statistical techniques used as classifiers within the classification task include those based on similarity, e.g. template matching, nearest neighbor; probability, e.g. Bayes rules; boundaries, e.g. decision trees, neural networks; and clustering, e.g. k-means, hierarchical. Structural pattern recognition, sometimes referred to as syntactic pattern recognition due to its origins in formal language theory, relies on syntactic grammars to discriminate among ECG data from different groups based upon morphological interrelationship or interconnection. Structural features often referred to as primitives, represent the signal building blocks and their relationship. Morphologies used to extract structural features from the signal result in primitives, such as edges, curves, and regions. Structural feature extraction techniques include chain codes, piecewise-linear regressive and curve fitting. The classification task comes to an identification using parsing: the extracted structural features are identified as being representative of a particular group if they can be successfully parsed by a syntactic grammar. A summary of the differences between statistical and structural approaches to pattern recognition is shown in Figure 28.

[0183] The essential dissimilarities are twofold: (1) the description generated by the statistical approach is quantitative, while the structural approach produces a description composed of building blocks; and (2) the statistical approach discriminates based upon numeric differences among features from different groups, while grammars are used by the structural approach to define a "language" encompassing the acceptable configurations of primitives for each group.

[0184] The quantitative property of statistical pattern recognition makes it sensitive to numerical changes, hence statistical methods are suitable for discrimination among groups based on statistical features of ECG signals- i.e. heart rate. However, this approach is not adapted to discrimination among groups based on the morphological features of ECG signals, because it normally lacks an efficient method to reflect the morphological building blocks and their interrelationships. The morphological features of ECG signals can be described by the fundamental primitives of the structural approach. The syntactic grammars for ECG diagnosis are readily available based on the rules gained through the experience of cardiologists. However, due to the fundamental complications associated with the implementation of the description and classification tasks, the usefulness of the statistical pattern recognition approach is also limited. For the purposes of the present invention, the applicants have adopted the statistical pattern recognition technique, but morphological features are quantified according to a set of independent definitions and the rules of experience of cardiologists.

[0185] The statistical and structural approaches adopt different signal features because of their different theoretical

Petitioner Ex-1004, 0298

BNSDOCID: <EP_____1724684A1_I_>

foundations, and thus employ different diagnostic techniques to implement both the description and classification tasks. The approximate periodic property of ECG signals reflects the regularity of cardiac behaviours, which is the foundation of ECG diagnosis. In view of the signal features and theoretical foundations, the diagnostic techniques can be classified into several categories: time domain, frequency domain, time-frequency, wavelet, neural networks and chaotic modelling.

[0186] In cardiac contraction, heart electrical signals originate from the sinoatrial node, and then rapidly spread from atrial to ventricular via an A-V pathway. Hence cardiac electrical potentials have rapid changes and high magnitude. While in cardiac expansion, cardiac electrical potentials will rapidly return to the baseline potential and keep to this potential until the next heart beat. Observing the potential changes of ECG signals is thus the main measurement of time domain analysis. The changes of cardiac electrical potentials are quantified and used to extract the statistical features from ECG signals in the time domain. Fortunately, in contrast to other domain analyses, the statistical features in the time domain have been studied in detail. Time domain analysis is based on peak measurement, which evaluates each event of a heart beat in an ECG signal. The evaluation methods comprise feature extraction (pattern) and template matching (recognition). The template in time domain analysis can either be defined as the sample set of a waveform complex, or the particular extracted statistical features. The common statistical features of the ECG signals include extreme amplitude, an optional extreme slope/curvature, and the duration of QRS, etc, which can be obtained by detecting the waveform of the complex. By tracking the change of ECG time series, the template matching method requires huge computation to obtain the correlation coefficient between signal and template. In one known method, the template matching algorithm is expressed as follows, and is designated correlation waveform analysis (CWA).

$$\rho = \frac{\sum_{i=1}^{N} ((t_i - \bar{t})(s_i - \bar{s}))}{\sqrt{(\sum_{i=1}^{N} (t_i - \bar{t})^2 \sum_{i=1}^{N} (s_i - \bar{s})^2)}}$$

Where :

ρ = the correlation coefficient
N = the number of template points
t_i = the template sample point
s_i = the signal sample point under analysis
$\bar{t}$ = the average value of the template samples, and
$\bar{s}$ =the average value of the signal samples.

[0187] The correlation coefficient falls within a range $-1 < \rho < +1$, where +1 indicates a perfectly matched signal and template. Applying to a data set with the length k, the CWA has a computational complexity of $O(k*(n^4+n^2+1))$. A simplified implementation of the CWA is provided to decrease computation overhead. Since the ECG signals in the expansion time have electric amplitudes nearly equal to the zero isoelectric baseline, it has no contribution to recognition of rhythm. Therefore, only the ECG signals in the contraction time are applied to perform template matching in the simplified CWA. For a healthy adult, the heart rate (HR) is around 60bmp to 100bmp under normal conditions and the length of QRS complex is no more than 200ms, which means that there is only 20% to 33.3% (0.2*HR/60) computation cost for this simplified CWA compared to those of classical CWA. This simplified implementation needs reliable QRS position information before effecting template matching. The position information can be obtained by analysing the morphological attributes of QRS complex, based on the mean and standard deviation computations. The relative formulation is well known and doesn't require any complex calculation. When adopting a statistical approach to define morphological features of a QRS complex and to describe a pattern template in time domain analysis, the computational complexity can be markedly decreased to O(n). A heart rhythm can be classified basing on the predefining syntax analysis of the statistical features. From this point on, the statistical features indicate the original statistical features and the morphological features defined by the statistical approach. In time domain analysis, the statistical features are directly extracted from original ECG signals, which include the peak-to-peak amplitude, the waveform slope, the length of the QRS complex, the sequence of slope patterns, and the sequence of amplitude threshold intercross points. Time domain techniques have the advantage of relatively easy implementation. They have thus been widely applied in real-time AED systems. The main drawback of time domain analysis is the limitations of its anti-noise ability. The ECG signal, especially in AECG, is a faint electrical signal of cardiac activity which is often diminished or modified by a variety of noises caused by physical and technical effects. It is thus necessary to perform signal preprocessing and conditioning to get better

Petitioner Ex-1004, 0299

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SNR signal for the subsequent feature extraction and rhythm classification tasks.

[0188] The ECG signal has statistical features in the frequency domain that consists of a variety of spectral components. The different waveforms of ECG signal, i.e. P wave, QRS complex, and T wave, have their particular spectra that are respectively represented as the atrial frequency and the ventricular frequency. For a healthy adult, the frequencies of atrial and ventricular are approximately equivalents that are equal to 1 to 1.7 Hz. Because the P and T wave are often undiscernible from artefacts in AECG, the practical cardiac frequency is represented by the ventricular frequency (QRS). The interferences caused by noise are unavoidable in AECG. The different origins of interference have different frequency components. For example, the frequency of electrical interference is 50 Hz (France) or 60 Hz (America), the frequency of baseline drift is normally less than 0.1 Hz, and muscle tremor has a frequency of more than 40Hz. Therefore, and in accordance with the present invention, a band-pass filter which has the frequency range of 0.1 to 40 Hz is used to remove the spectral components of noise. The theory of frequency domain analysis is based on the assumption of signal stationarity. The ECG signal is a discrete-time random process that is thus assumed to have wide sense stationarity. The power spectral density (PSD) of a wide sense stationary random process is the Fourier transformation of the autocorrelation function. Defining x(t) as a ECG signal, where t = 0,1,2,... the autocorrelation function is defined by $r(t_1, t_2) = E[x(t_1)x(t_2)]$. For a wide sense stationary process, the mean is constant and the autocorrelation depends only on the time difference $\tau = t_1 - t_2$, so that $r(t_1,t_2) = r(\tau)$, $r(\tau)=E[x(t+)\times(t)]$. The PSD is thus denoted by :

$$S(\omega)=\sum_k r(k)e^{-jwk} \quad \text{(Fourier)} \qquad S(z)=\sum_k r(k)z^{-k} \quad \text{(Z)}$$

[0189] Frequency domain techniques aim to analyse the frequency components of ECG and their relative power spectral density. Applying to a data set of length k, Fourier transform has a computational complexity of O(klogk). The assumption of frequency domain analysis is based on the ECG signal having wide sense stationarity. In practise, however, because of its wide origin and the nature of its information, the ECG signal can hardly be regarded as a wide sense stationary process under any condition. It is often necessary to divide the ECG recording into shorter stationary sequences. The identification of non-stationarity which includes transient phenomena, i.e. spikes and slow variance, i.e. trends, is thus more difficult. Frequency domain analysis is often proposed for the classification of rhythms, but little success has been solidly demonstrated for the recognition of ventricular tachycardia (VT). Examination of longer segments of 1000ms to 15,000ms yields the same phenomenon because the power presented in small visually distinctive high frequency notches is insignificant compared to the remainder of the signal, and the changes in polarity of the waveform, easily recognized in the time domain, are simply not revealed by frequency analysis.

[0190] Wavelet analysis is a new and promising technique for analysing ECG signal. Like Fourier analysis consists of breaking up a signal into sine waves of various frequencies, similarly, wavelet analysis is the breaking up of a signal into shifted and scaled versions of the original (or mother) wavelet. The continuous wavelet transform (CWT) is defined for a signal (x(t)) as the sum over all time of the signal multiplied by scaled, shifted versions of the wavelet function ($\Psi_{a,b}(t)$) :

$$C(a,b)=\int_{-inf}^{+inf} x(t)\,psi_{(a,b)}(t)\,dt$$

[0191] Where a and b is the scaling and shifting factor respectively. The results of the CWT are many wavelet coefficients C(a, b), which are a function of scale and position. Wavelet functions are located in time by the shift factor b, while the scale factor a indicates the width of the wavelet. Actually, there is a correspondence between wavelet scales and frequency as revealed by wavelet analysis:

Low scale a => Compressed wavelet => Rapidly changing details => High frequency w.
High scale a => Stretched wavelet => Slowly changing, coarse features => Low frequency w.

[0192] In order to improve the efficiency of wavelet analysis, discrete wavelet transforms (DWT) are introduced. It determines scales and positions based on powers of two so called dyadic scales and positions. The DWT represents a signal (x[n]) defined at n sequential points at n points in times as a linear combination of a family of wavelets ($\psi_{j,k}[n]$) :

Petitioner Ex-1004, 0300

BNSDOCID: <EP_____1724684A1_I_>

$$x[n]=\sum_{j,k\in Z} C_{jk}\psi_{j,k}[n], a=2^j, b=ka, j,k\in Z$$

[0193] Where $C_{j,k}$ is the coefficient of the wavelet function $\psi_{j,k}[n]$. The DWT produces a family of hierarchically organized decompositions termed approximation and detail respectively. The approximations are the high-scale, low-frequency components of the signal. The details are the low-scale, high-frequency components. The wavelet decomposition tree shows in Figure 29a (order=3). The cA_x are the approximation components of ECG, and cD_x are the details components (see Figure 29b).

[0194] Since wavelets have scale aspects and time aspects, wavelet analysis can reveal the frequency and time characteristics of ECG signals. The motivation for applying the wavelet transform to the analysis of ECG signal lies mainly in the monitoring of non-stationary signals and the long-term evolution of the power spectrum, such as the removal of baseline wandering, ECG de-noising and QRS complex detection. The capacity of wavelet decomposition lies in the removal of undesired components, essentially noise, from the signal by a thresholding operation. A new de-noising technique has also been described which uses a low pass filter (LPF) named Daubechies filter to smooth waveform transform coefficients instead of the thresholding of Donoho's method. There is also a rhythm classification technique for the discrimination of ventricular tachycardia from supraventricular tachycardia (SVT) based on wavelet coefficients. Applying to a data set of length k, the wavelet transform has a computational complexity of O(klogk). The statistical features of wavelet transform, such as wavelet coefficients and power spectrum, describe the local "frequency" and "morphology" properties of a non-stationary time series in the neighbourhood of each time point. The wavelet transformation employs basis waveforms generated by scaling and translating a mother wavelet, thereby enabling the technique to extract features that are both global and local within a time series. The basis waveforms, however, are derived from a single morphology as defined by the mother wavelet. The main advantage of wavelet analysis is that there is no need for any pre-processing tool for ECG fluid point detection, since the wavelet algorithms can work without any additional information intervention. However, wavelet decomposition and reconstruction of the approximation must be performed more than once, with the result that computational overhead is significantly higher in comparison to other methods based mainly on polynomial interpolation.

[0195] Time-frequency analysis has emerged for monitoring the spectral properties of the signal as time elapses, especially, when "long" time periods are under consideration. The temporal location of the spectral components may give more information than one single spectrum. Time-frequency spectral analysis is an advanced spectral analysis method which can generate multiple spectra over time instead of a single spectrum for the whole data segment, as is the case with the FFT (Fast Fourier Transform Algorithm) method. Furthermore, time-frequency analysis based on the so called "quadratic Time-Frequency Distribution (TFD)" can provide good resolution in both time and frequency. As an example of quadratic TFDs, the Wigner distribution (WD) is given:

$$Wx(t,w)=\int x(t+\nu)x*(t-\nu)\exp(-iw\tau)d\tau, \nu=\tau/2$$

[0196] The Smoothed Pseudo Wigner-Ville Distribution (SPWVD) was used in other work to analyse the spectral components of heart rate variability (HRV) during anesthesia. The discrete Wigner distribution (DWD) was applied to a non-stationary time series, and a modified algorithm was proposed for auto- and cross-DWD. The cross-terms were suppressed by means of a smoothing data window and a Gauss frequency window. This approach has been employed further in a study of the influence of respiration on heart rate, showing its ability to estimate spectral changes in non-stationary RR interval time series.

[0197] Classification of the electrocardiogram using neural networks has become a widely used method in recent years.

[0198] The efficiency of these classifiers depends upon a number of factors including extracted features, system architecture and network training. The statistical features must be carefully selected from feature vectors. The features that are crucial for identification rhythm will be kept and then the others will be excluded from feature vectors. A well-chosen training algorithm, results in an ANN which is capable of generating a non-linear mapping function with the capability of representing relationships between given ECG features and cardiac disorders. In designing an ANN, the key factors with regard to the system architecture include: the appropriate number of hidden layers, the nodes numbers of each layer, the activation function and its configuration. Golam Hosseini et al presented an extraction technique of the features for ANN-based ECG classifiers to enhance the performance of automatic detection and classification of cardiac arrhythmias. Chris. D. Nugent et al developed prediction models, based on Neural Networks and Genetic Pro-

Petitioner Ex-1004, 0301

BNSDOCID: <EP_____1724684A1_I_>

gramming respectively, to indicate the point at which training should stop for Neural Network based Electrocardiogram classifiers in order to ensure maximum generalization. The results show that both approaches provide close fits to the training data. Farrugia et al designed an artificial neural network classifier to recognize tachycardias from the ventricular intra-cardiac electrogram. It performed classification on a set of easily extracted features that characterize waveform morphology and rate.

[0199] Chaos theory is a new branch that is applicable to the modelling of non-linear dynamical systems. The most recent discussions have applied chaotic modelling to non-stationary time series, in particular the analysis of ECG. Cohen et al studied the Poincaré equation :

$$x(t) = Ax(t-1)(1-x(t-1)),\ 2 \le A \le 4$$

and some of its solutions as an example of a chaotic system. The first order difference plot was introduced by presenting x(t+1) vs. x(t), and given as a measure of the degree of chaos in a system. In Huikuri et al., an ellipse was fitted to the plot and the centroid of this ellipse and the lengths of both axes were determined. The second-order difference, obtained by presenting (x(t+2)- x(t+1)) vs. (x(t+1) - x(t)), would show the degree of theoretical chaos. A quantitative measure of the degree of variability in a second-order difference plot, the measure of central tendency (CTM), takes the form :

$$CTM = \frac{\sum_{i=1}^{N-2} \delta(d(t))}{N-2},$$

$$\delta(d(t)) = \begin{cases} 1, & if \sqrt{(x(t+2)-(x(t+1))^2 + (x(t+1))-x(t))^2} < r \\ 0, & otherwise \end{cases}$$

[0200] Where N is total number of time series values and r is the radius of the central area. Several popular methods exist for studying chaos in cardiovascular time series, but the indices proposed for measuring it should be applied cautiously and results obtained should be interpreted with care. The basic condition is the need for large amounts of data which make these methods not well-suitable for real-time analysis. The problem also lies in discriminating a chaotic system from a random one, and calculation of the correlation dimension.

[0201] The objective of developing a real-time embedded ECG diagnosis system determines that the AED methods according to the invention must be both simple and efficient. A simple algorithm means two basic things: the first is to provide easy implementation of the algorithm, which ought to have a compact system architecture and thus capable of being integrated into microprocessors or be carried out by VLSI; the second is to ensure low computational overhead of the algorithm, so that it only requires minimal resources and power consumption. An efficient algorithm will enable accuracy and reliability of an AED system that is the crucial to a cardiac surveillance system. Based on the considerations mentioned above, the applicants' method employs techniques of time domain analysis that ensure simplification of the method. In order to improve system efficiency, some particular techniques are adopted that are presented hereafter.

[0202] ECG features, statistical features and morphological features defined by statistical methods, are extracted from ambulatory ECG in a features extraction module of the AED method of the invention. There are three main phases in this module: first, a QRS detection procedure locates the positions of QRS complexes and then obtains the statistical features of ECG signals, i.e. heart rate. Consequently, the QRS extraction procedure analyses the morphological attributes of the QRS complex and extracts the associated morphological characteristics, such as the peaks of the R wave, slopes and duration of QRS complex. Finally, the QRS correction procedure identifies the detected QRS complexes and corrects fault detections based on the standard feature vector. The two main problems of ambulatory ECG processing, i.e. the interferences caused by motion artefacts and the unreliability of the QRS complex, need to be handled specially in the features extraction module.

[0203] Due to the non-stationary and easily-disturbed natures of ambulatory ECG data, ECG acquisitions must be de-noised before further making detection. Most artefacts, such as baseline shift, electrical noise and muscle tremor interference, can be effectively eliminated or reduced by choosing suitable filters.

[0204] There are three ECG time series used in the method according to the invention that are represented as R(t), D(t) and RC(t) respectively. R(t) represents the raw ECG acquisitions acquired directly from a wireless ECG sensor (WES) via electrodes, which is generally contaminated by various noises. D(t) indicates the differential signal based on

Petitioner Ex-1004, 0302

BNSDOCID: <EP_____1724684A1_I_>

R (t). It represents the deviation change between two consecutive samples and is expressed as D(t) = R*(t) R*(t-1), R*(t) = FILTER(R(t)), where FILTER is the operation of a set of de-noising filters. RC(t) is the reconstruction signal based on the differential signal D(t) and its expression is RC(t) = RC(t-1)+SMOOTH(D(t)), where SMOOTH is the operation of a set of simple smoothing and amplifying filters. The signal preprocessing module is shown in Figure 30, and describes the relationships of the three ECG time series.

[0205] In view of the spectral components of AECG, the high-frequency components of noise, i.e. electrical noise and the interference caused by muscle tremor, can be effectively removed by operation of a low-pass filter and/or notch filter. The electrical noises which have the frequency of 50 Hz (France) or 60 Hz (America) are eliminated by a notch filter, and the interferences caused by muscle tremor are removed by a low-pass filter with a cut-off frequency of 40 Hz.

[0206] It should be noted that it is possible that the frequency spectrum of high-frequency noises overlaps the ECG frequency. From the point of view of wavelet analysis, the high-frequency components reflect the details of signal, and the low-frequency components manifest the approximations of signal. The low-frequency component can be used to reveal the features and trends of ECG signals. In the present application therefore, the high-frequency components of signal are removed. The AECG often overlaps with the low-frequency components of noises, especially the motion artefacts and interferences due to baseline wandering. Because the features that are used to classify rhythm are extracted from low-frequency components of ECG signals, low-frequency interferences have serious repercussions on the performance of the diagnostic algorithm. In practise, a high-pass filter with a cut-off frequency of less than 0.1 Hz simply eliminates very low frequency components of ECG signal, but cannot sufficiently reduce the influences of baseline wandering and motion artefacts . The solutions used in the present invention to reduce low-frequency noise in our algorithm are twofold:

differential series D(t) are adopted to locate QRS complexes and estimate heart rate;
piecewise segments of RC(t) series are used to extract morphological features.

[0207] Differential operation effectively removes the interference of baseline drift of ECG series, but distorts the morphologies of the ECG signals. The differential series D(t) have a stable baseline reference and distinctive magnitude of amplitudes of electrical , potentials in QRS length, shown in Figure 31 b. Once these signals are de-noise filtered, smoothed and amplified, the reconstruction signal RC(t) is cleaner and has a better SNR than R(t), as shown when comparing the raw signal R(t) in Figure 31 a with that of the filtered and reconstructed signal in Figure 31 c. The piecewise segment in RC(t) has a length of 200ms and the onset of the segment is determined by each QRS position obtained in the D(t) series. The influences of low-frequency noise can thus be effectively reduced in a segment with a length of only 200 ms.

[0208] Conventional filter operations of ECG series, e.g. notch filter, low-pass filter, and high-pass filter, effectively remove or reduce most interference. However, motion artefacts, being both irregular in their occurrence and morphological attributes, can not be eliminated by these kinds of filters, see for example in Figure 33a, and 33b. These artefacts can cause significant problems in QRS detection when QRS-like artefacts are encountered, with the result that it is necessary to provide a method for eliminating motion artefacts in order to guarantee the accuracy of diagnosis. One of the solutions to eliminate motion artefacts is wavelet analysis. It removes artefacts by decomposing and then recomposing ambulatory signals. Multi-order wavelet transformation can effectively decompose high-and low-frequency components of ECG signals. However, the high-orders of wavelet transformation will cause serious waveform distortion, and bring huge computational complexity as well as huge resource consumption. Consequently, wavelet analysis is obviously not fit for a real-time embedded AED system. In the method of the present invention, an adaptive filter (AT) is used to reduce motion artefacts. The resultant signal series, named A(t) or Aecg(t), are generated by performing AT operation for the original ECG series R(t). The expression of AT is

$$\begin{cases} Aecg(0)=R(0) \\ Aecg(t)=\alpha * Aecg(t-1)+(1-\alpha)R(t) \end{cases} \quad 0 < \alpha < 1,\ t=1\cdots N \ ,$$

where α is the balance coefficient of AT, which is an important factor in influencing the performance of AT. If the value of α is increased, the previous estimated value Aecg(t-1) then gives greater proportionality in the estimation of Aecg(t). The result of this is that the obtained A(t) is stable and does not reveal changes in the ECG signals. In contrast, if the value of α is reduced, the current original value R(t) will then have greater proportionality, and the obtained A(t) will be more dynamic and adaptive to the changes in ECG signals. Thus, the value of α is carefully selected to make A(t) both stable and adaptive to the changes of R(t). The value of α is relative to the sample frequency of ECG signals. In the

Petitioner Ex-1004, 0303

BNSDOCID: <EP_____1724684A1_I_>

STAR system of the present invention, the sample frequency is set to 500 Hz to obtain good signal resolution. The waveforms of the QRS complex with varying adaptive filter coefficient α are shown in Figure 32. The coarse solid line represents the original complex R(t). If $\alpha < 0.5$, the Aecg(t) series has a curve that almost matches the original R(t), and so at this coefficient value AT does not reduce motion artefacts. The thin solid line represents the QRS complex with α =0.75, which has an approximate waveform with R(t). The dashed line represents the QRS complex with α =0.98, in which the motion artefacts are removed by AT, but the waveform is excessively smoothed and thus insensitive to the changes of ECG. The dash-dot line represents the QRS complex with α = 0.95, in which not only motion artefacts are removed by AT, but also the changes of complex can be monitored. One can thus see from the above that the value of the adaptive filter coefficient α can be chosen to be comprised between about 0.5 to about 0.98, but is preferably chosen to comprise a value of about 0.75 to about 0.95, and more preferably is selected to be 0.95.

[0209] A comparison of various filter techniques and adaptive filtering is shown in Figure 32, which illustrates an ECG signal series with different filters. Signal (a) is the original ECG signal which is polluted by noise. Signal (b) represents the reconstructed series RC(t) mentioned above. The filters adopted in the "FILTER" operation include a notch filter, a low-pass filter and a high-pass filter. Figure 32b clearly shows that the RC(t) signal still contains interference generally caused by baseline drift and motion artefacts. Signal (c) of Figure 32 is the adaptive filter signal Aecg(t) when the original signal R(t) is directly filtered by AT, and which has markedly better signal quality than RC(t). Signal (d) is the reconstructed signal RC*(t) based on the adaptive filter signal Aecg(t). In contrast to initially reconstructed signal RC(t), signal RC*(t) shows a much improved signal quality and better signal to noise ration (SNR), in which motion artefacts are effectively eliminated. Another advantage of the AT used in the present invention is that it is simple and compact, and therefore enables AT to be implemented by VLSI or directly integrated into an embedded system.

[0210] QRS detection is a crucial component of the AED system. In the present method of the invention, QRS detection is the basic foundation stone to the later feature extraction module, the accuracy of the QRS detection having a direct bearing on performance of the feature extraction method. Over the past twenty years or so, much research has been directed to the reliability of QRS detection from ambulatory ECG signals. Some algorithms use information from a frequency domain or a wavelet description of the signals, while others make use of the information derived directly from the ECG signals' time domain description. In order to reduce the overhead of the ECG signal analysis method, the procedure of the preset invention detects QRS complexes directly from ambulatory ECG time domain signals, as this results in lower computational costs than detection of a frequency domain or wavelet analysis. In the present invention, the applicants have come up with a new class of optimum QRS detector which efficiently cope with noise, artefacts and variability of ECG morphology by exploiting a self-adaptive threshold method, hereafter abbreviated to SAT, and a particular state transition recognition procedure, hereafter abbreviated to STR. The SAT method is used to estimate the peaks of ECG sub-segments and the means of contextual thresholds, thereby allowing for effective evaluation to obtain the optimum thresholds in segment space. The STR procedure traces the changes of waveform of signal series and identifies QRS complexes based on the optimum thresholds and the particular rules of state transition.

[0211] A short-term redundant data, for example a segment of 5 seconds of ECG data, is important in QRS detection. Firstly, the short-term segment enables the contextual correlative analysis of complexes, and reduces the interferences of baseline drift. In view of the low-frequency nature of baseline drift, a short-term segment has fewer disturbances caused by baseline wandering than an equivalent long-term signal. The redundant data enable the QRS detector to identify the current QRS complex by comparing with the preceding and following QRS complexes. This property is very useful when removing motion artefacts. Furthermore, in view of the unpredictability and variability of network quality, appropriate data redundancy is one important element for the data retransmission mechanism and reliable network communication. Having due regard to algorithm performance, network reliability and resource costs, the segment length was defined in the present invention as 5 seconds. Since in the STAR device according to the present invention the sampling frequency of is 500 Hz, any given 5s segment will have 2500 sample points. This data segment is forms a diagnostic unit of the QRS detector, and is called a Diagnostic Segment Window, hereafter abbreviated to DSW. As is apparent from the baseline stability shown in Figure 34, the differential series D(t), which represents the changes of the series A(t), is used to locate QRS complexes.

[0212] The waveform of the QRS complex in AECG presents rapid fluctuations and high amplitudes of electrical potential, these features being correctly represented by the differential series D(t). The signals of the QRS complex have higher absolute amplitudes compared to the signals of other phases in a cardiac cycle of D(t) series, see Figure 34. The schema of QRS detection is to carry out a search for the optimum pair-peak for each QRS complex, i.e. the positive and negative peaks of a cardiac cycle. In a DSW, there are generally multiple pair-peaks because several heart beats will occur over a period of five seconds. These pair-peaks make up a pair-peak group in a DSW. Based on the pair-threshold obtained from the pair-peak group of a DSW, the STR procedure described hereinafter is then able to locate the QRS complexes. The absolute amplitude of each peak is generally greater than the associated absolute threshold in D(t). Furthermore, because the offset of location between the series D(t) and A(t) is a constant, we can thus obtain the positions of QRS complexes in A(t) by locating the complexes of D(t).

[0213] The SAT method aims to determine the optimum pair-threshold, which is estimated from two elements: the

Petitioner Ex-1004, 0304

BNSDOCID: <EP_____1724684A1_I_>

mean of the pair-peak group, both positive and negative, of a DSW and the pair-threshold of the previous DSW. The pair-threshold results from the means of the negative and positive pair-peaks group of a DSW. In order to accurately estimate these pair-peaks, the diagnostic segment window is divided into 5 sub-segments each having a period of one second. It is based on the fact that the average heart rate of a healthy adult is 60 bmp to 100bmp, thus each sub-segment usually contains one heart beat. Since the differential signals of the QRS complex have the maximum absolute amplitudes in a cardiac cycle, a pair-peak can thus represent a QRS complex in the sub-segment and then be used to estimate the thresholds. Furthermore, the shorter the length of the sub-segment, the less interference of baseline drift the sub-segment it will show. A sub-segment with a length of one second can thus be regarded as a stationary series. In order to improve the reliability of the pair-threshold, the SAT method is used to handle some abnormal case scenarii. In general, these abnormal peaks are caused by uncontrollable noise, particularly interference due to motion artefacts, which are typically representative of transient spikes. This class of artefacts, occurring randomly and transiently, has more acute changes of waveform and higher amplitudes than normal QRS complexes. In this case, the pair-peak obtained in a sub-segment is an artefact which has very high amplitude. In a case where the heart beat of patient is less than 60 bmp, it is possible that no heart beat will be present in a given sub-segment. In this case, the SAT method will extract a pseudo pair-peak at this sub-segment. This pseudo pair-peak thus has very low amplitudes, which are close to the value of the baseline. The abnormal pair-peaks can be removed from the pair-peaks group by comparing their amplitudes with others before estimating the mean amplitudes. Because of the regularity of ECG rhythms and the correlation of ECG signals, the previous pair-threshold is used to evaluate and adapt the current pair-threshold. For example, where the electrode pad has completely detached from the person under surveillance, signal amplitudes will change suddenly and then come back to the baseline potential, and consequently the estimated pair-threshold will be significantly different to the previous pair-threshold. Thus, the correlation evaluation procedure of the present invention is used to manage abnormal cases by analysing the differences in thresholds. The pair-threshold, defined as T, is expressed as $T = \rho * M$, where M represents the mean of the pair-peak group of a DSW, and ρ is the threshold coefficient. The threshold coefficient ρ is thus an important factor that influences accuracy of the estimation procedure. Empirical studies by the applicants have led to the selection of a value of 0.45 as the optimal threshold coefficient. The estimation steps of the pair-threshold are described below :

Detect and record five pair-peaks from the relative sub-segments in current DSW;
Calculate the relative mean of positive and negative peaks, and then exclude the peaks that are too far from the means;
Repeat step 2 for the remaining pair-peaks;
Verify current pair-threshold with the previous estimated pair-threshold

[0214] With regard to the morphological properties of a QRS complex in a D(t) series, the complexes are categorized into two groups: positive and negative. The different states are thus defined to outline the phases of a QRS complex in D(t). Figure 36 shows the positive states of a QRS, S2 to S9, and the correspondingly identified S20 to S29 represent negative states. An adaptive and self-corrected procedure, named STR (State Transition Recognition), has been developed by the applicants to automatically track the changes of signal series, to correct error detection and to record detected complexes. The state transitions are based on three basic reference lines: baseline, positive threshold and negative threshold. The state transition diagram, shown in Figure 36, illustrates the transition rules of QRS complex. A data structure named ECG_COMPLEX has been defined by the applicants to record the information of a QRS complex, as illustrated below. It includes the type of QRS complex and the positions of key points, i.e. onset point, peaks and end point. The STR procedure will generate a QRS complex result list, in which each member is a detected QRS complex.

ECG_COMPLEX

```
Struct ECG_COMPLEX
{
int tstart;
int tpic1;
int vpic1;
int tpic2;
int vpic2;
int tstop;
int etype;
int pattern[MLQRS];
}
```


Petitioner Ex-1004, 0305

BNSDOCID: <EP_____1724684A1_I_>

[0215] The objective of a feature extraction procedure is to obtain the measurements of features information from a AECG. The ECG features, including statistical features and morphological features, are used to classify heart rhythms and interpret cardiac arrhythmias. Since the QRS detection procedure according to the invention has located the QRS complexes, the statistical features, i.e. heart rate or RR interval, can be obtained by calculating the time distance between two consecutive complexes. The main problem of the QRS extraction procedure is thus to extract quantified morphological features from the complex. The present invention provides a Geometric Analysis Method, hereafter abbreviated to GAM, to simulate and quantify morphological features.

[0216] GAM extracts morphological features from an ambulatory ECG de-noised series RC(t). Due to the constant offset distance between RC(t) and the differential series D(t), the positions of complexes in RC(t) can be determined according to the complexes detected in D(t). GAM analyses the morphology of each QRS complex in a sub-segment of 300ms, which is equivalent to 150 samples in STAR device of the present invention, and which sub-segment begins from the onset point of the complex. There are two advantages to building a complex sub-segment: the first is to reduce interference from noise, especially baseline drift; the second is to exclude the influence of the preceding and folowing complexes. The period of 300ms is an optimum length which is longer than the duration of the QRS, but shorter than the duration of the occurrence of the next complex. Hence, the artefacts detected in the QRS detection procedure can be removed by analysing the duration of the QRS and the RR length.

[0217] The baseline and fiducial peaks are the foundation of GAM. The onset point of a QRS complex is supposed to the zero electrical baseline point as it represents the onset position of the changes in QRS detection procedure. GAM provides a policy to detect changes in waveform and to estimate the baseline point and fiducial peaks. The policy is composed of the following three phases. The changes in a complex are caused by either ventricular depolarization or artefacts. Changes that are too small or rapid and that are generally caused by noise, i.e. muscle tremor or motion artefacts, can be removed from records by comparing their amplitude and their length of time with a normal QRS complex. The evaluation steps of the baseline and peaks of complex are shown as follows, where Tmax and Tmin indicate the positions of maximum and minimum peaks, and Vmax and Vmin are the amplitudes of these two peaks :

Trace the changes of sub-segment data and record peaks information. The peak estimation criterion is a continuous three incremental samples and subsequently a continuous three decremental samples, and vice versa.
Estimate Tmax and Tmin peaks and calculate the slope of each peak. The R wave fiducial point will be detected from the two peaks. The slope reflects the gradient of the complex.
Remove the peaks which have too small/large slopes and too dull/steep changes of amplitudes between two consecutive peaks .These kind of peaks are generally caused by noise.
Repea steps 2 and 3 in the remaining peaks set and then obtain more accurate Tmax and Tmin.

[0218] By studying the morphologies of the V1 to V6 ECG leads and the morphologies of ventricular arrhythmias, QRS complexes of cardiac rhythms can be categorized into 6 classes:

Positive single-peak;
Negative single-peak;
Positive multi-peaks;
Negative multi-peaks;
Positive-negative peaks; and
Negative-positive peaks.

[0219] GAM provides a sub-procedure to do this classification task based on the set of peaks obtained in the previous phase. The operations of the classification sub-procedure are shown below:

Verify the Tmax and Tmin peaks. The criterion is that the Tmax and Tmin peaks must have rather high absolute amplitude and absolute slope compared to those of other peaks and the Tmax and Tmin peaks of a previous QRS complex are also used to verify these two peaks. The aim of this step is to exclude the pseudo-Tmax/Tmin caused by noise.
Pre-estimate the type of complex (rhythm). The criterion is to compare the absolute amplitudes of Tmax and Tmin. If Vmax >> Vmin, set class 1; else if Vmax << Vmin, set class 2; else, continue to next step.
Estimate the type of complex (rhythm). For class 1 or 2, search for the second peak that has similar peak characteristics to the Tmax (1) or Tmin (2). If one is found, adjust class to class 3 or class 4, the second peak is then marked as Tmax2 or Tmin2. For other situations, if Tmax >= Tmin, set class to class 5, else set class to class 6. In classes 3 to 6, there are two peaks to indicate the peak features of a complex. The two values named Tpeak1 and Tpeak2 are thus defined to mark the positions of two fiducial peaks, where Tpeak1 is set to less than Tpeak2. The R peak is one of two fiducial peaks, which is estimated according to the class of morphology and the contextual

Petitioner Ex-1004, 0306

BNSDOCID: <EP_____1724684A1_I_>

complexes.
The evaluation criteria for the peaks of Tpeak1 and Tpeak2 are shown below. If necessary, the baseline position of the current QRS complex can be adjusted according to Tpeak1 and its previous peak. The characteristic VR (Amplitude of R wave) of a complex can thus be determined in this phase.

Estimation criteria for Tpeak1 and Tpeak2 :

```
if class 1 or 2 then
        TR=Tmax/Tmin;
        Tpeak1=TR, Tpeak2=TR;
else if class 3 then
        TR=Tmax;
        Tpeak1=MIN(Tmax, Tmax2), Tpeak2= MAX(Tmax, Tmax2);
else if class 4 then
        TR=Tmin;
        Tpeak1=MIN(Tmin, Tmin2), Tpeak2= MAX(Tmin, Tmin2);
else if class 5 then
        if (Vmax>Vmin) TR=Tmax; else TR= Tmin;
        Tpeak1=Tmax, Tpeak2=Tmin;
else if class 6 then
        if (Vmax>Vmin) TR=Tmax; else TR= Tmin;
        Tpeak1=Tmin, Tpeak2=Tmax.
end if
```

[0220] The triangular-like or triangular-component morphology of a QRS complex makes it possible to extract features by a geometric analysis method (GAM). This method consumes relatively little resources, which means that it is ideally suited to embedded real-time diagnostic applications. Another advantage of GAM is its prediction ability, making it equally suited to estimating key sample points of a QRS complex under noisy conditions.

[0221] The key sample points of a complex include the R wave peak, the end point of Q wave (Qt) and the onset point of S wave (S_i). The R wave peak is obtained from Tpeak1 or Tpeak2 as described above and comprises a single peak or a multitude of peaks. The measurement and the detection phases of the Qt and S_i points are illustrated as follows:

Define two-level thresholds for left and right sides of the R wave in a QRS complex respectively. The left two-level thresholds are defined as LH=1/4*Vpeak1,
LL=3/4*Vpeak1; correspondingly, the right-level thresholds are RH=1/4*Vpeak2, RL=3/4*Vpeak2.
Calculate the intersections between threshold values and the complex signal. Generally, there are 4 intersections which are used to estimate the approach lines of left and right side waveforms. The slopes of two approach lines represent two other characteristics of the complex: SP (Positive Slope) and SN (Negative Slope).
Obtain the length of the QRS (LQRS), which is the distance between two intersections on the baseline and two approach lines.

[0222] Once these steps have been completed, the morphological features of complex have been extracted from a ambulatory ECG. However, due to the non-stationary and easily disturbed features of a ambulatory ECG, the results are preferably evaluated further before interpretation of cardiac arrhythmia.

[0223] The most obvious error of ECG signals is incorrect electrode placement on the chest of a person under surveillance. Since QRS complexes vary with the position of the electrodes, each ECG lead views the heart at a unique angle in a unique electrode placement. The method of the invention interprets cardiac arrhythmia on the basis of the morphological features of each ECG lead, and so correct electrode placement is important in order to be able to accurately classify rhythms. In one preferred embodiment of the invention, and before starting the diagnostic algorithm, the system should indicate to the person under surveillance to attach the electrodes in the correct positions.

[0224] A further problem to be solved is the accurate and effective detection and extraction of a QRS complex from an ECG series contaminated by artefacts. The applicants of the present invention have therefore developed QRS correction methods. Since all detected complexes are supposed to be caused by true heart beats, GAM extracts the features from all detected complexes. Because of the irregular morphology and irregular occurrence of motion artefacts, the feature values of artefacts have obvious differences with those of a normal QRS complex, and are determinant for the recognition of an artefact signal. The method of the invention comprises a two-level correction mechanism to remove artefacts and correct QRS complexes.

Petitioner Ex-1004, 0307

BNSDOCID: <EP_____1724684A1_I_>

[0225] The first level of correction, also named pre-correction, also forms the basis of second level correction. It aims to detect artefacts from single-lead ECG signals. The decision factors include the signal quality ratio, the feature vector of the current complex and its class-complex. As mentioned in the description of the QRS extraction procedure, each complex is classified into a class-complex in terms of its morphological features. Consequently, the feature values of the normal complex are used to calculate the feature mean of a class-complex. By comparing the feature values of the current complex and its class-complex template, the correction procedure can recognize most of the irregular complexes. The method can also help evaluate the standard QRS type of an ECG lead. As the changes of a QRS complex under clean conditions are regular, the number of peaks of a QRS complex, obtained in the feature extraction procedure, is regarded as a quality index that is used to quantify signal quality of the QRS complex. The result of the peak numbers of current complex divided by the peak numbers of normal QRS complex indicates the quality ratio of the complex. This quality ratio is one of the factors for level-1 QRS correction. If the quality ratio is much greater than 1, AECG signals are severly polluted by noise. The criteria for level-1 correction are presented and explained below.

Level 1 correction criteria

```
State = 0; % Artifact Flag
if (RRcur< 0.8* RRnormal ) then
Slopecur = Max(SP, SN); % max slope of current complex
Dev = Slopecur / Slopenormal ; % Slope ratio
if (Dev<0.3 || Dev >3 ) then
State = 2;
end if
Peakcur = Max(|Vpeak1|, |Vpeak2|); % max peak of current complex
Dev = Peakcur / Peaknormal ; % Peak ratio
if (Dev<0.3 || Dev >3 ) then
State = 2;
end if
if (LQRScur>100) then % the duration of QRS
State = 2;
end if
if (State==2 && Numpeak>10) then % noise situation
State = 1;
```

```
end if
if (Numpeak > 12) then % strong noise situation
State = 1;
end if
if (RRcur< 0.3* RRnormal) then % Impossible RR
State =1;
end if
end if
if (Numpeak > 8 && (Tpeak1 > 50 || Tpeak2 > 100)) then %inaccurate baseline
State = 1;
end if
```

[0226] An artifact flag is attached to detected artefacts for subsequent correction. An artefact is an irregular occurrence, and thus it also causes an irregular RR which may have a similar RR length to tachycardia arrhythmia. The correction procedure of the invention therefore handles cases of short RR. The artifact flag is initialized to 0 at the beginning of level-1 correction.

The morphological features of the current complex will be compared with the feature mean of the associated class-complex. If an abnormal complex is found, the artefact flag is set to the transient state 2 because tachycardia arrhythmia may be causing similar abnormal morphologies.

When the artefact flag is set to state 2 and the signals are obtained under noisy conditions, as determined by the quality ratio, the artefact flag is set to 1. If the signals are obtained under high noise conditions or RR is too short, the artefact

Petitioner Ex-1004, 0308

BNSDOCID: <EP_____1724684A1_I_>

flag is also set to 1.

If the signals are obtained under a weak noise condition and the R peak position has a large offset in the sub-segment, the artefact flag is also set to 1. This case may be caused by the inaccurate baseline of complex.

[0227] The level-1 correction phase sometimes leads to incorrect determinations when considering various uncertain factors, particularly interference caused by noise. For example, in some cases, ventricular arrhythmias have similar characteristics to artefacts, therefore leading to a potentially incorrect decision relating to the rhythm class. The applicants thus take two other criteria into account in order to correct these potential errors: contextual decision and multi-lead fusion. In order to simplify the method and improve efficiency, these two methods are combined together to discriminate artefacts from ventricular arrhythmia. These two methods are also used to diagnose and interpret cardiac arrhythmia.

[0228] Level-2 correction adopts contextual analysis to aid in decision-making. A missed or additional QRS complex can bring transient irregular change of the RR interval time and consequently heart rate will change acutely. This sudden change is possibly reflected by some forms of heart diseases, but most of such changes result from various technical and physiological disturbances. Clinical experience has revealed that sudden change of the RR interval has a contextual correlation and that a normal RR interval is regular and periodic. Hence, the preceding and subsequent RR interval values and the average RR interval values can be used to estimate the current QRS complex.

[0229] Multi-lead monitoring provides the ability to continuously view cardiac behaviour from multiple angles. The greater the number of ECG leads used, the greater the information obtained for cardiac arrhythmia analysis. Multi-lead ECG signal analysis therefore improves the reliability of the method of the invention. When meeting the abnormal rhythm or irregular RR interval, data segments of other leads in the same DSW will be processed to assist in making a correct decision. In fact, the influence of a patient's motion is generally limited to a certain electrode and causes artefacts only in one of the leads; the other leads generally remain unaffected. This means that, even if one lead's signal is completely destroyed by noise, the diagnostic algorithm will still continue to work.

[0230] There are two potentially abnormal situations that require level-2 correction: the first is a pseudo-complex caused by QRS-like artefacts; the second is a loss of the true QRS complex. The level-2 QRS correction procedure is shown and explained below.

Level 2 correction

```
if (Additional Interval) then
Estimate Pnxt = Ppre+ RRavg;
Call CHECK(Pnxt) to verify complex at Pnxt position(multi-leads);
 if (Find a complex) then
Call DETECT(Pcur), analysis methods contain
comparing with pattern Template, calculating signal
pollution ratio of current window, analyzing contextual
complexes.


 else
Call CHECK(Pcur);
 if (Find a complex) then
Call DETECT(Pcur);
 end if
end if
else if (Missing interval) then
Estimate Pnxt = Ppre+ RRavg;
 while (Pnxt < Pcur) do
Call CHECK(Pnxt);
 if (Find a complex) then
Call ADD(Pcur);
 end if
Pnxt = Pnxt+ RRavg;
 end while
end if
```


Petitioner Ex-1004, 0309

BNSDOCID: <EP_____1724684A1_I_>

[0231] The correction process can be described as follows :

Decide the class of the abnormal situation by evaluating the RR interval of the current complex;
If RR interval is too short, the complex is perhaps an additional pseudo-complex, so then

(a) estimate the position of expected complex resulting from the position of previous complex and the average RR interval: Pnxt = Ppre+ Rravg;
(b) search the expected complex at the position of Pnxt in multi-lead ECG signals. If one is found, then the current complex is more likely to be an artefact, call Delete(Pcur) to exclude from current complex; else if one is not found, then the current complex is either arrhythmia or artefact, need to further Check(Pcur) before calling Delete(Pcur). If RR interval is too long, it is possible that a complex interval is missing, then

(a) estimate Pnxt as the method in step2-(a)
(b) if Pnxt < Pcur, search the expected complex at the position of Pnxt in multi-lead ECG signals. If one is found, then call Add(Pnxt) to supply a complex, and then continue step 3-b) until Pnxt > Pcur.

[0232] Based on the feature values extracted from ECG signals by the feature detection procedure, a self-diagnosis expert system has been implemented to classify heart rhythms and interpret cardiac arrhythmias. The diagnostic rules of the expert system rely on the rules of experience gained from self-learning capability of the system and cardiological definitions. Cardiac arrhythmias originated from the atria, conduction system and ventricles, and show up as a change in heart rate and rhythm. Cardiac arrhythmias that are associated with the symptoms of heart diseases can be classified and recognized, and their diagnostic criteria obtained by studying the characteristics of ECG signals, empirical clinical experience.

[0233] An arrhythmia is a change in the normal rate or control of the heart's contractions. Cardiac arrhythmias are classified into two classes: those originating in the atria and those originating in the ventricle. Furthermore, in view of the change in heart rate, cardiac arrhythmias have two modes: bradycardia and tachycardia. Not all cardiac arrhythmias are harmful or associated with heart disease. For example, sinus arrhythmias, which may cause anxiety during an episode, are for the majority of people completely harmless. However, studies have confirmed that some cardiac arrhythmias, especially ventricular arrhythmias, are associated with heart disease and require medical treatment to keep the heartbeat regular. The various categories of cardiac arrhythmia are described below:

Sinus arrhythmias are the cyclic changes of sinus rhythm under the influence of the
SinoAtrial (SA) node. Common in children and often found in adults. This kind of cardiac arrhythmia is generally benign and includes following classes: Sinus Bradycardia (SB) Sinus Tachycardia (ST)
Sick sinus syndrome: The sinus node does not fire its signals properly, so that the heart rate slows down. The identifiable classes include: Dropped beats (DB), Sinus pause (SP), and Sinus arrest (SA)
Heart blocks: interference with the conduction process in the AV node (atrioventricular node), bundle of His (or atrioventricular bundle), or the bundle branches can lead to this phenomenon. Heart blocks have similar features of heart rate to Sick sinus syndrome, the identification of which depends on the recognition of the P wave.
Premature beats: ectopic (out of place) beats occur when a focus stimulates an early contraction of the myocardium. Where the focus is in the atria, atrial ectopic beats occur with normal ventricular operation. Where the focus is in the ventricular myocardium, broad QRS complex beats occur. There are thus two identifiable classes shown: Premature atrial contractions (PAC), Premature ventricular complexes (PVC) or extrasystole ventricular (ESV)
Supraventricular arrhythmias are caused by non standard conduction and origin within the atria. The main classes are: Supraventricular tachycardia (SVT) or Atrial tachycardia (AT), Atrial Flutter and Atrial Fibrillation
Ventricular arrhythmias are caused by an irregular depolarization and repolarization pathway in the ventricle. In ventricular rhythms, the depolarization wave spreads through the ventricles irregularly and therefore takes a slower pathway. The QRS complex is thus wide and abnormal. Repolarization pathways are also different, causing the T wave to have an unusual morphology. The classes of ventricular arrhythmias are: Ventricular tachycardia (VT) and Ventricular Fibrillation (VF)

[0234] Heart rhythms can be classified into two categories: if originating in the atria, normally from the SA node, the QRS complex is a sinus rhythm; but if originating in the ventricles, the QRS complex is a ventricular rhythm which is generally an aberrant beat. This implementation of classification is based on the extracted feature values obtained in the extraction task described above. The diagnostic criteria are based on the expert knowledge and rules obtained by studying a training set. In the system according to the present invention, cardiac arrhythmias are graded into three alarm levels : red, yellow and white, to identify the priority of each arrhythmia alarm with the gravity of its corresponding heart disease. The diagnostic criteria and alarm levels of cardiac arrhythmias are defined in Figure 37.

Petitioner Ex-1004, 0310

BNSDOCID: <EP_____1724684A1_I_>

[0235] The determination system of the present is composed of three phases: a pre-learning machine, a rhythm classifier and an arrhythmia interpreter. Figure 38 shows the diagnostic module. Based on the clinical cardiological experience and the results of the training procedure, the pre-learning machine builds and estimates the diagnostic rules for every lead ECG signal of a person under surveillance. The rhythm classifier classifies each detected heart rhythm into one of two categories : sinus rhythm or ventricular rhythm. Depending on the rhythm type and the diagnostic rules, the cardiac arrhythmia interpreter correlates cardiac arrhythmia with the symptoms of the corresponding heart disease. The interpretation is preferably carried out separately for the two types of cardiac arrhythmias, i.e. bradycardia and tachycardia, although it is within the skilled persons remit to envisage a single interpretation step for both types.

[0236] On initialisation of the system according to the invention, there is a procedure to correct electrode placement which displays 10 seconds of ECG signals. This 10 second data stream is also used to determine the diagnostic rules used by the pre-learning mechanism of the system. In this phase, the initial cardiac status, rhythm type, statistical and morphological features can be obtained. The rhythm that occurs the most frequently during the 10 second period will be considered as the reference rhythm of the patient, and its feature values are extracted to form the analytical rules. Furthermore, the feature values are also used to describe the normal rhythm and thus to build the rhythm template, i.e. class-complex, for the subsequent rhythm classification task. Additionally, the analytical results will be fed back to the automatic learning machine, which are used to adjust the coefficients of the analytical rules. Unlike resting ECG, long-term ambulatory ECG has continuous tiny changes due to the influences of the exterior environment and the patient's physical status. These tiny changes are generally normal and so the coefficients of the analytical rules are updated regularly to correspond to said changes.

[0237] The rhythm classifier recognizes two classes of rhythms: sinus rhythm that has a narrow and regular QRS complex and ventricular rhythm that has a broad and normally irregular QRS complex. The rhythm classifier adopts a "template matching" method to classify a QRS complex based on the feature values obtained from the feature extraction module. The signal features, such as the RR interval, the QRS length (LQRS), the left- and right-sides slopes of R wave (SP & SN), the amplitude of R wave (VR), the complex type and the two peaks (Tpeakl & Tpeak2), describes the details of a heart rhythm. They can thus be used to recognize a rhythm by comparing with the features of the rhythm template. The template matching method of the rhythm classifier is based on the feature comparison. Since the features were obtained from a normal rhythm, i.e. the rhythm template in the pre-learning machine, the classification process compares the features of the current rhythm to the rhythm template. The classification equation can be expressed as:

$$F_{estimate}=\sum_{i\in N}\beta*(1-|\frac{W_i-T_i}{T_i}|)$$

[0238] Where, the $F_{estimate}$ is the classification factor which is used to classify the heart rhythm, N indicates the number of the features. The β_i is the weighting coefficient of the feature i, which satisfies the equation $\sum_{i\in N}\beta_i=1$. This coefficient indicates the contributions of the feature i to the rhythm classification. W_i is the value of the feature i of current rhythm, and T_i is the value of the feature i of rhythm template. The expression $1-|(W_i-T_i)/T_i|$ indicates the deviation ratio of the W_i comparing to T_i.

[0239] Current rhythm can be recognized and interpreted by the arrhythmia interpreter of the invention on the basis of the analytical rules. Firstly, the arrhythmia interpreter classifies the rhythms into two categories - bradycardia and tachycardia - by comparing current heart rhythm (HR) with the mean HR of the rhythm template. Then, two interpretation procedures are called respectively to process the two classes of cardiac arrhythmias which are shown below :

Petitioner Ex-1004, 0311

BNSDOCID: <EP_____1724684A1_I_>

Bradycardia interpretation

```
if (RRcur>5s) then
VA; return;
else if (LABEL(last) ==tachy && RRnxt ~=RRavg) then
NORMAL; return;
else if (ventricular rhythm) then
VE; return; %ventricular Escape complex
else if (sinus rhythm) then %delay
if (RRcur==2*RRavg) then
DB; return;
else if (RRcur>3s) then
SA; return;
else if (RRcur>1.7s && RRcur<3s) then
SP; return;
end if
SB;
end if
```

Tachycardia interpretation

```
if (sinus rhythm) then
if (HR>120bmp) then
PAC;
```


Petitioner Ex-1004, 0312

BNSDOCID: <EP_____1724684A1_I_>

```
if (continuous PAC>=3) then
if (HR >150bmp &&HR <250bmp) then
STV; return;
else
ST; return;
end if
end if
end if
if (RRcur+RRnxt ~=2*RRavg) then
C-PAC; return; %compensated
end if
if (RRcur+RRnxt ~=Rravg && RRcur~=RRnxt) then
D-PAC; return; %double
end if
if (PATTERN(N,V,N,V,N,V,...)) then
B-PAC; return; %Bigeminy
end if
else if (ventricular rhythm) then
if (HR>120bmp) then
PVC;
if (continuous PVC>=3) then
VT; return;
end if
if (PATTERN(N,V,N,V,N,V,...) ) then
B-PVC; return; %Bigeminy
end if
if (PATTERN(N,N,V,N,N,V,...)) then
T-PVC; return; %Trigeminy
end if
end if
else if (no QRS complex) then
if (EXIST(VT) && HR > 250bmp) then
VT;
end if
end if
```

[0240] In accordance with the different cardiac arrhythmias event detected, a multi-level alarm system is defined. An emergency message will be sent to the user to report the occurrence of serious cardiac arrhythmias events. The STAR system according to the present invention provides a multi-level alarm system, which will be described in further detail hereafter. In the arrhythmia interpreter, heart rhythms are identified and classified into two basic categories: normal cardiac rhythms and cardiac arrhythmias, whereby the cardiac arrhythmias can be further divided into two classes: known cardiac arrhythmias and the unknown cardiac arrhythmias. The known cardiac arrhythmias are normally the cardiac tachycardias events which are caused by serious heart diseases, including PVC, VT, VF, SVT and PAC, etc. Known cardiac arrhythmias have distinctive QRS complexes and rapid heart rates which are interpreted accurately. Unknown cardiac arrhythmias are usually related to cardiac bradycardia events, which are caused by less serious or benign heart diseases. Known cardiac arrhythmias have regular heart rhythms, but slow heart rates, rendering identification unreliable when one uses only the heart rate to analyse any given event.

[0241] The signal analysis system of the present invention comprises two independent modules, i.e. a feature extraction unit and a cardiac arrhythmia classification unit. Performance evaluation of such a system thus contains two aspects: one is the evaluation of the QRS detector; the second is the evaluation of the rhythm classifier. The evaluation of the QRS detector demonstrates the efficiency of locating the QRS complex. The evaluation of the rhythm classifier reveals the accuracy of the cardiac arrhythmia interpretation. The applicants have tested the performance of both units of their analytical system. The diagnostic algorithm was assessed with respect to two ECG databases: the MIT-BIH arrhythmia database and the CSD database, an internal database of data generated from true life clinical patient study by the applicants. The MIT-BIH Arrhythmia Database contains 48 half-hour excerpts of two-channel ambulatory ECG recordings, obtained from 47 subjects studied by the BIH Arrhythmia Laboratory in Boston between 1975 and 1979. Twenty-four distributing records have been freely published for performance comparison purposes. Each signal file is slightly

Petitioner Ex-1004, 0313

BNSDOCID: <EP_____1724684A1_I_>

over 30 minutes in length and contains two signals sampled at 360 Hz. The header files include information about the leads used, the patient's age, sex, and medication. The reference annotation files include beat, rhythm, and signal quality annotations. The CSD database records were obtained from 10 subjects at the Gabriel Montpied University Hospital in Clermont-Ferrand, France, using the systems, methods and devices of the present invention. The CSD records have lengths of from 7 to 18 minutes, and each signal file contains four-channel ambulatory signals sampled at 500 Hz. Each beat was manually annotated by the cardiologist to generate the reference annotation files. The CSD ECG records are recorded in the same format as the MIT-BIH Arrhythmia Database.

[0242] The locations or marks of the annotated beats in the reference annotation files have differing time positions. For example, the marks of the MIT-BIH database are mostly near to the onset of the Q wave, and the marks of the CSD database are close to the peak of the R wave. Suppappola and Sun determined a valid detection interval for evaluation of the performance of feature extraction. The interval can be modified by the user, whose borders include the onset and end of the QRS complex. The marks of the tested QRS complexes within the valid interval are considered true positive (TP) with respect to the annotations. Any additional marks in the valid interval are treated as false positive (FP). Detection marks outside of the intervals are classified as false negative (FN). The sensitivity (Se) and specificity (Sp) of the feature extraction procedure are thus normally computed by :

$$Se = 1 - \frac{FN}{TP+FN} = \frac{TP}{TP+FN}$$

[0243] Dotsinsky and Stoyanov defined four performance parameters to assess the efficiency of the QRS detector: TP (true positive), FP (false positive), FN (false negative) and shifted SH beats. The SH beat, representing a single fault, is assigned to a couple of adjacent erroneously detected FP and FN, if they are preceded and followed by TP beats. SH beats are in fact non-existing, like the FN beats, both are summed for the computation of Se. The formula below, as an extension of the original formula above, is used to calculate Se :

$$Se = \frac{TP}{TP+FN+SH}$$

[0244] Sp is calculated by formula :

$$Se = 1 - \frac{FP}{TP+FP} = \frac{FP}{TP+FP}$$

[0245] The QRS detector of the invention has two basic functions: QRS detection and Error correction. In order to compare the efficiency of feature extraction, the performance evaluation of the QRS detector is performed in three phases: QRS detection, level-1 correction and level-2 correction. The results of Se and Sp are obtained by evaluating the algorithm on the records of the MIT-BIH and CSD databases, and are shown in Figure 39. In the method according to the invention, the QRS detection procedure provides the ability to locate the QRS complex by analyzing the features of time-domain ECG signals. A sensitivity of 99.43% and a specificity of 98.55% were obtained by the QRS detection procedure of the invention in the detection of the 24 shared records of MIT-BIH database. A sensitivity of 99.25% and a specificity of 97.94% were obtained in the CSD records. The two-level correction procedure is adopted to remove additional artefacts and to add missed QRS complexes. The level-I correction is operated on the single channel ECG signals, the criterion of which is based on the feature comparison between the current QRS complex and the standard QRS complex or template. The results of the evaluation in the level-1 procedure are a sensitivity of 99.37% and a specificity of 99.68% for the MIT database and a sensitivity of 98.72% and a specificity of 98.73% for the CSD database. It is clearl that level-1 correction improves the specificity of algorithm, but slightly lowers the sensitivity. Level-2 correction is performed on multi-lead ECG signals, the criterion of which is based on the contextual relationship of ECG signals and the fusion of multi-lead signals. Under normal conditions, more signals generally means better performance. The multi-lead analysis had the advantages of removing additional artefacts and of supplementing missed beats by comparing the detected beats of different leads' signals. For example, the sensitivity and specificity of the level-2 correction on the CSD database increased respectively to 99.67% and 99.74%. In the diagnostic segment window of the feature extraction

Petitioner Ex-1004, 0314

BNSDOCID: <EP_____1724684A1_I_>

module, the detection algorithm selects an ECG lead with the best signal quality, and fusion of two-lead ECG signals does not need to be performed.

[0246] The rhythm classifier classifies heart rhythms into two categories : non-alarm and alarm-rhythms. The alarm-rhythms defined in the method of the present invention are cardiac tachycardias, i.e. PAC, PVC, SVT, VT, and VF. They represent normally serious heart diseases which need to be reported immediately. The non-alarm rhythms include the normal rhythms and some benign or less serious cardiac arrhythmias, such as cardiac bradycardia. The four parameters used to assess the method's overall performance are :

a true positive (TP) is a serious cardiac arrhythmia that has been correctly classified as an alarm- rhythm;
a false positive (FP) is an organized normal rhythm that has been incorrectly classified as an alarm- rhythm;
a true negative (TN) is any normal or less serious rhythm that has been correctly classified as a non-alarm rhythm;
a false negative (FN) is a serious cardiac arrhythmia that has been incorrectly classified as a non-alarm rhythm.

[0247] The sensitivity (Se) of the device is the number of true positive abnormal rhythms, expressed as a percentage of the total number of abnormal rhythms. Se is calculated using the formula given above. The specificity (Sp, also named positive predictive accuracy) is the number of organized rhythms that have been correctly classified as normal rhythms by the method, and is expressed as a percentage of the total number of normal rhythms which is calculated by the following formula:

$$Sp = \frac{TN}{FP + TN}$$

[0248] The values of Se and Sp were obtained by applying the rhythm classification method on recordings of the MIT-BIH and CSD database, and are given in Figure 39. The algorithm performance of the classification of non-alarm and alarm rhythms was tested. A sensitivity of 90.94% and a specificity of 95.50% were obtained by the classification procedure on MIT-BIH database. A sensitivity of 95.60% and a specificity of 99.54% were obtained with the CSD clinical diagnosis data. The results of the performance evaluation for the QRS detector and rhythm classifier of the present invention show that they satisfy the demands of a AED application. The QRS detection algorithm adopts fractional and geometric methods to locate the QRS complex from AECG signals. The signal preprocessing and conditioning procedure, adopting adaptive filter and bandpass filter, remove or reduce various interferences caused by physical and technical factors. Additionally, the most serious noises, i.e. motion artefacts, have effectively been eradicated by the adaptive filter. Accuracy of detection has been improved using a two-level correction procedure to remove additional artefacts and supplement missing beats. Compared to other known algorithms, the overall results of the detection method of the invention show high sensitivity and specificity. The method of the invention has very low computational consumption and fast detection ability, thus meeting the requirements for real-time diagnostics. Compared to other known methods of classification, the overall results of the classification method of the present invention show excellent performance. Furthermore, the classification method of the invention can directly use the experience gained clinically by cardiologists, thereby reducing the complexity of rules for training the systel and thus improving accuracy of classification. The method of the invention is also capable a very broad spectrum cardiacl arrhythmias, in fact, far more than any other system to date.

[0249] In accordance with still yet another object of the present invention, the inventions provides a continuous remote real-time detection, monitoring and control system for cardiac arrhythmia, known as STAR. The main aim of the STAR system is to provide a rapid detection and analytical method for the high-risk population of cardiac arrhythmia sufferers to prevent sudden death. It can also be used for long-term heart surveillance for a population who has a history of heart disease, or to do periodic heart examinations for a healthy population of individuals.

[0250] The function of STAR system according to the invention is as follows :

[0251] A wireless ECG sensor acquires and analyses ECG signals in real-time from a person under surveillance. When a cardiac abnormal event is detected, an alarm message is sent to the local access station via local wireless technologies, such as WiFi and Bluetooth. If the patient stays indoors and the fixed wire network infrastructures are available, the local access station then transmits the alarm message, for example a ECG signals sequence, to a remote system via indoor network mediums, such as a cable modem, ADSL, ISDN, Ethernet, etc; if the patient is outdoors, the local access station transmit an alarm message, for example, a SMS or an email, to a remote system via wide wireless technologies, such as GSM, GPRS, UMTS and satellite, etc. Using such a system, a cardiologists can examine the abnormal events and respond within a very short period. In an alternative embodiment, the wireless sensor is capable of detecting, analyzing and classifying the signal and informing the person under surveillance, for example via a screen located on the sensor, of the actions to be taken when an abnormal event occurs, thus avoiding a diagnosis by a trained

Petitioner Ex-1004, 0315

BNSDOCID: <EP_____1724684A1_I_>

clinician. In such a situation, the wireless sensor is a self-contained unit that undertakes all of the roles that previously required a clinician's input.

[0252] The system according to the invention thus demonstrates an effective combination of WSN technologies, network communication technologies and AED technologies. The system of the invention is very flexibile and extensible. It can be made to work in various application environments, not just in arrhythmia detection, and can be configured to work in various operating modes. The real-time and reliable network communication that is located within the device is one of the foundations of the system. This was achieved by focusing on two particular aspects : signal compression techniques, that are used to reduce data transmission; an application layer protocol which provides a guaranteed real-time ECG signals transmission service.

[0253] The system of the invention integrates advanced wireless technology and distributed embedded real-time intelligent sensors that communicate over the Internet. In one preferred embodiment, it consists of two subsystems: a local subsystem and a remote subsystem, which contains four main configurable components. The local subsystem has a wireless ECG sensor (WES) and a local access server, and the remote system includes a remote access server and a remote surveillance system capable of diagnosis and visualization. Figure 40 shows the function modules of the system according to the present invention. According to desired application of the system, functional modules can be mounted on one of four system components.

[0254] The system according to the invention uses an energy-efficient compact wireless ECG sensor hereafter abbreviated to WES. The WES conforms to the basic characteristics of a wireless sensor device: tiny resources, tiny power-consumption and associated tiny cost. In addition, the WES of the invention comprises an embedded distributed real-time fault tolerant microkernel, dedicated hardware, and a specific TCP/IP protocol stack. An example of such a wireless ECG sensor typically has dimensions of about 70 mm by 100 mm, and incorporates in a preferred embodiment a Texas Instruments ultra-low-power MSP430 microcontroller. The sensor, when not equipped with a wireless adapter, consumes only 10mA of power. The key features of one preferred WES are:

Gain: 1000 CMMR(min): 120dB
Bandwidth: 0.05Hz to 125Hz
Programmable sample frequency more than 500Hz
Analogue to digital converter (ADC): 12 bits
Leakage current: 10μA.

[0255] The WES according to the invention makes it possible to capture 4 leads of ECG signals sampled at 500Hz in real-time, the sample frequency being reprogrammable. The sample signals are sent to a local server over a wireless medium such as WiFi or Bluetooth. In offline mode, ECG signals can be stored in an exterior or on-board flash memory card or chip. The store duration of the ECG signals depends on the capacity of the flash memory card, the sample frequency and the number of ECG leads. The sample frequency and the lead number can be configurable by the user. For example, a 128Mb flash memory card can store 24 hours continuous data from 4-lead ECG signals sampled at 500Hz. In this way, the WES works as a Holter or an RTEST.

[0256] The local access server may be implemented on a standard PC, a PDA, a mobile phone or a dedicated network access medium. It provides two classes of network connection services: connection with the WES via a local wireless medium e.g. WiFi or Bluetooth, and connection with the remote system via existing network media, such as cable modem, ADSL, ISDN, GPRS, satellite, etc... In view of the difference of network media, local servers, and network speeds caused by network traffic, the system of the invention provides adaptable communication techniques to guarantee a reliable data transmission service between the local server and the remote server. Furthermore, in order to provide real-time data transmission, it is important to minimize the amount of data transmission to reduce network traffics over the low-bandwidth network links. To this end, a lossless ECG signal compression algorithm is implemented in the system. If the local access server is implemented on a high-performance machine, such as a PC, the ECG diagnostic module can be migrated from the WES onto the local server and the cost of the WES will be reduced even further. In addition, it can be advantageous to obtain video information from the person under surveillance, as an auxiliary means for online diagnosis. Consequently, a webcam can be installed in, or connected, to a local server to provide images as desired.

[0257] The remote access server provides the capability of network connection between the local access server and the remote surveillance server. Depending on the type of network, it can support two types of access servers: a PPP server and a WAP server. The PPP server establishes connections between persons under surveillance and the clinician via a Public Switched Telephone Network (PSTN). It supports several network bandwidths: 56Kbps (cable modem), 512Kbps or more (ADSL). The WAP server establishes connections via a wide wireless network. It can tune automatically to different wireless bandwidths: 9,6Kbps (GSM) or 115Kbps (GPRS). In addition, if the persons under surveillance and the clinicians are in the local area, e.g. in a hospital or clinic, and share local network infrastructures, e.g. high-speed LAN, or they utilize the global network connections provided by commercial ISPs (Internet Service Providers), this component is optional and can be removed from the system architecture. Several function modules can be loaded onto

Petitioner Ex-1004, 0316

BNSDOCID: <EP_____1724684A1_I_>

the remote access server: a database service and a web service. The medical history records of a person under surveillance are important for analysis of the condition, for example, in this case, arrhythmia. Medical records in multimedia formats are stored in the patient database system on the remote access server, which include ECG signal sequences, cardiologists' diagnostic reports, patients' video, voice and individual profile information, etc. The Web service provides the capacity of Internet access to the patients' database system via a simple Web browser.

[0258] The remote surveillance server has an interactive visualization Graphical User Interface, with which the cardiologist can diagnose cardiac arrhythmia events in real-time and respond to alarm messages by monitoring the ECG signal sequence and the patients' images. This server supports multi-patient surveillances, and one patient on-line diagnosis by a cardiologist at a time. The four-lead ECG signals and related diagnostic results obtained from the the AED method of signal processing are displayed on the screen and stored into data files in the WFDB format. Diagnostic reports can be built automatically and printed with the ECG signal sequence and related statistical results. When the number of persons under surveillance is relatively low, e.g. when in use in a small clinic, the cardiologist at the remote surveillance server can connect directly with the patient at the local access server via the Internet. In this way, the database service and Web service can be implemented directly in the remote surveillance server.

[0259] The system according to the invention is very flexible and extensible. It can be applied to a number of configurations, and therefore can operate in various modes. The scenarios of the application modes are:

ECG Surveillance Automaton: the WES is configured to work as an absolute ECG surveillance automaton to carry out long-term monitoring of a patients' heart status. It displays the ECG signals on a LCD screen, and records the ECG signals and related diagnostic results into the external or internal flash memory card. The WES can integrate an optional ECG diagnostic chip and thus offer the possibility of real-time ECG diagnosis.

Clinical Surveillance: In this mode, the patients and cardiologists are in the local area and share the local network infrastructure. Where a limited number of users is envisaged, the ECG signals acquired by the WES are sent directly to the remote surveillance server via local wireless media. Where large-scale application is envisaged, the WES first sends the ECG signals to a local access server in which the ECG signals are rapidly processed and diagnosed, and then the compressed ECG signals and diagnostic results are sent to a remote surveillance server via a local high speed network. As a high-speed LAN infrastructure is used in this mode, the remote surveillance server supports the multi-user multi-lead continuous real-time ECG signal monitoring. In this case, the diagnostic method can be implemented on a remote surveillance server or a local access server. This is similar to the telemetry cardiac arrhythmia detection system commercialized by Agilent Technologies.

Remote Surveillance: In this mode, the patient is at a location remote from the hospital or clinic and may even be at home, at the office or travelling. Via the existent network infrastructures, In such an example, the platform establishes connections between patients and cardiologists via existing network infrastructures. For example, if the patient is at home or at the office, the local access server can be implemented on a PC, and thus connected to a remote PPP server via a dial-up connection; if the patient is travelling, the local access server can be implemented on a mobile phone, and connected to a remote WAP server via wide wireless technologies. This mode contains all of the system components and supports four operation modes.

[0260] The operation mode of the system according to the invention is configurable and modifiable by the doctor in view of the patient's heart status, hardware devices and network bandwidths. Each operation mode is defined as an alarm level with a unique message format. The system offers four operation modes. It should be noted that the cardiologist can change the operation mode in order to tune to the evolution of the patient's heart status:

Level-I: Real-time continuous ECG signals. Level-I is the highest alarm level. It is applied when the cardiologist needs to diagnose online a patient or the patient needs to be monitored continuously in real-time. In this mode, the continuous ECG signals acquired from the WES and the diagnostic results processed by the AED methods of the invention are displayed in real-time. By observing the ECG signals, the pre-diagnostic information and the patient's optional video or digital image information, the cardiologist can build a final diagnostic report. This operation mode is normally not suitable for simultaneously processing a large number of patients due to the limitations of network bandwidth, system resources and human resources.

Level-II: ECG signal sequence. The WES is configured to send a sequence of ECG signals, for example, the pre and the post five-second ECG signals of a cardiac arrhythmia event, to the remote system when a cardiac arrhythmia event defined by the cardiologist is detected. As the system stores and sends only the limited data of a cardiac arrhythmia event, it avoids generating huge data files and massive network traffic caused by long-term ECG monitoring. This operation mode is suitable for long-term multi-patient cardiac arrhythmia event surveillance for the lower-risk heart disease population.

Level-III: textual or SMS emergency message. In this mode, only a short textual emergency message is sent to the cardiologist when a cardiac arrhythmia event is detected. Depending on the seriousness of the symptom, the

Petitioner Ex-1004, 0317

BNSDOCID: <EP_____1724684A1_I_>

cardiologist decides to intervene immediately or to respond later. This mode may be operated on any access medium, i.e. fixed wire or wireless.

Level-IV: diagnostic report e-mail. this is the lowest-level operation mode. The local server will periodically send an e-mail to the cardiologist to report the patient's status. The time interval of dispatching e-mail is defined by the cardiologist. This operation mode is suitable for the heart care of a healthy population.

[0261] The most effective methods for reducing network traffic lie in decreasing the amount of signal transmission and in compression of the ECG signals. The 500 Hz sampling frequency of the WES offers high quality ECG signals for ECG diagnosis, but also generates huge network traffic for data transmission. For example, a 4-lead ECG signals at 500Hz sample frequency and 12 bits resolution ADC, will occupy 20,000 bytes over a period of 5 seconds (4 leads * 500Hz * 5s * 2 bytes). In order to support real-time transmission, the network speed must be more than 32Kbps (20,000 * 8bits / 5s) when the system works in the Level-I operation mode. This speed is obviously unfit for low bandwidth networks. Although the ECG signals with high sampling frequency are considered important to guarantee the accuracy of the ECG diagnostic algorithm, ECG signals with a relatively low sampling rate, often 128 Hz, are sufficient for the purposes of ECG observation in the remote visualization system. The sampling frequency of 128 Hz is typically used for an ECG signal. Hence, the sampling frequency of ECG signals acquired by a local server can be de-multiplied to reduce the network traffic. Furthermore, waveform features show that ECG signals have huge data redundancies. Hence, a good data compression algorithm can also reduce network traffic. The applicants have devised a lossless compression algorithm that deals with such problems : only the difference value between two consecutive samples is sent to the remote server. Since the electrical amplitudes of ECG signals in cardiac expansion are almost equal to the zero isoelectric value, the difference between the samples during cardiac expansion is almost equal to zero. The sample compression format is illustrated in Figure 41, where :

the "+/-" field indicates the positive/negative property of the difference data: 1 - positive and 0 - negative;
the "type" field indicates the type of data length and the "data" field stores the difference data.

[0262] Statistical results show that this compression algorithm has a 50% to 60% compression ratio. For example, with 4-lead ECG signals at 500Hz sample frequency and 12 bits resolution ADC, when applying the demultiply frequency technique to 125 Hz and the signal compression algorithm according to the invention, it is possible to reduce 87.5% to 90% of all network traffic.

[0263] In order to support real-time data transmission, the UDP protocol is used to deliver ECG signals. However, the UDP protocol does not offer a guaranteed datagram delivery service. Hence, a reliable data transmission mechanism must be implemented in the application layer. As the speed of the network communication system fluctuates and is affected by the network traffic and other interference factors, an application layer communication protocol dedicated to the system of the present invention was implemented, and is responsible for a real-time and reliable data transmission service over various hardware and network environments.

[0264] The data unit of transfer between two machines in the system according to the invention is called a STAR frame. STAR frames are used to establish/terminate STAR connections, to deliver data, e.g. ECG signals or images, and to configure operation modes or other system parameters. Each frame is divided into two parts, a STAR frame header followed by data. Figure 42 shows the STAR frame format. The type field is used to identify the type of STAR frame. Three types of STAR frames are defined in a STAR system according to the invention : a value of 0x01 indicates a system control frame; a value of 0x02 indicates an ECG signal frame; and a value of 0x03 indicates an image frame. Each type of STAR frame has a unique system priority identified by the type value (1 to 3, from high to low). Figure 42 (a) shows the format of the ECG signal frame. Each ECG frame has a unique identifier specified by the sequence number. Every time a local server sends an ECG frame, the sequence number will automatically increment by one for the next frame. It is therefore possible to calculate the surveillance time of heart monitoring from this value. The value of the signal number field indicates the channel number of ECG signals. In the present invention, the preferred number of channels is four, but of course, it is possible to have more or less than four channels. The value of the QRS number fields represents the number of QRS complexes detected by the AED method in this ECG frame. The default sampling frequency of the WES is 500 Hz, which is identified in the sampling frequency field. This value is alterable using a frequency demultiplier operation. As the signal compression algorithm changes the size of the original ECG frame, the frequency value is useful for determining the length of the uncompressed original frame on the remote server. The following area of the ECG frame stores the diagnostic results of the AED method. It is a QRS structure queue, the QRS member number of which is indicated in the QRS number field. Each QRS member, named QRSResult, consists of three elements: QRS position, QRS length and QRS state. The QRS position element indicates the onset position of a QRS in the uncompressed ECG frame. The heart rate of each beat can be calculated based on the positions of two consecutive QRSs. The QRS length represents the time interval of a QRS. The QRS state shows the type of heart rhythm and its related heart status classified by the AED method. The ECG signals field stores the compressed ECG

Petitioner Ex-1004, 0318

BNSDOCID: <EP_____1724684A1_I_>

signals. In the preferred STAR system of the invention, each ECG frame contains a five-second ECG signal. Figure 42 (b) shows the format of the image frame. The Sequence number field is unused for an image frame. The image field contains an image in the jpeg format, although other well known image formats could be used, for example, the portable network graphic format also known as the PNG format. Figure 42(c) shows the format of the system control information frame. The value of the control code field indicates the type of control code. The related control information is stored in this field.

[0265] Three kinds of UDP connections are established in the STAR communication system of the present invention. They are responsibile for the system control (udp_CMD), ECG signal transmission (udp_SIG) and images transmission (udp_IMG).

[0266] The STAR control frames of the present invention are responsible for system remote configuration, patient online / offline notification, and ECG frames retransmission management. The control frame is transferred via the udp_CMD connection. The system of the invention defines nine types of control frames defined as follows:

REQ_Connect
ACK_Connect
REQ_Terminate
ACK_Terminate
REQ_Configure
ACK_Configure
REQ_Restra
ACK_5Frames
ACK_Image

[0267] The control frames with the code of REQ_Connect and ACK_Connect are responsible to for establishing connection between patients and cardiologists. While the control frames with the code of REQ_Terminate and ACK_Terminate are responsible for terminating this same connection. Both the patients and the cardiologists have a right to open and close the udp_CMD connection voluntarily. The control frames with the code of REQ_Configure and ACK_Configure are responsible for the system configuration. The other control frames with codes REQ_Restra, ACK_5Frames and ACK_Image will be discussed hereafter.

[0268] The system according to the invention guarantees a reliable ECG signal delivery service by providing a signal retransmission mechanism. Two ECG frame queues are defined respectively for the local server peer, Hold_Queue, and the remote surveillance server peer, Wait_Queue. The standard length of the two queues is five frames. The retransmission mechanism is described below:

Remote Surveillance Peer Retransmission

```
If (an ECG frame is recieved )
If (Seq_cur == Seq_exp)
Insert current frame to wait_queue; The position of current frame in wait_queue is decided by its Seq_cur;
Seq_exp++;
else if (Seq_cur < Seq_exp)
drop it;
Send Control Frame REQ_Restra to the local server;
else if (Seq_cur > Seq_exp)
Add current frame to the tail of wait_queue ;
end
if (continuous Five frame is received)
```


Petitioner Ex-1004, 0319

BNSDOCID: <EP_____1724684A1_I_>

```
Send Control Frame ACK_5Frames to the local server;
end
end
```

Local Acess Peer Retransmission

```
If (ACK_5Frames frame is received)
Release the ECG frames whose Seq_fra <= Seq_ack from the
hold_queue;
else if (REQ_Restra frame is received )
Retransmit an ECG frame of Seq_req to the remote surveillance server;
Release the ECG frames whose Seq_fra < Seq_req from the hold_queue;
end
if (an ECG frame is ready)
Send an ECG frame of Seq_cur to remote surveillance server;
Seq_cur++;
end
```

[0269] When an ECG frame with the sequence number k is lost during network transmission, the remote surveillance server sends a retransmission request frame with a control code of REQ_Restra, the local server responds to this request by retransmitting the ECG frame k. When five consecutive ECG frames are received by the remote surveillance server, a control frame with the ACK_5Frames code is sent to the local server to inform the local server to release the backup ECG frames in Hold_Queue.

[0270] As mentioned above, the system according to the invention has three types of data frame. Each data frame type has a unique transmission priority. The system control frame has the highest priority in the system. Furthermore, because the ECG signals are more important than the images for the purposes of diagnosis, the ECG frame has higher priority than the image frame. In order to guarantee a real-time ECG signal transmission service, a data competition mechanism is implemented in the system, shown below :

Competition Mechanism : Remote Surveillance Peer

```
If (an Image frame is received)
If (the length of wait_queue >= 5) //25 seconds delays
Send a Control frame ACK_Image to the local server ;
Set the Image_Enable = TRUE;
else
Set the Image_Enable = FALSE;
end
end
if ( an ECG frame is received)
If (the length of wait_queue > 5 && Image_Enable == FALSE )
Send a Control frame ACK_Image to the local server ;
```


Petitioner Ex-1004, 0320

BNSDOCID: <EP_____1724684A1_I_>

```
Set the Image_Enable = TRUE;
end
end
```

Competition Mechanism : local access peer

```
If (Image_Enable == TRUE)
Send an Image frame to the remote surveillance server ;
Set the Image_Enable = FALSE;
end
if ( a Control frame ACK_Image is received)
Set the Image_Enable = TRUE;
end
```

[0271] When the queue length of Wait_Queue is equal to or greater than five, there are at least 25 seconds of ECG signals that have been reserved on the remote surveillance server. It is therefore acceptable to allow the local server to transmit images. However, when the queue length of Wait_Queue is smaller than five, it means that the network speed has began to fluctuate and network quality has dropped, so the system will stop image transmission to reduce network traffic.

[0272] Currently, the STAR system according to the invention and dedicated to real-time remote continuous cardiac arrhythmia detection has been evaluated on about ten patients at the Gabriel Montpied University Hospital hospital in Clermont-Ferrand, France. Diagnostic algorithms have also been evaluated by using the MIT-BIH cardiac arrhythmias database. Insofar as VT and ESV are concerned, the average detection rate is about 95%. It is to be noted that the quality of the ECG signals on our system is significantly better than corresponding HP telemetry systems, as illustrated in Figure 43.

[0273] The test platform that corresponds to Figure 43 is configured to operate as a Clinical Surveillance application, and runs in level-1 mode, i.e real-time continuous ECG signals mode. The local access server is a laptop on which the real-time cardiac arrhythmia program is implemented. The remote access server and the remote surveillance server are installed in the same laptop or a standard PC, which connect with the local server via the local high-speed network. The system of the invention supports continuous remote cardiac arrhythmia monitoring and allows the patient to continue with his daily activities, both indoors and outdoors. The results of the tests and evaluations show the system to be fully functional, and is an efficient system for diagnosing cardiac arrhythmia, opening up a new clinical approach to more accurately evaluating a larger number of high-risk patients. Furthermore, it may be used by cardiologists to remotely heart monitor and evaluate the efficacy of drugs or to discuss difficult cardiac pathology cases with other colleagues.

[0274] As a variant to the general system described above, the applicants have also designed and implemented an Intelligent Wireless ECG Sensor (IWES) by integrating the cardiac arrhythmia detection algorithm onto a ICAC chip. The ICAC has been evaluated and tested on an FPGA. Thus, the alternatively preferred embodiment of the system platform contains both an IWES and a remote server. With the IWES, when the patient is outdoors, the sensor will automatically disconnect from the remote server. When cardiac arrhythmia events are detected, an ECG signal sequence will be recorded locally on a flash memory card. Only an emergency short message will be sent to a remote server, for example a WAP server, via a mobile phone connection as a SMS text. The emergency message may be defined by the cardiologist according to the physical state of the patient. The IWES will periodically attempt to connect to the remote server, and if the network connection is established, a cardiac arrhythmia report along with all the recorded events is sent periodically.

[0275] It was mentioned above that the ECG signals that are classified in the system of the present invention are far more stable and regular than those of a corresponding commercial telemetry sensor. An exemplary circuit diagram of the filter and signal conditioning system is shown for the purposes of illustration in Figure 44. One of the reasons for the stability of the ECG signals acquired in the present invention is due to the fact that the ECG signal entry, indicated as A and B on Figure 44, into the filtering circuit is asynchronous. This goes against all current train of thought in this field, because it has always been felt that a synchronized ECG signal entry was required in order to obtain a sufficiently stable signal. Indeed, the present applicants compared the system with synchronous ECG signal entry, but all of the experiments carried out demonstrated a loss in signal stability, with more baseline drift over time, compared to the asynchronous ECG signal entry adopted and used in the device of the present invention.

[0276] Although some of the present objects have been identified in relation to software programs and languages, it is perfectly possible for most of the functions to be implemented as hardware, i.e. using VLSI or VHDL techniques that are well known to the skilled person per se. Consequently, any of the components of the system that are currently

Petitioner Ex-1004, 0321

BNSDOCID: <EP_____1724684A1_I_>

implemented via software can be readily integrated directly into a chip via the usual lithographic techniques known in the integrated circuit manufacturing industry, such that the chip actually provides for a physical structure engraved in, for example, silicon, representing the various sequences of instructions, tests, comparisons, and operations that the software implementation carries out.

Claims

1. Real-time true multi-tasking operating system loaded or engraved on a data support media comprising an executable microkernel capable of addressing a microprocessor for execution of instructions, and comprising a task scheduler, wherein the scheduler deals with two classes of tasks, a periodic task class and a priority task class and wherein :

   - a periodic task has a very short execution time and deterministic response time, and has a highest priority level, preferably a priority level of 10, said periodic task being interruptible but non-pre-emptible;
   - a priority task is interruptible at variant-time intervals, and has a predictable response time, and is also pre-emptible, with a priority level comprised from low to high, preferably from 1 to 9.

2. Real-time operating system according to claim 1, wherein the priority levels range from 0 (lowest) to 10 (highest).

3. Real-time operating system according to claim 1, wherein a priority level of 0 is attributed to a daemon, or an idle task.

4. Real-time operating system according to claim 1, wherein the task scheduler has a two-tier scheduling scheme wherein :

   - periodic tasks are handled on a FIFO (first in, first out) basis;
   - and priority tasks are handled on a "priority-based pre-emptive" basis, wherein any first task is selected preferentially on the basis of a comparison of its priority level with respect to the priority level of any other priority task, a higher priority level of the first task being selected in preference to a lower priority level of an other task.

5. Real-time operating system according to claim 4, wherein priority tasks are always executed before periodic tasks.

6. Real-time operating system according to claim 1, wherein the microkernel also comprises a tuple based messaging system.

7. Real-time operating system according to claim 1, wherein the microkernel also comprises a tuple space dedicated to task communication and synchronization.

8. Real-time operating system according to claim 1, wherein each message associates with a tuple in a shared system and application tuple space.

9. Real-time operating system according to claim 1, comprising a set of primitives that are defined by a Meta language.

10. Real-time operating system according to claim 9, wherein the system primitives consist of the SND() and RCV() primitives.

11. Real-time operating system according to claim 1, wherein "task switching" or "context switching" occurs as follows :

    - determine whether a currently running task should continue to run ; if said currently running task should not continue to run, suspend said current task and goto next step;
    - determine which task should run next;
    - save an environment of the task that was suspended;
    - set up a running environment of an other task that will run next;
    - allow this other task to run.

12. Real-time operating system according to claim 1, wherein a task is initialized to a "sleep" state when it is created.

13. Real-time operating system according to claim 1, wherein the data support media is a semi-conducting material, and the operating system instructions are integrated directly into said semi-conducting material.

Petitioner Ex-1004, 0322

BNSDOCID: <EP_____1724684A1_I_>

14. Real-time operating system according to claim 1, wherein the data support media is volatile or non-volatile, and is preferably chosen from the group consisting of rom, eeprom, ram, optical recording media, cd-rom, dvd-rom, rewritable dvd, and magnetic tape, and magneto-optical storage media.

15. Method of analysis of an ECG signal, comprising :

- acquiring one or more ECG signals over a period of time;
- filtering said one or more ECG signals with at least one filter selected from the group consisting of a low pass filter, a high pass filter, and an adaptive filter; and
- extracting one or more features from said filtered signal.

16. Method according to claim 15, wherein the low pass filter has a cut off of 40 Hz.

17. Method according to claim 15, wherein the high pass filter has a cut off of 0.1 Hz.

18. Method according to claim 15, wherein the acquired signal is subjected to differentiation before filtering.

19. Method according to claim 15, wherein the acquired signal is subjected to reconstruction after filtering.

20. Method according to claim 15, wherein the adaptive filter (AT) is used to reduce motion artefacts, and the filtered signal series, named A(t) or Aecg(t), are generated by performing the AT filter operation on the original ECG series R(t) according to the following expression :

$$\begin{cases} Aecg(0)=R(0) \\ Aecg(t)=\alpha * Aecg(t-1)+(1-\alpha)R(t) \end{cases} \quad 0 < \alpha < 1,\ t=1\cdots N \ ,$$

where α is the balance coefficient of AT and has a value comprised between about 0.5 and 0.98, preferably between about 0.75 and 0.95, and most preferably is equal to 0.95.

21. Method according to claim 15, wherein in step (a), the period of time does not exceed 5 seconds, thereby forming a diagnostic segment window (DSW).

22. Method according to claim 15, further comprising the step of identifying QRS complexes from the filtered signals.

23. Method according to claim 22, wherein the QRS complexes are identified via application of the self-adaptive threshold (SAT) method and the state transition recognition (STR) method.

24. Method according to claim 23, wherein the SAT method comprises determining the pair-threshold by :

- dividing up a given DSW into 5 sub-segments of 1 second each;
- detecting and recording five pair-peaks from the relative sub-segments in a current DSW;
- calculating the relative mean of positive and negative peaks, and then excluding the peaks that are too far from the mean;
- repeating step (b) for the remaining pair-peaks;
- verifying the current pair-threshold with the previous estimated pair-threshold.

25. Method according to claim 22, wherein the STR comprises applying the transition rules identified in Figure 26.

26. Method according to claim 15, wherein the feature extraction is effected by applying a geometrical analysis method (GAM), in which the following steps are carried out to evaluate the baseline and peaks of a QRS complex, and where Tmax and Tmin indicate the positions of maximum and minimum peaks, and Vmax and Vmin are the amplitudes of these two peaks :

- trace the changes of sub-segment data and record peaks information;
- estimate the Tmax and Tmin peaks and calculate the slope of each peak;

Petitioner Ex-1004, 0323

BNSDOCID: <EP_____1724684A1_I_>

- remove the peaks which have too small / large slopes and too dull / steep changes of amplitudes between two consecutive peaks;
- repeat steps (b) and (c) in the remaining peaks set and then obtain more accurate Tmax and Tmin.

27. Method according to claim 26, further comprising classification of the peaks as follows :

- verifying the Tmax and Tmin peaks;
- pre-estimating the type of complex by comparing the absolute amplitudes of Tmax and Tmin;
- if Vmax >> Vmin, set class 1;
- else if Vmax << Vmin, set class 2;
- else, continue to next step;
- estimating the type of complex : for class 1 or 2, search for the second peak that has similar peak characteristics to the Tmax (1) or Tmin (2);
- if one is found, adjust class to class 3 or class 4, the second peak is then marked as Tmax2 or Tmin2;
- for other situations, if Tmax >= Tmin, set class to class 5;
- else set class to class 6.

28. Method according to claim 27, wherein the measurement and the detection phases of the Qt and S_i points are determined as follows:

- defining two-level thresholds for left and right sides of the R wave in a QRS complex respectively, where the the left two-level thresholds are defined as LH=1/4*Vpeak1, LL=3/4*Vpeak1, and the right-level thresholds are RH=1/4*Vpeak2, RL=3/4*Vpeak2;
- calculating the intersections between the threshold values and the complex signal;
- obtaining the length of the QRS (LQRS), which is the distance between two intersections on the baseline and two approach lines.

29. Method according to claim 15, wherein after the feature extraction step, error correction is carried out.

30. Method according to claim 29, wherein the error correction is a level 1 error correction according to the following schema :

Petitioner Ex-1004, 0324

BNSDOCID: <EP_____1724684A1_I_>

```
State = 0; % Artifact Flag
if (RRcur< 0.8* RRnormal ) then
Slopecur = Max(SP, SN); % max slope of current complex
Dev = Slopecur / Slopenormal ; % Slope ratio
if (Dev<0.3 || Dev >3 ) then
State = 2;
end if
Peakcur = Max(|Vpeak1|, |Vpeak2|); % max peak of current complex
Dev = Peakcur / Peaknormal ; % Peak ratio
if (Dev<0.3 || Dev >3 ) then
State = 2;
end if
if (LQRScur>100) then % the duration of QRS
State = 2;
```


Petitioner Ex-1004, 0325

BNSDOCID: <EP_____1724684A1_I_>

```
end if
if (State==2 && Numpeak>10) then % noise situation
State = 1;
end if
if (Numpeak > 12) then % strong noise situation
State = 1;
end if
if (RRcur< 0.3* RRnormal) then % impossible RR
State =1;
end if
end if
if (Numpeak > 8 && (Tpeak1 > 50 || Tpeak2 > 100)) then %inaccurate baseline
State = 1;
end if.
```

31. Method according to claim 29, wherein the error correction is a level-2. correction according to the following schema :

```
if (Additional Interval) then
Estimate Pnxt = Ppre+ RRavg;
Call CHECK(Pnxt) to verify complex at Pnxt position(multi-leads);
if (Find a complex) then
Call DETECT(Pcur), analysis methods contain
comparing with pattern Template, calculating signal
pollution ratio of current window, analyzing contextual complexes.
else
Call CHECK(Pcur);
if (Find a complex) then
Call DETECT(Pcur);
```


Petitioner Ex-1004, 0326

BNSDOCID: <EP_____1724684A1_I_>

```
end if
end if
else if (Missing interval) then
Estimate Pnxt = Ppre+ RRavg;
while (Pnxt < Pcur) do
Call CHECK(Pnxt);
if (Find a complex) then
Call ADD(Pcur);
end if
Pnxt = Pnxt+ RRavg;
end while
end if
```

32. Method according to claim 15, further comprising a classification step after extraction of the features comprising :

- a pre-learning step;
- a rhythm classifier; and
- an arrhythmia interpreter.

33. Method according to claim 32 wherein the arrhythmia interpreter distinguishes between bradycardia and tachycardia arrhythmias.

34. Method according to claim 33, wherein the test for bradycardia arrhythmias is as follows:

```
if (RRcur>5s) then
VA; return;
else if (LABEL(last) ==tachy && RRnxt ~=RRavg) then
NORMAL; return;
else if (ventricular rhythm) then
VE; return; %ventricular Escape complex
```


Petitioner Ex-1004, 0327

BNSDOCID: <EP_____1724684A1_I_>

```
else if (sinus rhythm) then %delay
if (RRcur==2*RRavg) then
DB; return;
else if (RRcur>3s) then
SA; return;
else if (RRcur>1.7s && RRcur<3s) then
SP; return;
end if
SB;
end if
```

35. Method according to claim 33, wherein the test for tachycardia arrhythmias is as follows :

Petitioner Ex-1004, 0328

BNSDOCID: <EP_____1724684A1_I_>

```
if (sinus rhythm) then
if (HR>120bmp) then
PAC;
if (continuous PAC>=3) then
if (HR >150bmp &&HR <250bmp) then
STV; return;
else
ST; return;
end if
end if
end if
if (RRcur+RRnxt ~=2*RRavg) then
C-PAC; return; %compensated
end if
if (RRcur+RRnxt ~=Rravg && RRcur~=RRnxt) then
```


Petitioner Ex-1004, 0329

BNSDOCID: <EP_____1724684A1_I_>

```
D-PAC; return; %double
 end if
if (PATTERN(N,V,N,V,N,V,...)) then
B-PAC; return; %Bigeminy
 end if
else if (ventricular rhythm) then
if (HR>120bmp) then
PVC;
 if (continuous PVC>=3) then
VT; return;
 end if
if (PATTERN(N,V,N,V,N,V,...) ) then
B-PVC; return; %Bigeminy
 end if
if (PATTERN(N,N,V,N,N,V,...)) then
T-PVC; return; %Trigeminy
 end if
end if
else if (no QRS complex) then
if (EXIST(VT) && HR > 250bmp) then
VT;
 end if
end if
```

36. Method according to claim 32, wherein the rhythm classifier compares the features of the current rhythm to a rhythm template, and the classification equation can be expressed as:

$$F_{estimate} = \sum_{i \in N} \beta * (1 - |\frac{W_i - T_i}{T_i}|)$$

Petitioner Ex-1004, 0330

BNSDOCID: <EP_____1724684A1_I_>

where:

the $F_{estimate}$ is the classification factor which is used to classify the heart rhythm; N indicates the number of the features;

β_i is the weighting coefficient of the feature i, which satisfies the equation $\sum_{i \in N} \beta_i = 1$, this coefficient indicating the contributions of the feature i to the rhythm classification;

W_i is the value of the feature i of the current rhythm; and

T_i is the value of the feature i of rhythm template.

37. A wireless sensor network device comprising :

- a power subsystem;
- a computation subsystem to communicate and process sensor data;
- a sensor subsystem including at least one sensor;
- a wireless communication subsystem,

wherein the computation subsystem comprises an embedded real-time operating system according to any one of claims 1 to 14.

38. A wireless sensor network device according to claim 37, wherein the sensor subsystem comprises at least one ECG sensor, and preferably four ECG sensors.

39. A wireless sensor network device according to claim 37, wherein the computation subsystem also comprises a dedicated real-time minimal TCP/IP stack.

40. A wireless sensor network device according to claim 37, wherein the wireless communication subsystem communicates with other devices or a network via a Bluetooth or Wifi protocol.

41. A wireless sensor network device according to claim 37, wherein the sensor subsystem also comprises means integrating the method of any one of claims 15 to 36.

42. A wireless sensor network device according to claim 37, wherein the sensor subsystem comprises one or more executable software programs on a data storage media which correspond to the method of any one of claims 15 to 36.

43. A wireless sensor network device according to claim 37, wherein the computation subsystem also comprises means integrating the method of any one of claims 15 to 36.

44. A wireless sensor network device according to claim 37, wherein the computation subsystem comprises one or more executable software programs on a data storage media which correspond to the method of any one of claims 15 to 36.

45. A wireless sensor network device according to claim 37, wherein the device further comprises memory storage means adapted to store captured ECG signals and other relevant data transiently or permanently.

46. A wireless sensor network device according to claim 45, wherein the transient memory storage means is chosen from the group consisting of a smartcard, secure digital (SD) card, a smartmedia card, and a usb memory stick.

47. Method for the diagnosis of cardiac arrhythmia, wherein the method comprises :

- placing a wireless sensor network device according to any one claims 37 to 47 on a person to be put under cardiac surveillance;
- placing ECG sensors in appropriate locations on said person;
- activating the device to capture ECG signals and process them in accordance with any one of claims 15 to 36;
- upon detection of arrhythmia by the device, issuing warnings to the person under surveillance via the device, a packet switched telephone network, wireless telephone network or via a computer network connection to a

Petitioner Ex-1004, 0331

BNSDOCID: <EP_____1724684A1_I_>

nearby computer terminal;
- optionally transmitting the data collected and analysed to a remote clinical facility for diagnosis or confirmation of diagnosis by a trained physician.

48. Method according to claim 47, wherein the method further comprises reprogramming or resetting the wireless sensor network device remotely via the network.

49. Method according to claim 47, wherein multiple wireless sensor network devices may be placed on multiple persons to be put under surveillance, thereby enabling a population of persons to be studied in real time.

50. Method according to claim 47, wherein the trained physician reprograms the operating mode of the device remotely from the patient via the network.

Petitioner Ex-1004, 0332

BNSDOCID: <EP_____1724684A1_I_>

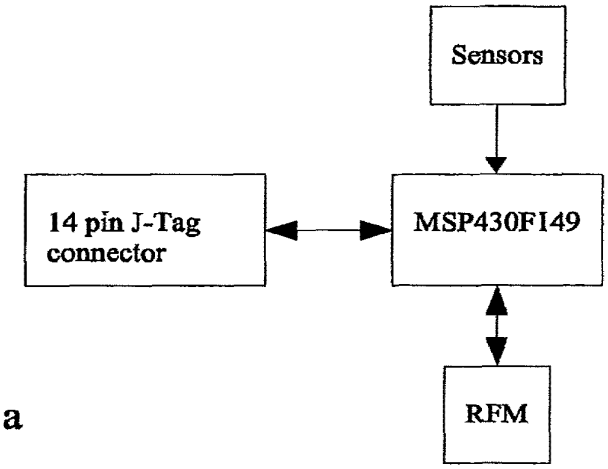


Fig. 1a

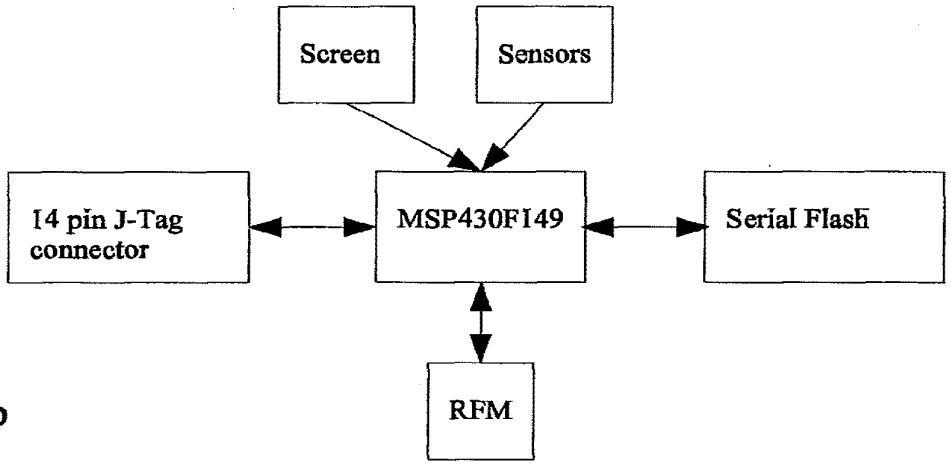


Fig. 1b

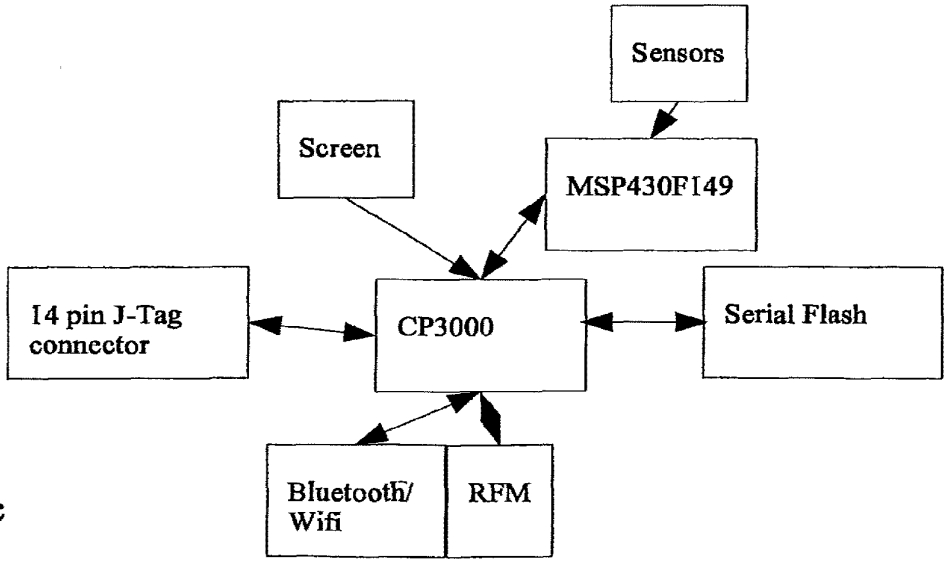


Fig. 1c

Petitioner Ex-1004, 0333

BNSDOCID: <EP_____1724684A1_I_>

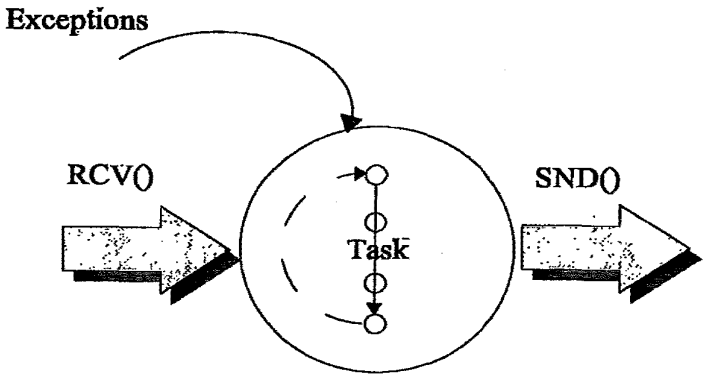


Fig. 2a

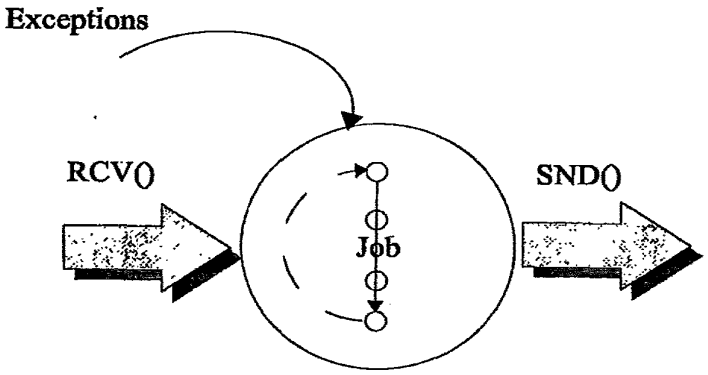


Fig. 2b

Petitioner Ex-1004, 0334

BNSDOCID: <EP_____1724684A1_I_>

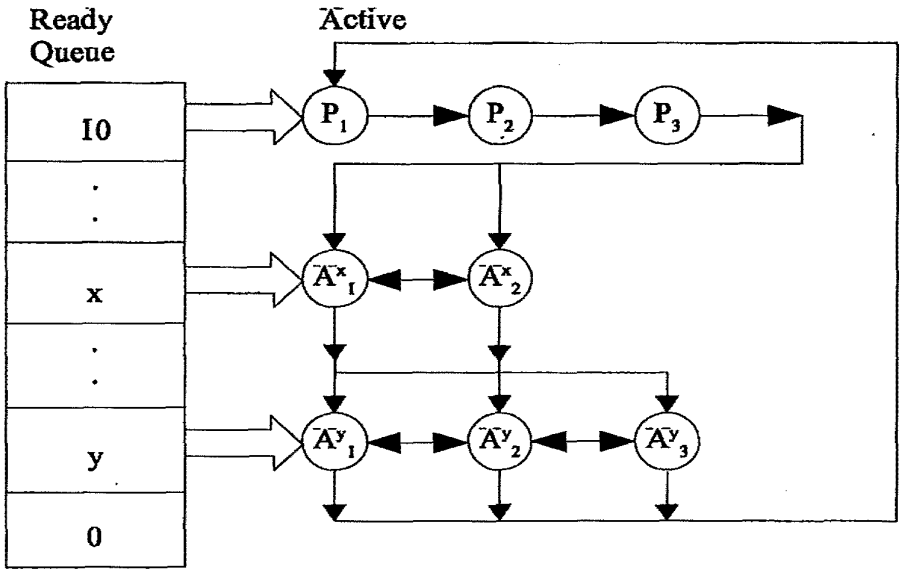


Fig. 3

Petitioner Ex-1004, 0335

BNSDOCID: <EP_____1724684A1_I_>

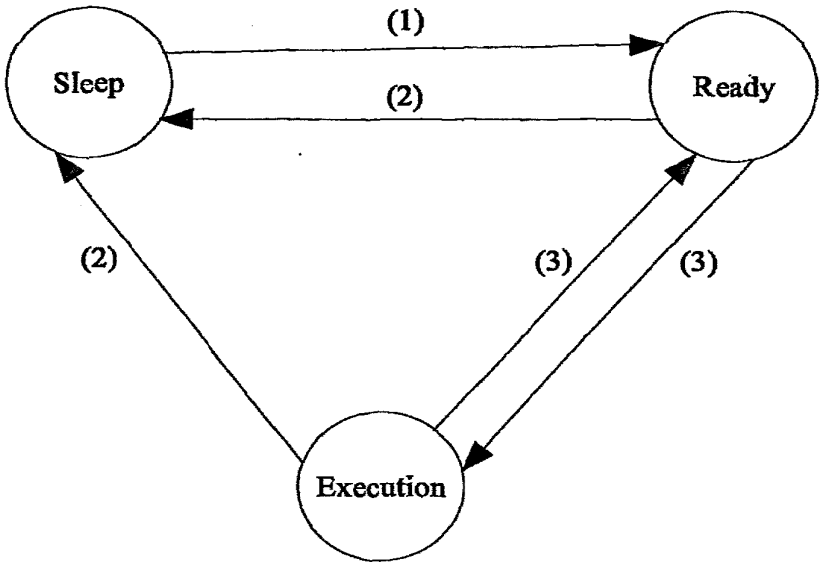


Fig. 4a periodic task

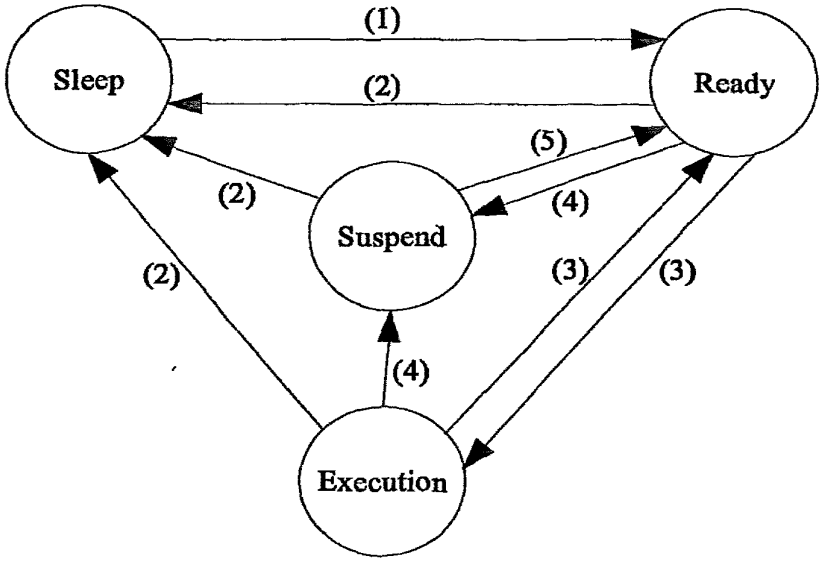


Fig. 4b priority task

Petitioner Ex-1004, 0336

BNSDOCID: <EP_____1724684A1_I_>

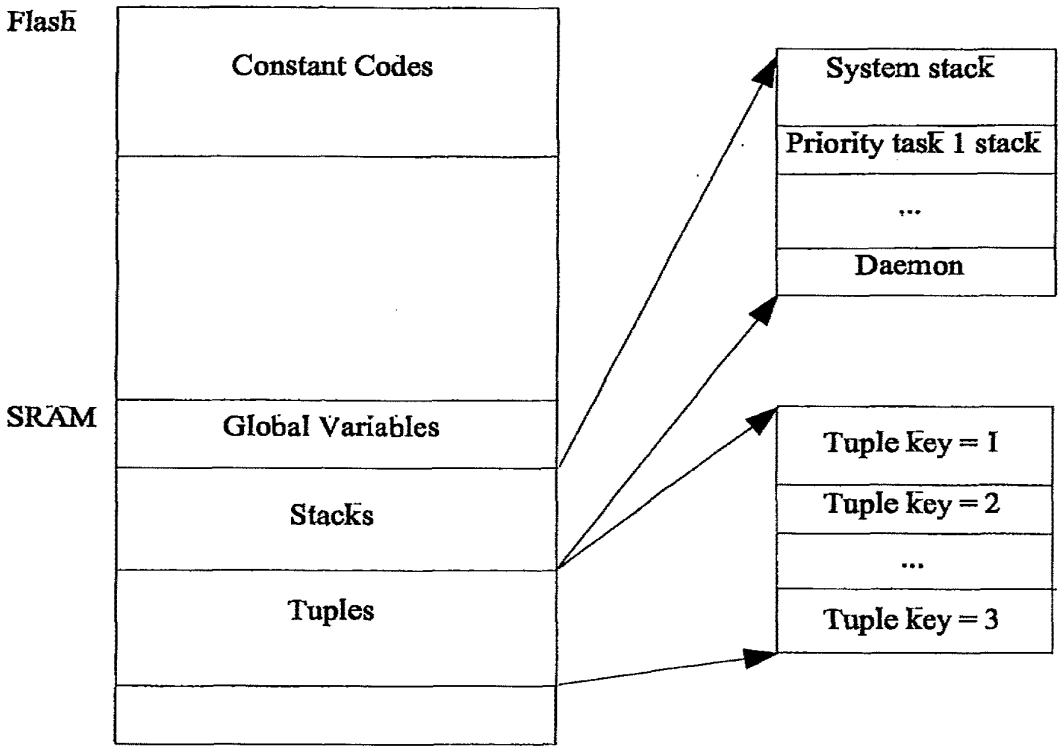


Fig. 5

Petitioner Ex-1004, 0337

BNSDOCID: <EP_____1724684A1_I_>

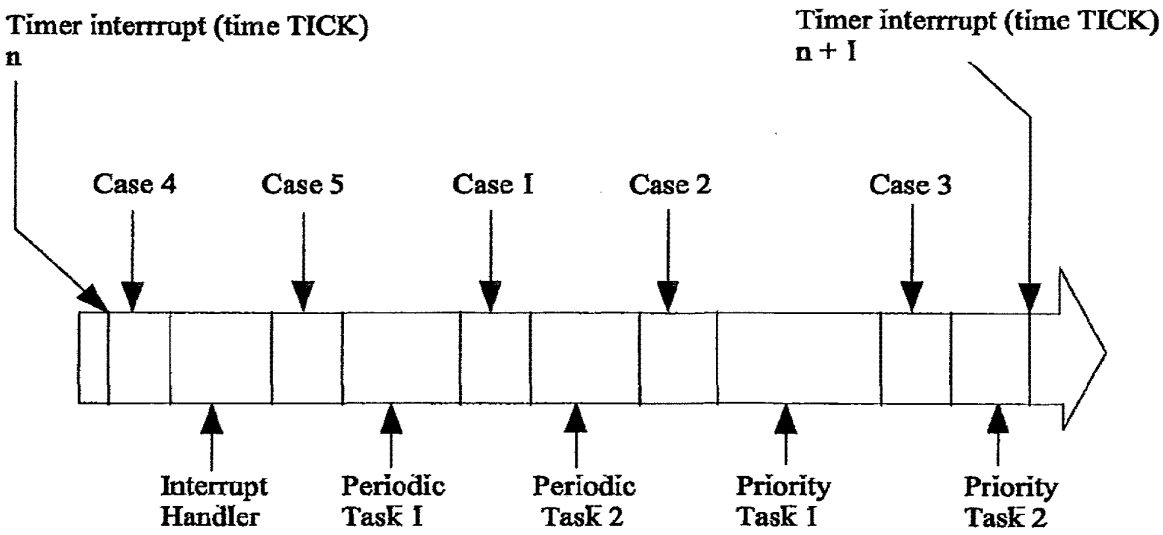


Fig. 6

Petitioner Ex-1004, 0338

BNSDOCID: <EP_____1724684A1_I_>

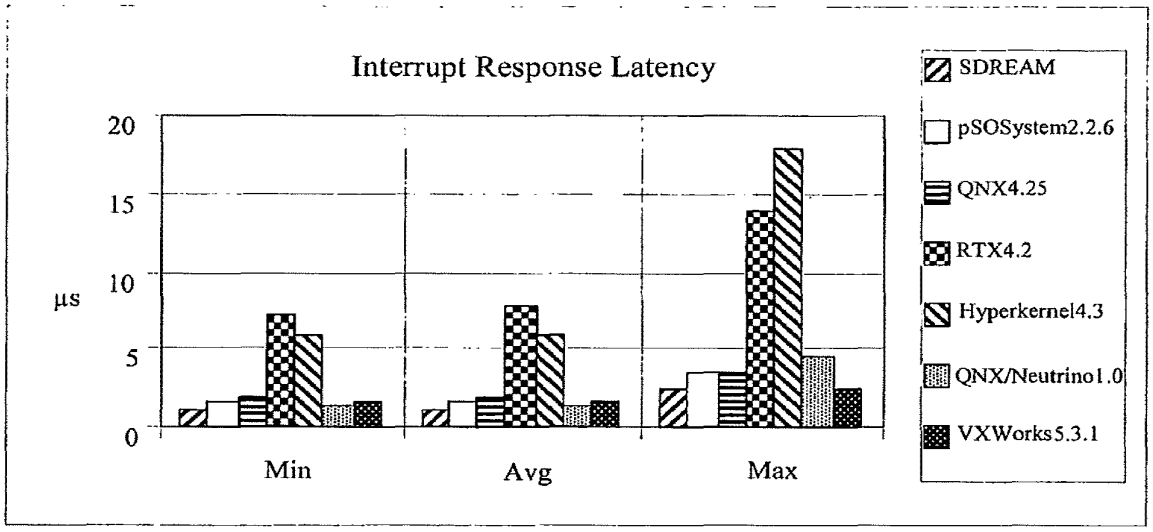


Fig. 7a

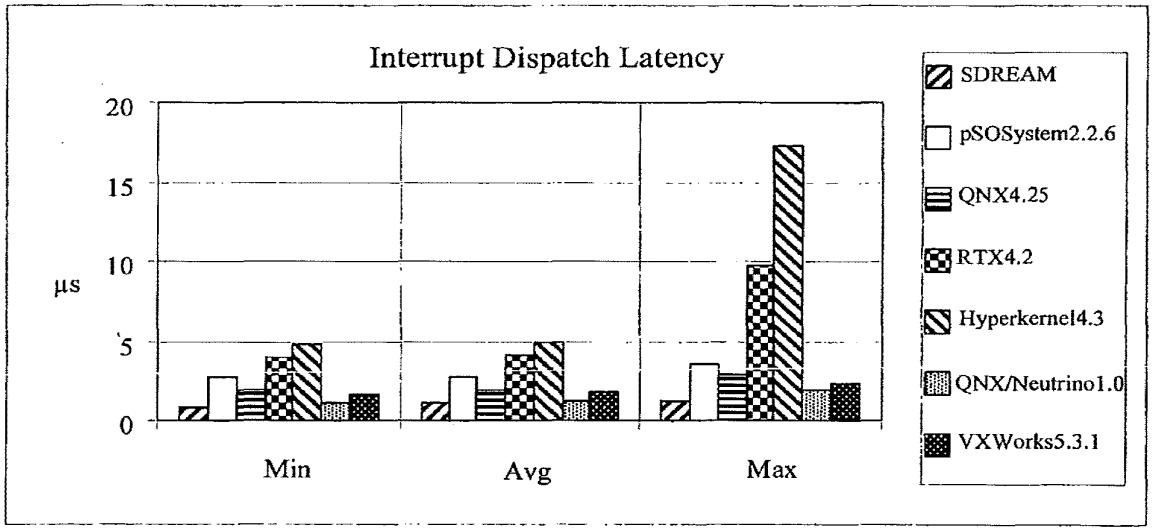


Fig. 7b

Petitioner Ex-1004, 0339

BNSDOCID: <EP_____1724684A1_I_>

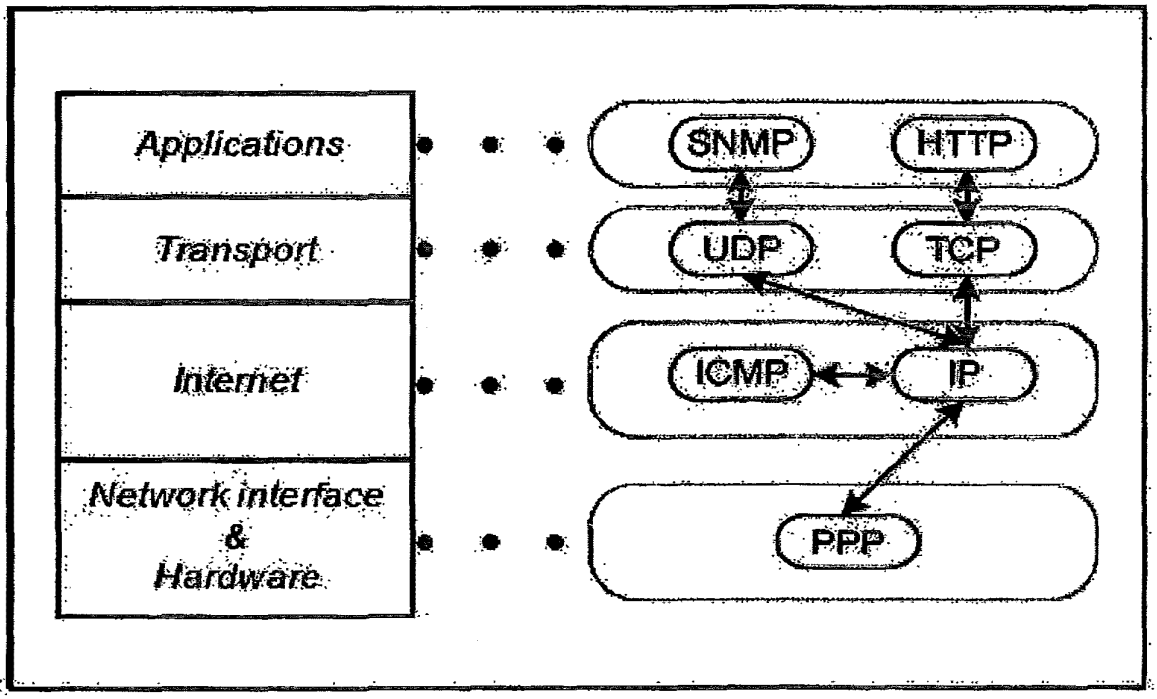


Fig. 8

Petitioner Ex-1004, 0340

BNSDOCID: <EP_____1724684A1_I_>

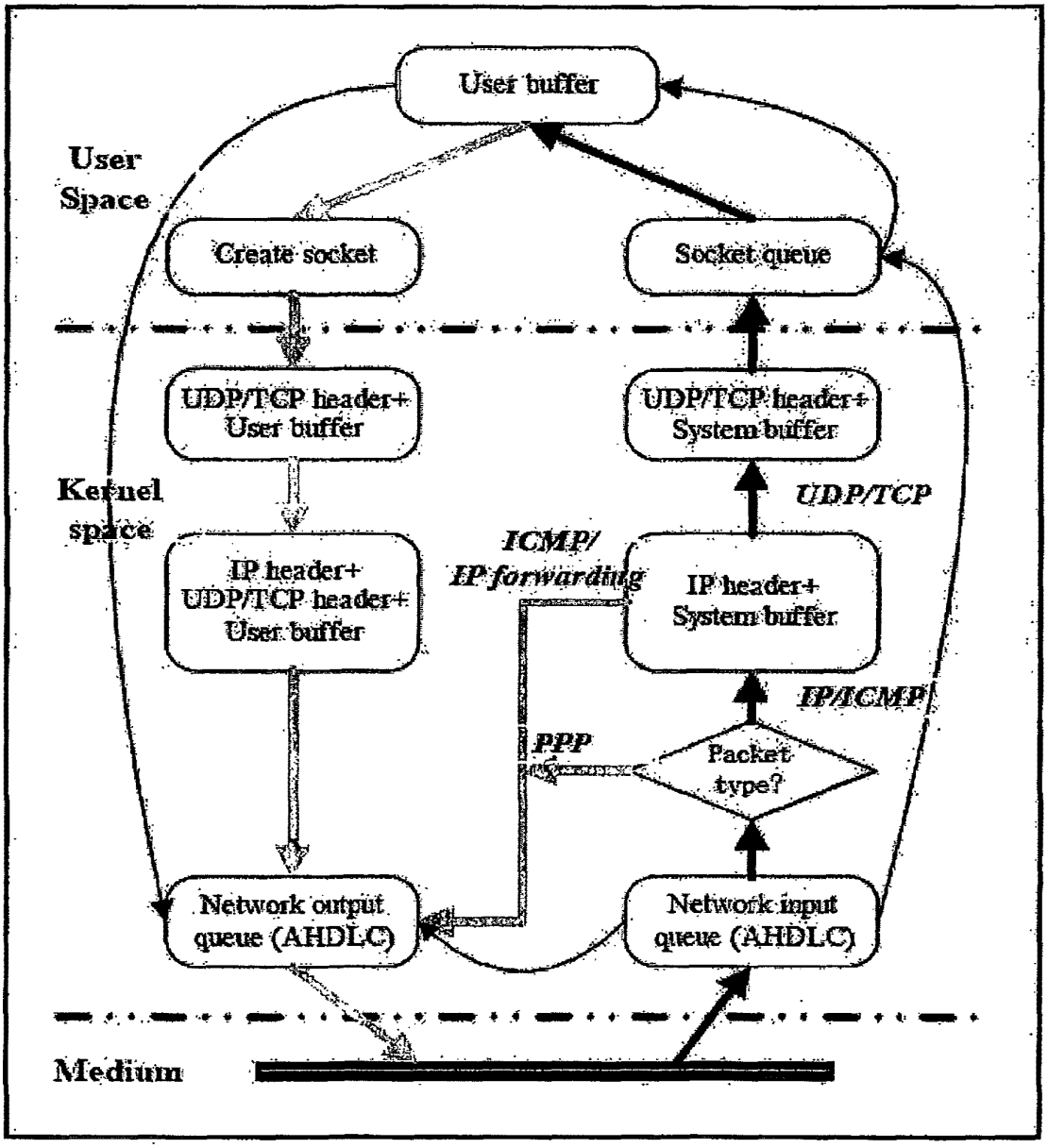


Fig. 9

Petitioner Ex-1004, 0341

BNSDOCID: <EP_____1724684A1_I_>

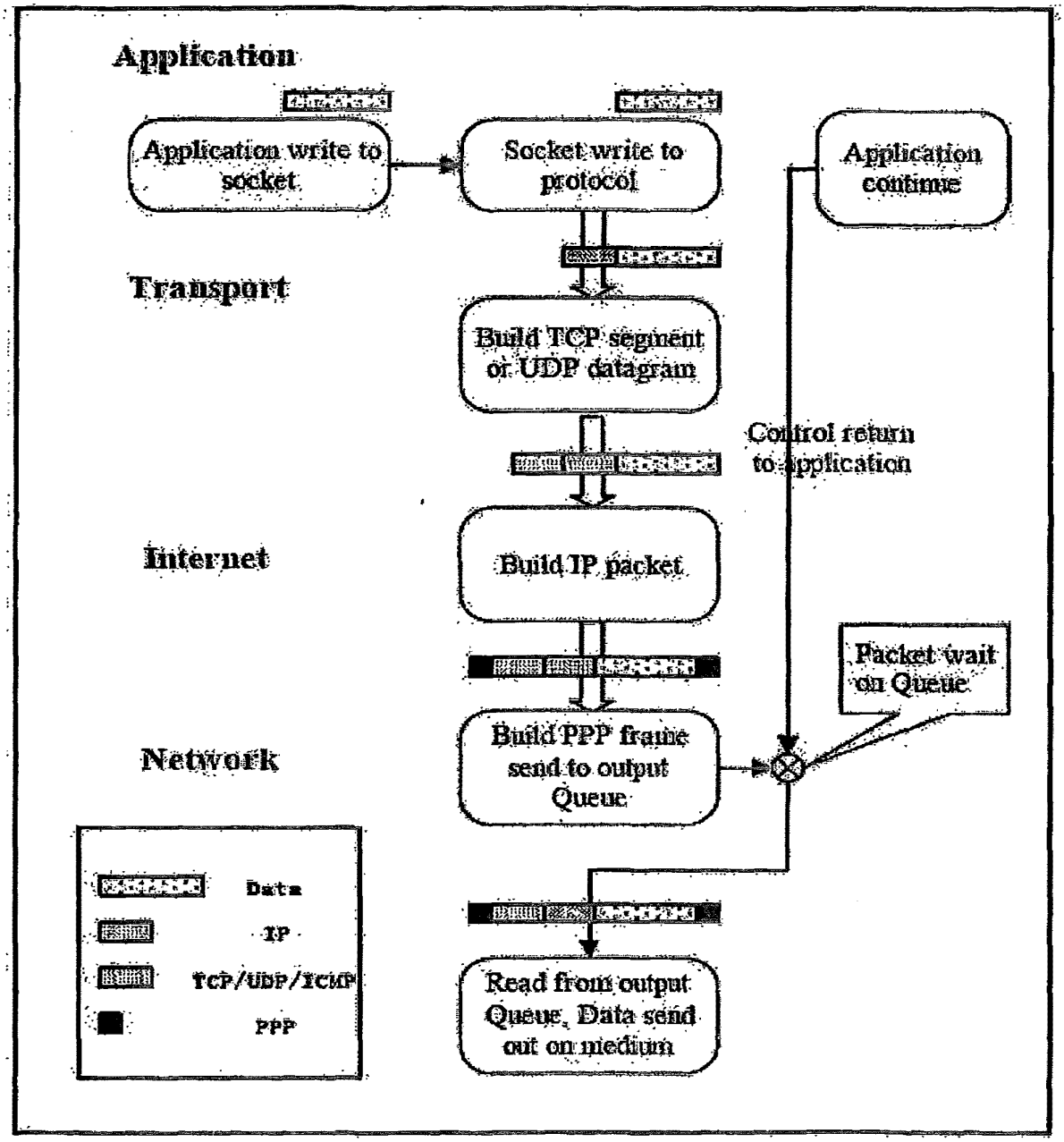


Fig. 10

Petitioner Ex-1004, 0342

BNSDOCID: <EP_____1724684A1_I_>

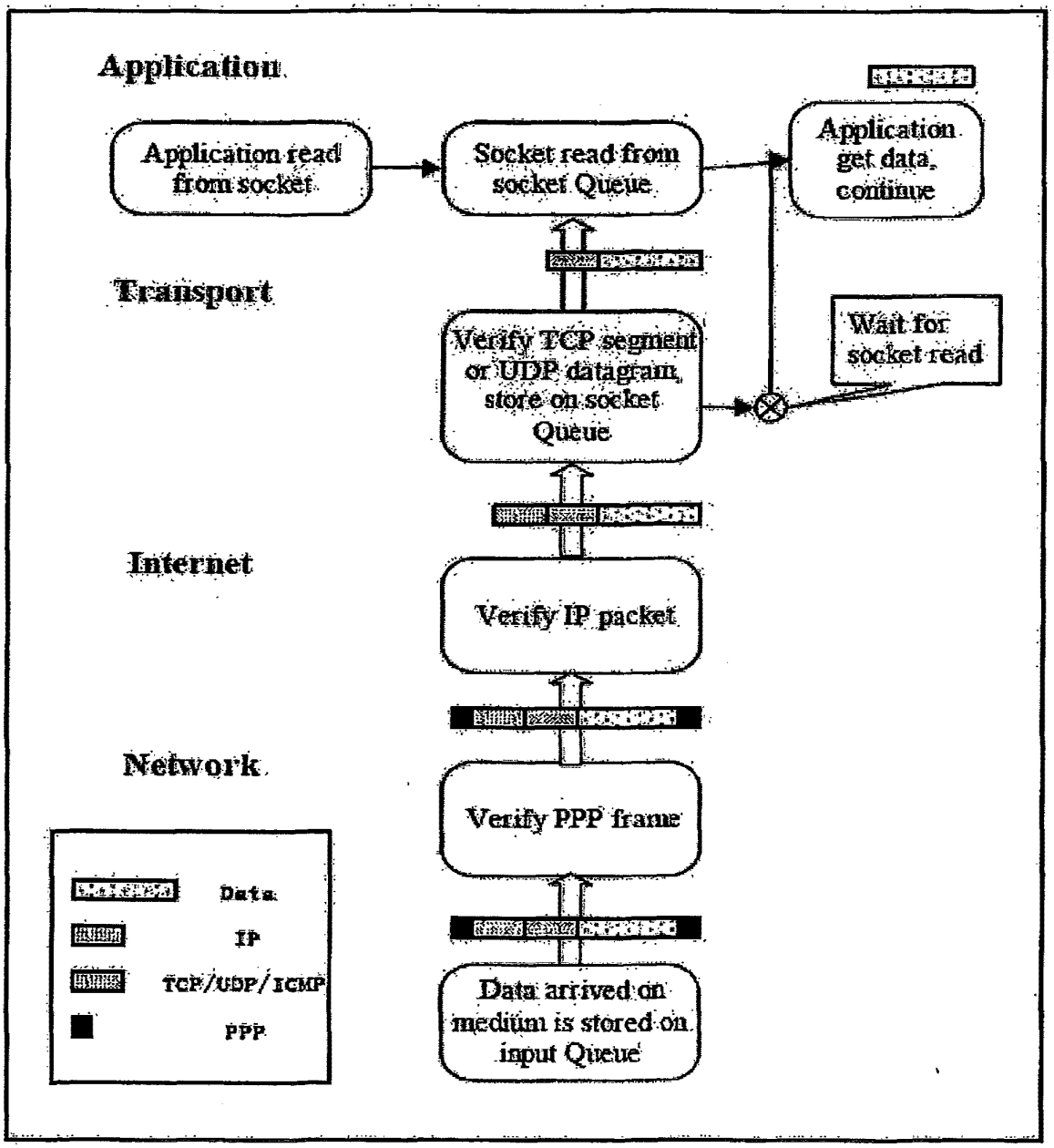


Fig. 11

Petitioner Ex-1004, 0343

BNSDOCID: <EP_____1724684A1_I_>

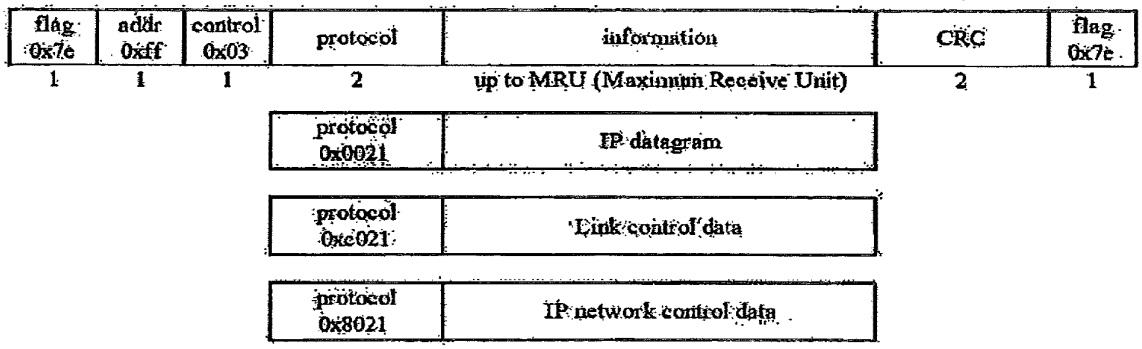


Fig. 12a

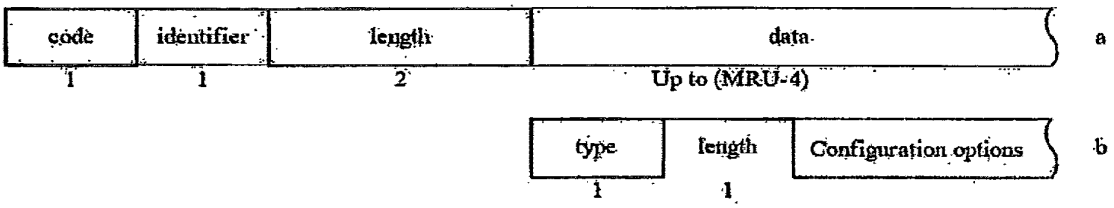


Fig. 12b

Petitioner Ex-1004, 0344

BNSDOCID: <EP_____1724684A1_I_>

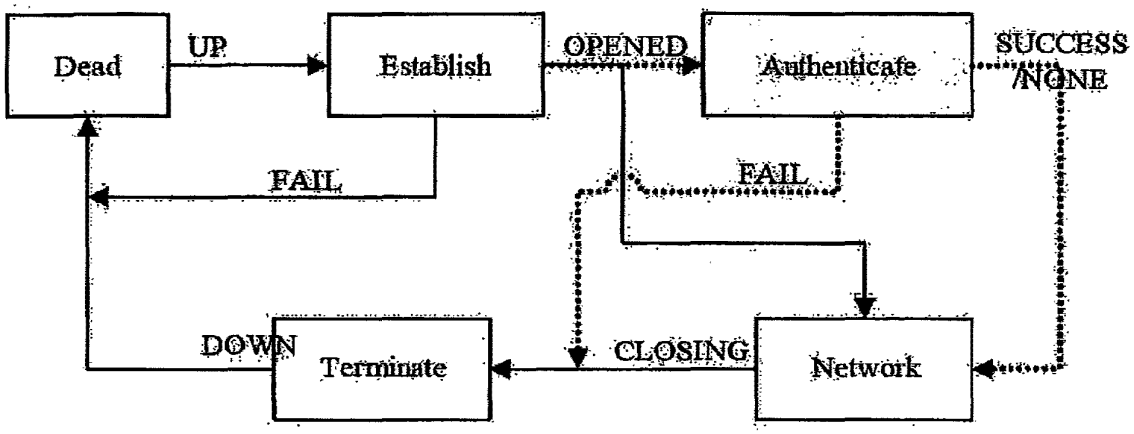


Fig. 13

Events		Actions		States
Up	Lower layer is Up	Tlu	This-Layer-Up	Initial/Closed
Down	Lower layer is down	Tld	This-Layer-Down	Closing
TO+	Timeout with counter >0	Irc	Initialize-Restart-Count	Req-sent
TO-	Timeout with counter expired	Zrc	Zero-Restart-Count	Ack-Rcvd
RCR-	Receive-Configure-Request (Good)	Scr	Send-Configure-Request	Ack-Sent
RCR+	Receive-Configure-Request (Bad)			Opened
RCA	Receive-Configure-Ack	Sca	Send-Configure-Ack	
RCN	Receive-Configure-Nak/Rej	Scn	Send-Configure-Nak/Rej	
RTR	Receive-Terminate-Request	Str	Send-Terminate-Request	
RTA	Receive-Terminate-Ack	Sta	Send-Terminate-Ack	
RUC	Receive-Unknown-Code	Scj	Send-Code-Reject	

Fig. 14

Petitioner Ex-1004, 0345

BNSDOCID: <EP_____1724684A1_I_>

State / Events	0 Initial(Closed)	1 Closing	2 Req-Sent	3 Ack-Rcvd	4 Ack-Sent	5 Opened
Up	tlu;irc,scr/2	-	-	-	-	-
Down	-	0	0	0	0	tld,irc,str/1
TO+	-	str/1	scr/2	scr/2	scr/4	-
TO-	-	tld/0	tld/0	tld/0	tld/0	-
RCR+	irc,scr,sca/4	sta/1	Sca/4	sca,tlu/5	sca/4	tld,scr,sca/4
RCR-	irc,scr,scn/2	sta/1	Scn/2	scn/3	scn/2	tld,scr,scn/2
RCA	-	sta/1	irc/3	scr/2	irc;tlu/5	tld,scr/2
RCN	-	sta/1	irc,scr/2	scr/2	Irc,scr/4	tld,scr/2
RTR	-	sta/1	sta/2	sta/2	sta/2	tld, zrc, sta/1
RTA	-	tld/0	2	2	4	tld,scr/2
RUX	-	scj/1	scj/2	scj/3	scj/4	scj/5

Fig. 15

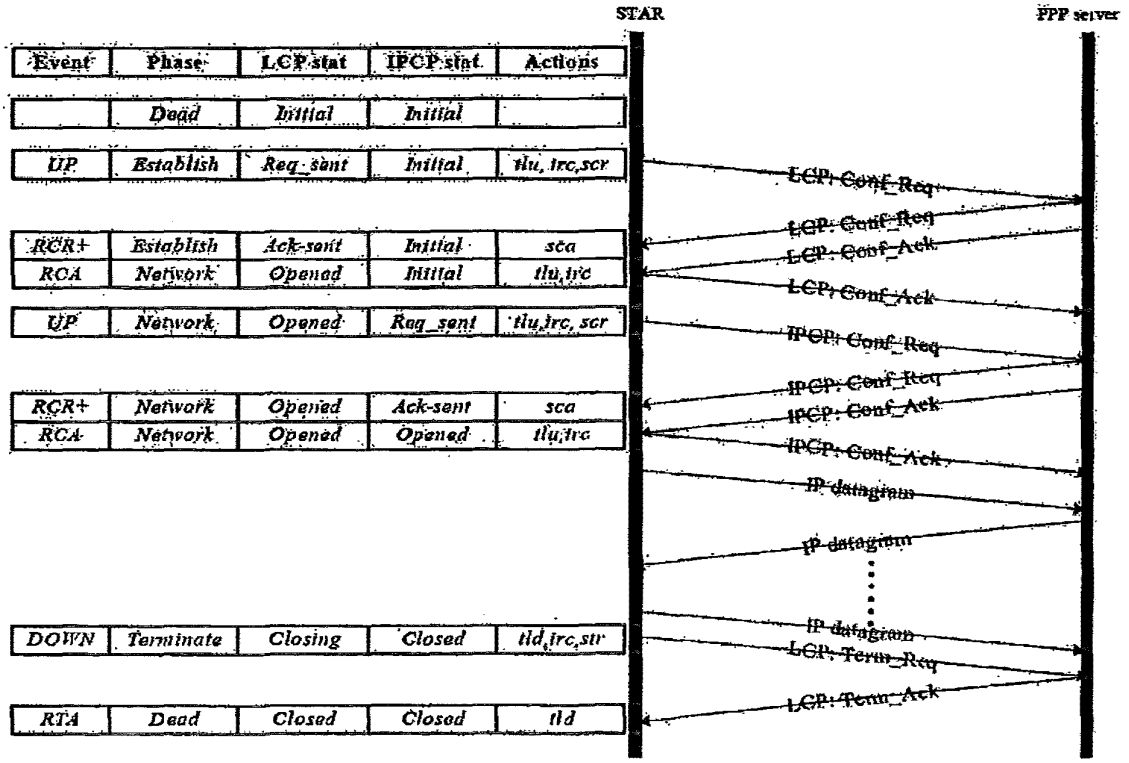


Fig. 16

Petitioner Ex-1004, 0346

BNSDOCID: <EP_____1724684A1_I_>

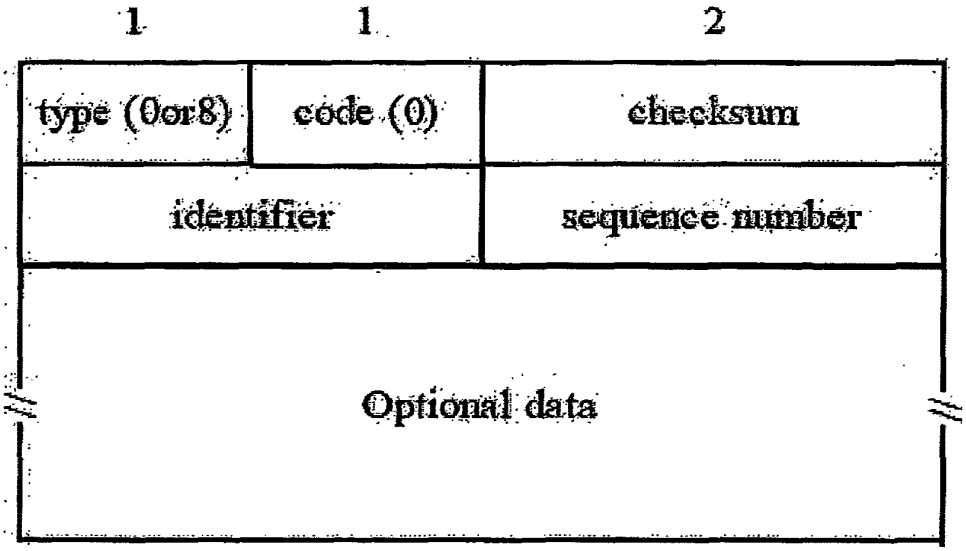


Fig. 17

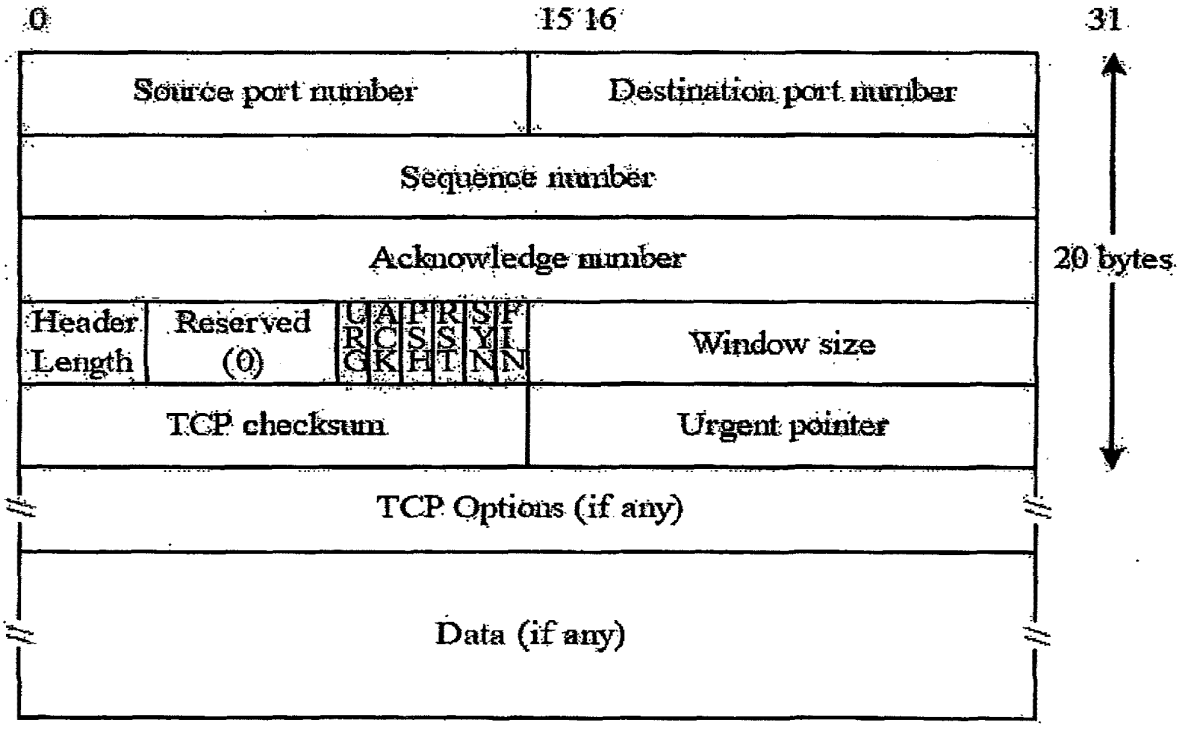


Fig. 18

Petitioner Ex-1004, 0347

BNSDOCID: <EP_____1724684A1_I_>

Flag bit	Meaning if Bit is set to 1
URG	The Urgent pointer field is valid
ACK	The Acknowledgement field is valid
PSH	This segment requests a push, the data should be sent to the application as soon as possible
RST	Reset the connection
SYN	Synchronize sequence numbers to initiate a connection
FIN	The sender is finished sending data

Fig. 19

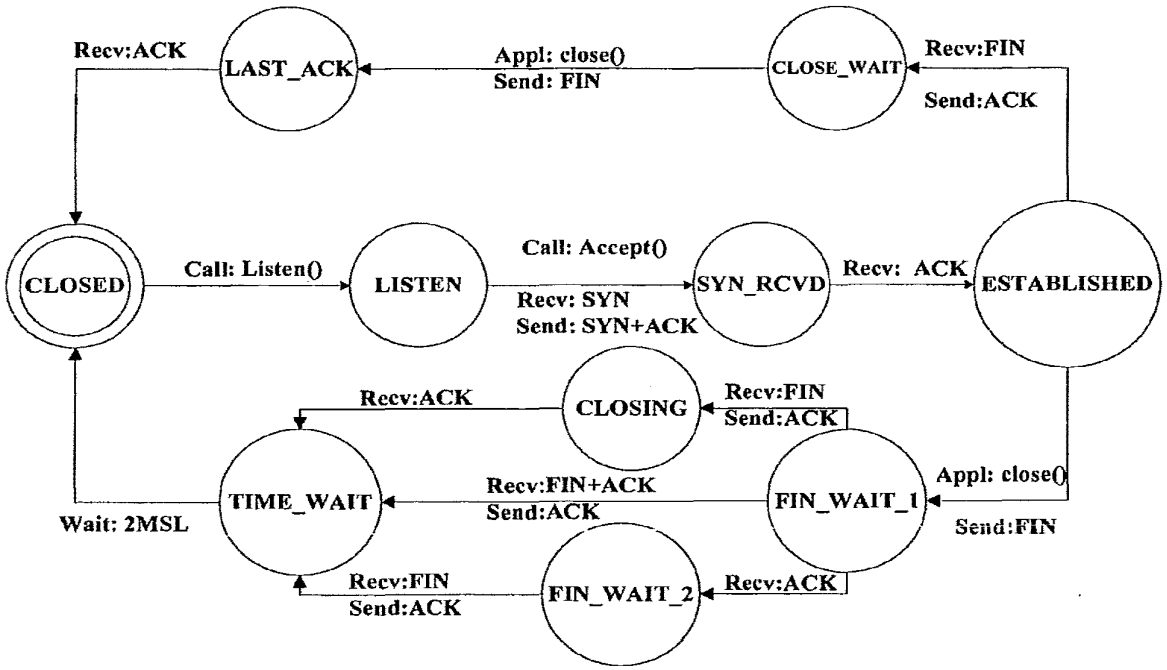


Fig. 20

Petitioner Ex-1004, 0348

BNSDOCID: <EP_____1724684A1_I_>

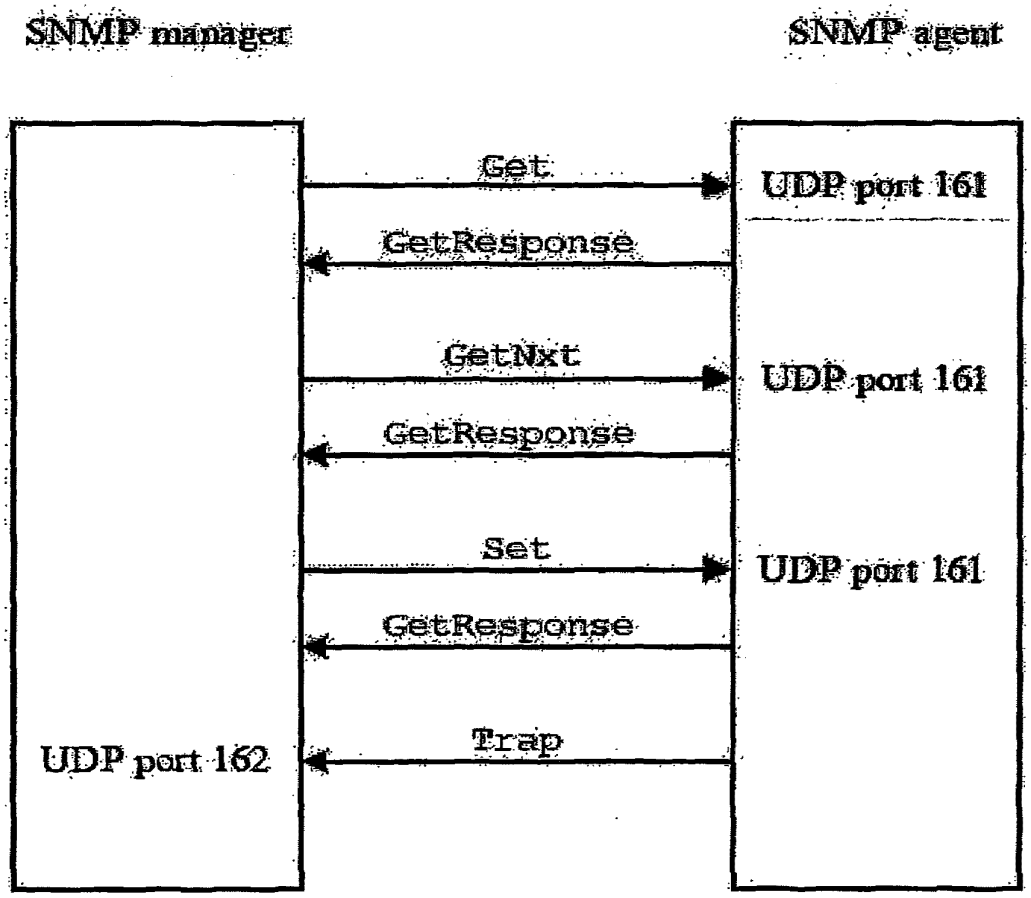


Fig. 21

Petitioner Ex-1004, 0349

BNSDOCID: <EP_____1724684A1_I_>

MIB	Name	Data type	R/W	Description
System (1.3.6.1.2.1.1)	SysDesr(1)	BYTE	R	Textual description of entity.
	SysObjectID(2)	OID	R	Vendor's ID within the subtree 1.3.6.1.4.1
	SysUpTime(3)	TIMETICKS	R	Time in hundredths of a second since network management
	SysContact(4)	BYTE	R & W	Name of contact person and how to contact them
	SysName(5)	BYTE	R & W	Node's fully qualified domain name
	SysLocation(6)	BYTE	R & W	Physical location of node
STAR (1.3.6.1.4.1.?.1)	PrlTskNum(1)	INT	R	Number of priority processes
	PrdTskNum(2)	INT	R	Number of period processes
	ECGONOFF(3)	INT	R & W	One-off of ECG telemedicine process
	TimePeriod(4)	INT	R	Switch time(ms) of STAR system scheduler
	MTU(5)	INT	R	Maximum Transmit unit of network packets
	SrvAddress(6)	IPADDR	R	IP address of SNMP agent

Fig. 22

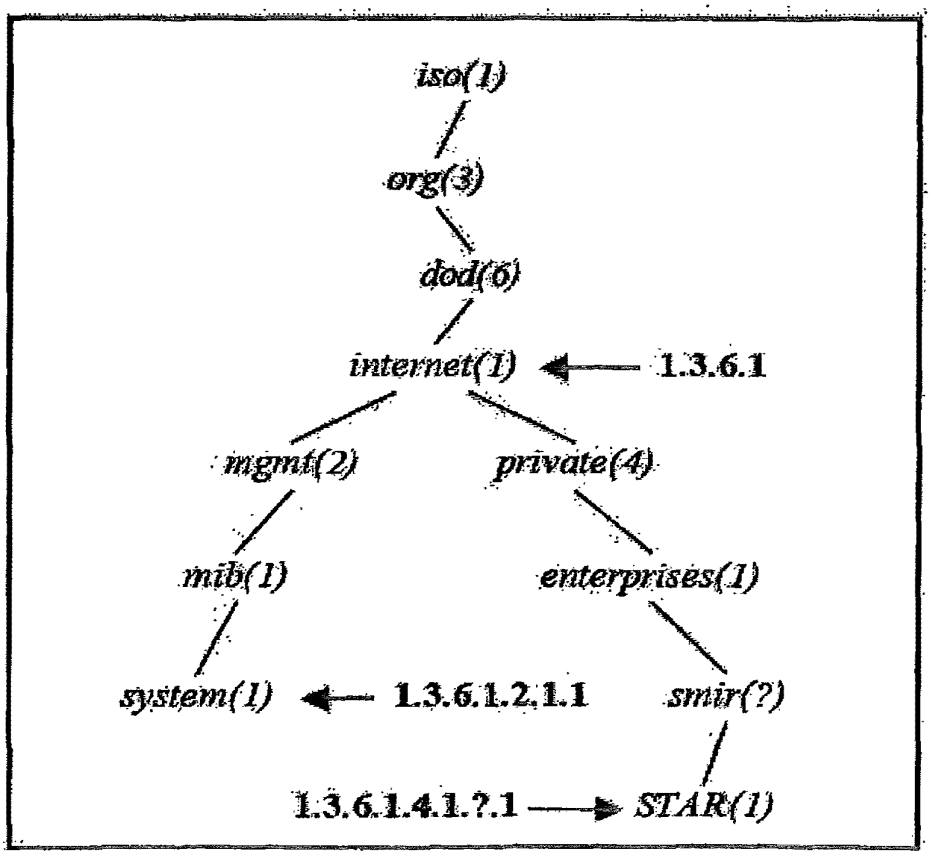


Fig. 23

Petitioner Ex-1004, 0350

BNSDOCID: <EP_____1724684A1_I_>

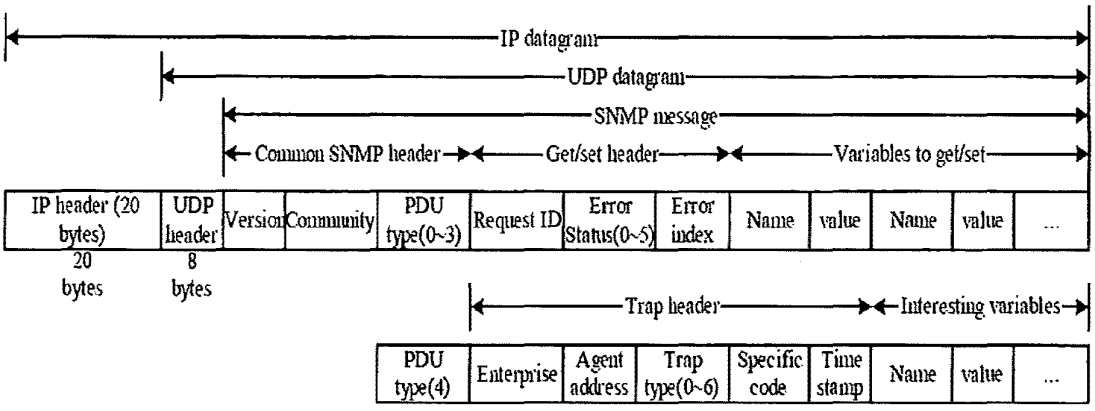


Fig. 24

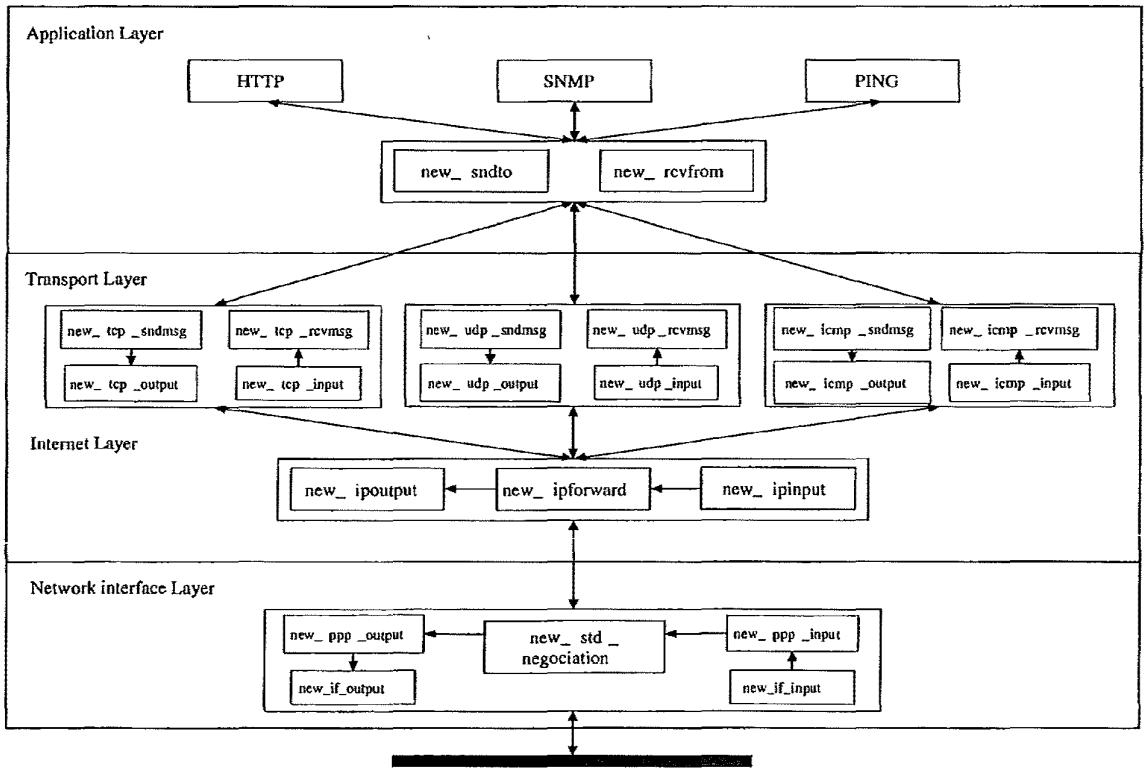


Fig. 25

Petitioner Ex-1004, 0351

BNSDOCID: <EP_____1724684A1_I_>

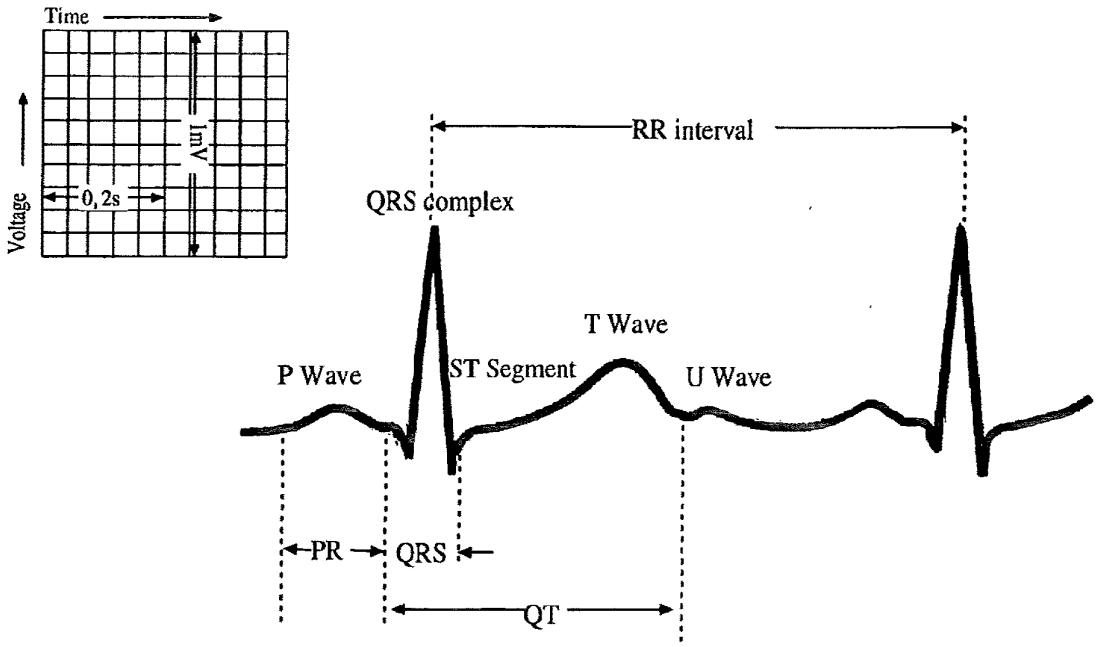


Fig. 26

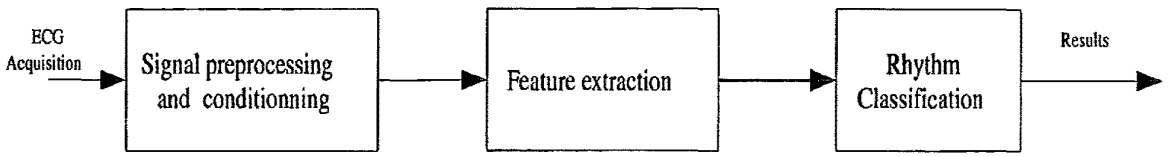


Fig. 27

Petitioner Ex-1004, 0352

BNSDOCID: <EP_____1724684A1_I_>

	Statistical	Structural
Foundation	Statistical decision theory	Human perception and cognition
Description	Quantitative features	Morphological primitives
	Fixed number of features	Variable number of primitives
	Ignores feature relationships	Captures primitive relationships
	Semantics from feature position	Semantics from primitive encoding
Classification	Statistical classifiers	Parsing with syntactic grammars

Fig. 28

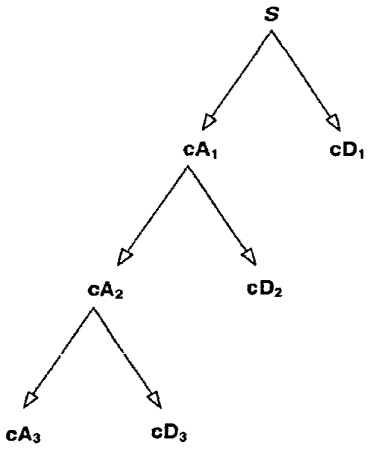


Fig. 29a

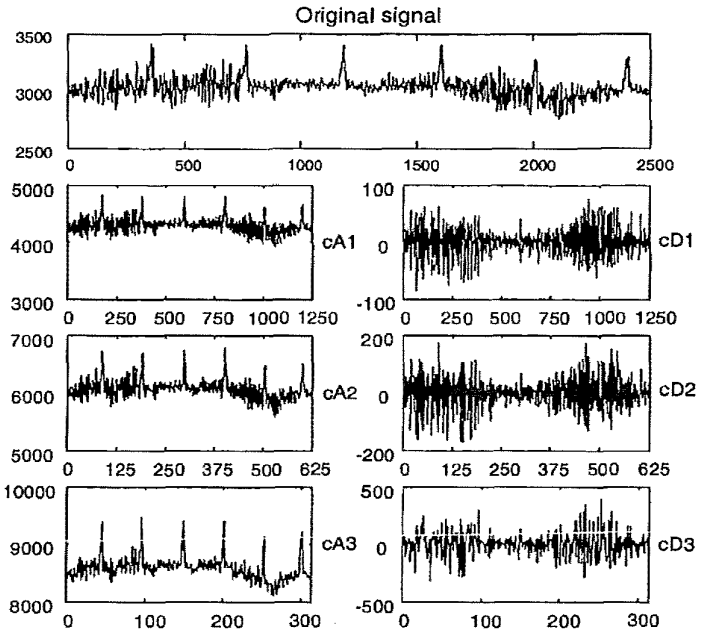


Fig. 29b

Petitioner Ex-1004, 0353

BNSDOCID: <EP_____1724684A1_I_>

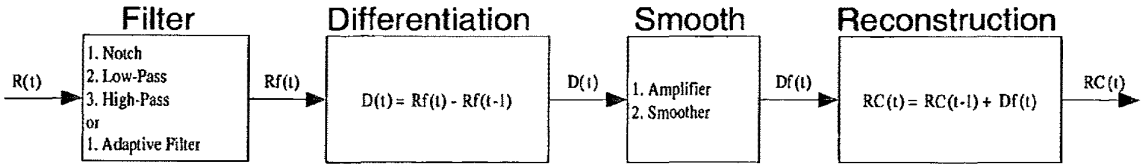


Fig. 30

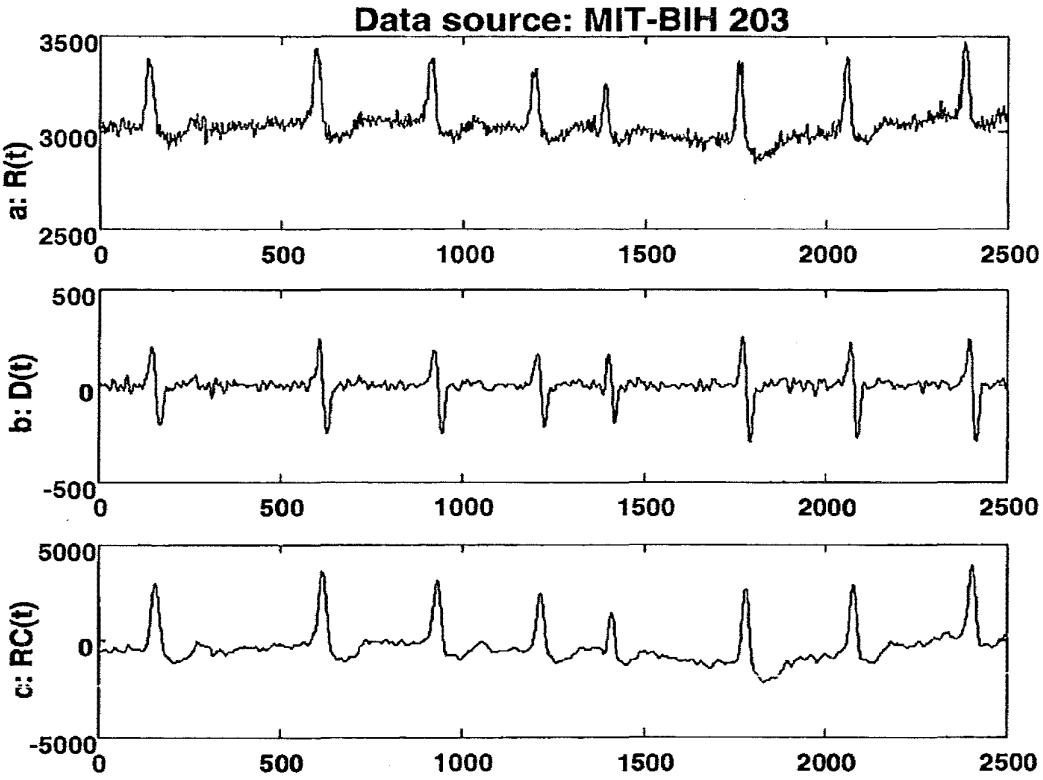


Fig. 31

Petitioner Ex-1004, 0354

BNSDOCID: <EP_____1724684A1_I_>

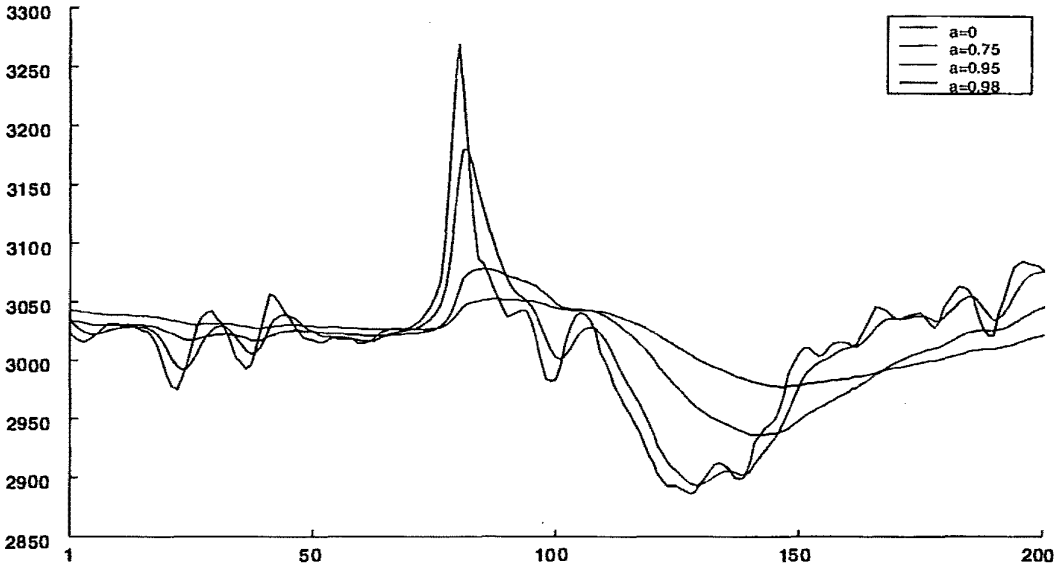


Fig. 32

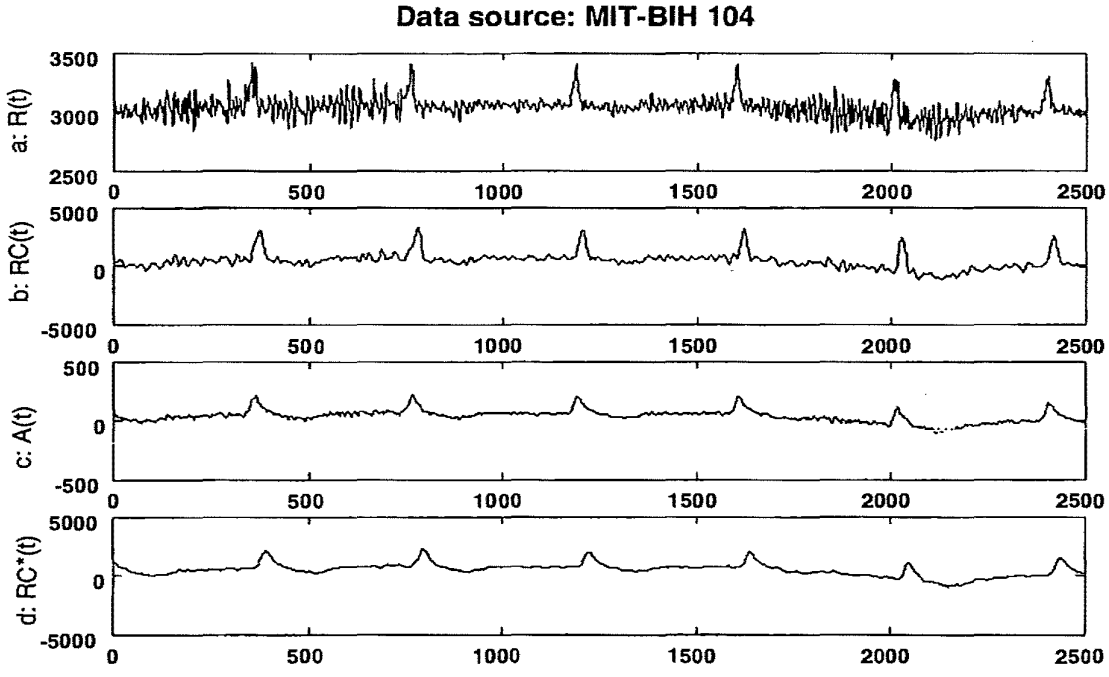


Fig. 33

Petitioner Ex-1004, 0355

BNSDOCID: <EP_____1724684A1_I_>

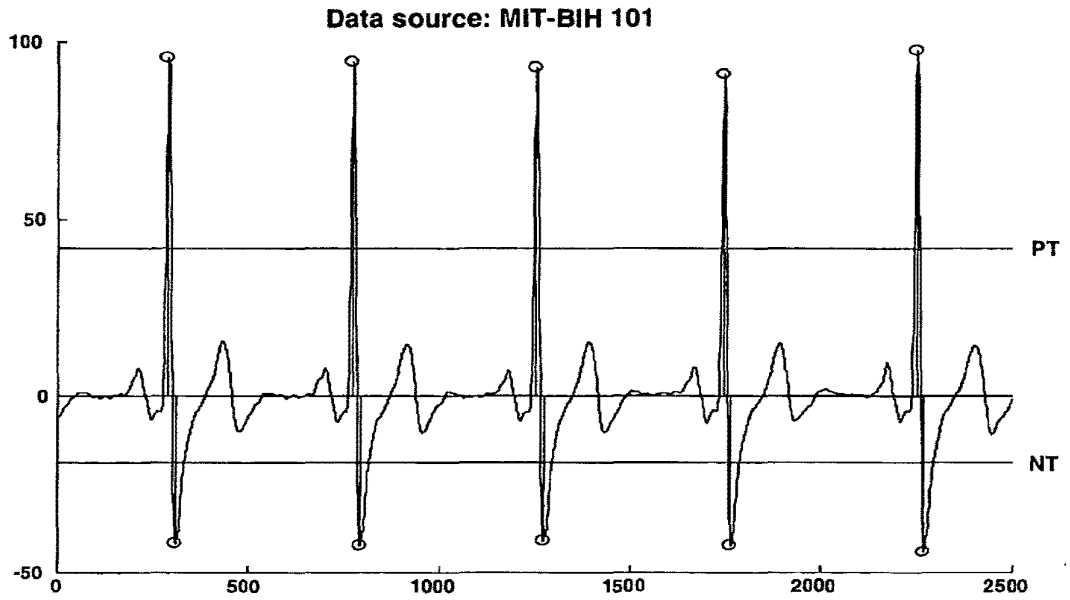


Fig. 34

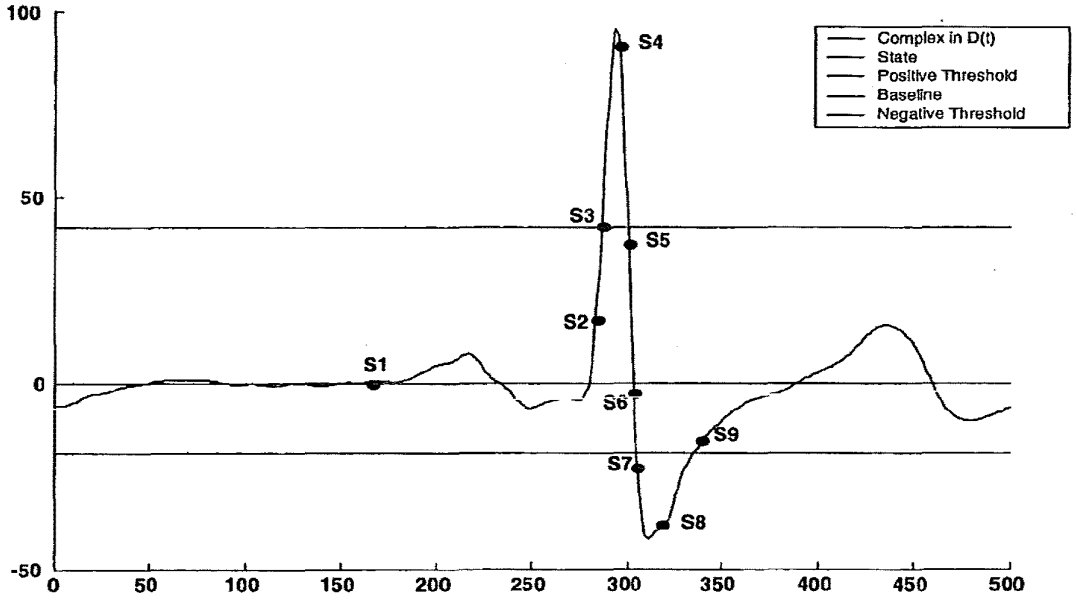


Fig. 35

Petitioner Ex-1004, 0356

BNSDOCID: <EP_____1724684A1_I_>

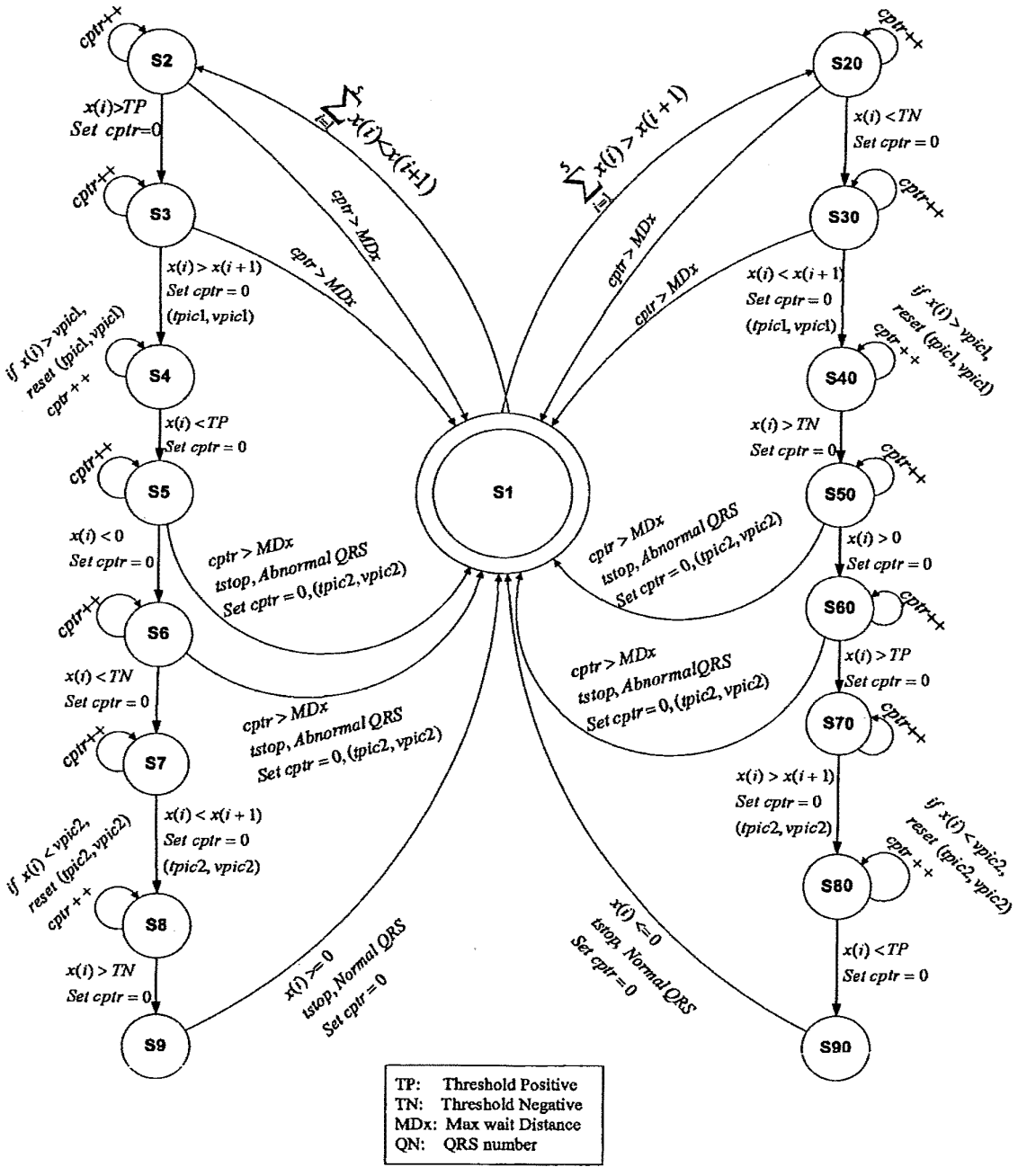


Fig. 36

Petitioner Ex-1004, 0357

BNSDOCID: <EP_____1724684A1_I_>

Label	Rhythm	Criteria/ definition	Alarm Level
VA	Ventricular Asystole	• Cardiac arrest, no QRS complexes for 5 s	Red
VF	Ventricular Fibrillation	• Absence of QRS complexes • Consecutive irregular waveforms with high enough amplitude and rate	Red
VT	Ventricular Tachycardia	• HR(cur) > 120bmp • >= 3 ESVs	Red
PVCs/ ESV	Premature Ventricular Contraction	• rate > 120bmp • LQRS >120ms (Wide QRS Complexes) • Ventricular rhythm	Yellow
PACs	Premature atrial Contraction	• Regular waveforms (Narrow QRS complexes) • Irregular sinus rhythm	Yellow
SB	Sinus Bradycardia	• Consecutive HR(cur)<50bpm • Sinus rhythm	Yellow
ST	Sinus Tachycardia	• Consecutive HR>120bpm && HR>1.5*HR(avg) • Sinus rhythm	White
SVT	Supraventricular Tachycardia	• A sequence of Continuous HR(cur) >150bmp && HR(cur) <250bmp • Sinus rhythm	Yellow
DB	Dropped beats	• HR(cur) = N* HR(avg), N=2,3,... • Sinus rhythm	White
SP	Sinus pause	• RR > 1.7s && RR < 3s • Sinus rhythm	Yellow
SA	Sinus arrest	• RR >3s • Sinus rhythm	Yellow

Fig. 37

Petitioner Ex-1004, 0358

BNSDOCID: <EP_____1724684A1_I_>

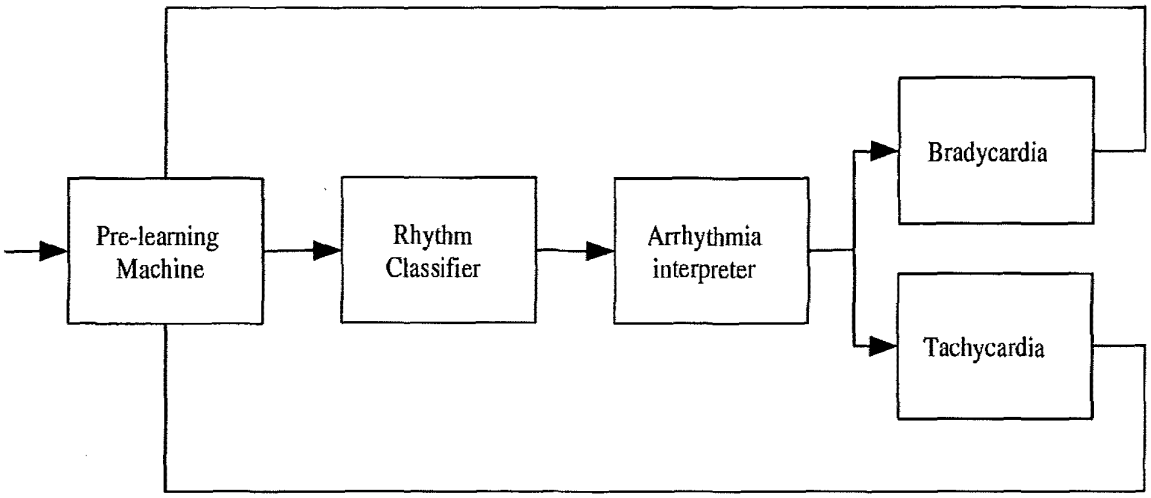


Fig. 38

Petitioner Ex-1004, 0359

BNSDOCID: <EP_____1724684A1_I_>

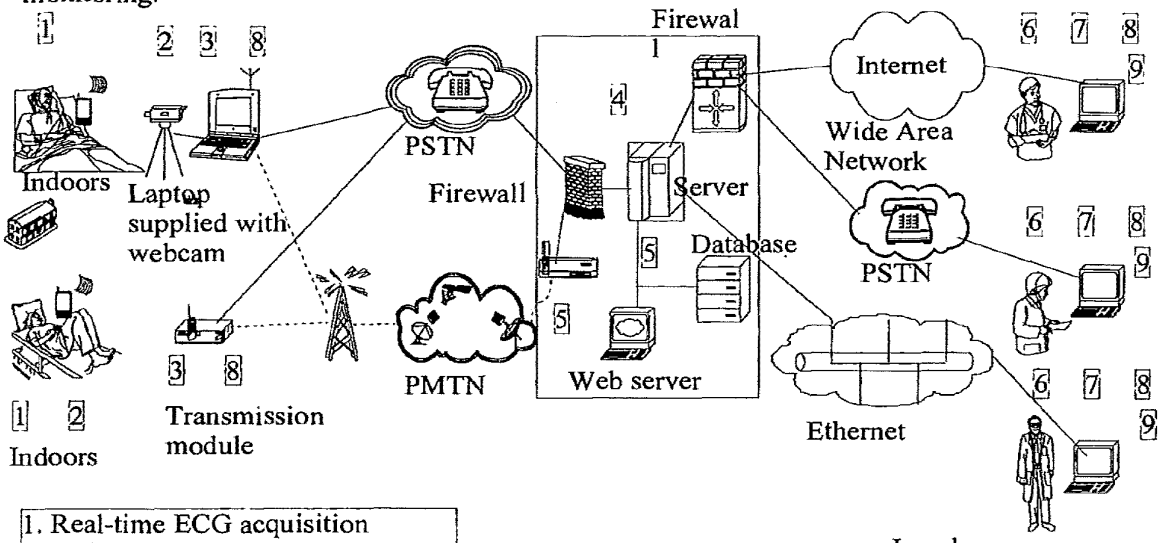
Data base	File	Beats	QRS detection				Level-I correction				Level-II correction			
			TP	FN	FP	SH	TP	FN	FP	SH	TP	FN	FP	SH
MIT-BIH	100	2273	2273	0	0	0	2273	0	0	0	2273	0	0	0
	101	1865	1864	1	4	0	1864	1	1	0	1862	3	2	0
	102	2187	2187	0	0	0	2187	0	0	0	2187	0	0	0
	103	2084	2083	1	0	0	2083	1	0	0	2083	1	0	0
	104	2229	2225	1	30	1	2223	5	5	0	2221	8	5	0
	105	2572	2509	63	153	10	2525	47	78	15	2512	60	56	13
	106	2027	2014	13	42	1	2009	18	3	2	1991	36	2	1
	107	2137	2115	11	6	2	2124	12	4	2	2125	12	5	2
	118	2278	2274	4	19	0	2279	4	2	0	2261	17	3	1
	119	1987	1987	0	193	0	1987	0	1	0	1955	32	37	31
	200	2601	2600	1	31	0	2594	7	2	0	2592	9	4	0
	201	1963	1952	11	116	9	1945	18	11	6	1946	17	19	3
	202	2136	2130	6	6	3	2131	5	3	2	2070	66	1	1
	203	2980	2917	63	97	21	2866	114	23	7	2872	108	14	6
	205	2656	2648	8	11	0	2648	8	7	1	2647	9	2	1
	208	2955	2933	22	19	5	2933	22	7	3	2921	34	6	2
	209	3005	3000	5	7	1	2998	7	4	1	2999	6	4	1
	210	2650	2638	12	8	1	2635	15	3	0	2636	14	3	0
	212	2748	2739	9	16	9	2745	3	5	3	2726	22	4	4
	213	3251	3249	1	0	0	3249	1	0	0	3250	1	0	0
	214	2262	2255	7	12	1	2254	8	5	2	2254	8	4	1
	215	3363	3347	16	3	0	3346	17	0	0	3362	1	1	0
	217	2208	2199	9	70	3	2199	9	20	2	2198	10	4	2
	219	2154	2152	2	2	0	2151	3	1	0	2148	6	3	0
	Total	58571	58300	268	855	67	58243	325	185	46	58091	480	180	69
	Result		Se=0.994287 Sp=0.985546				Se=0.993670 Sp=0.996834				Se=0.990638 Sp=0.996911			
CSD	P1	541	541	0	2	0	539	2	0	0	541	0	0	0
	P2	1470	1440	30	29	2	1438	32	22	2	1465	5	4	0
	P3	1127	1120	7	20	6	1120	7	10	6	1124	3	5	2
	P4	820	812	2	5	0	811	3	1	0	817	2	0	0
	P5	975	969	0	5	0	969	0	1	0	972	0	1	0
	P6	994	972	15	21	4	972	15	11	5	985	4	7	0
	P7	1295	1284	4	23	0	1283	5	10	2	1289	5	3	2
	P8	1279	1272	1	15	0	1272	1	5	0	1275	4	0	0
	P9	1050	1044	1	35	1	1032	12	33	12	1047	2	5	0
	P10	1062	1053	4	66	2	1040	17	42	15	1057	5	3	1
	Total	10613	10507	64	221	15	10476	94	135	42	10572	30	28	5
	Result		Se=0.992537 Sp=0.979400				Se=0.987184 Sp=0.987277				Se=0.996700 Sp=0.997358			

Fig. 39

Petitioner Ex-1004, 0360

BNSDOCID: <EP_____1724684A1_I_>

Platform dedicated to real time remote continuous arrhythmia detection and monitoring.



1. Real-time ECG acquisition module
2. Real-time ECG diagnosis module
3. Real-time communication module
4. Dial-up server module
5. Database module
6. ECG visualisation module
7. Report point module
8. Remote communication module
9. Remote surveillance module

Fig. 40

1 bit	2 bits	1 or 5 or 9 or 13 bits
+/-	type	data
	00	1
	01	5
	10	9
	11	13

Fig. 41

Petitioner Ex-1004, 0361

BNSDOCID: <EP_____1724684A1_I_>

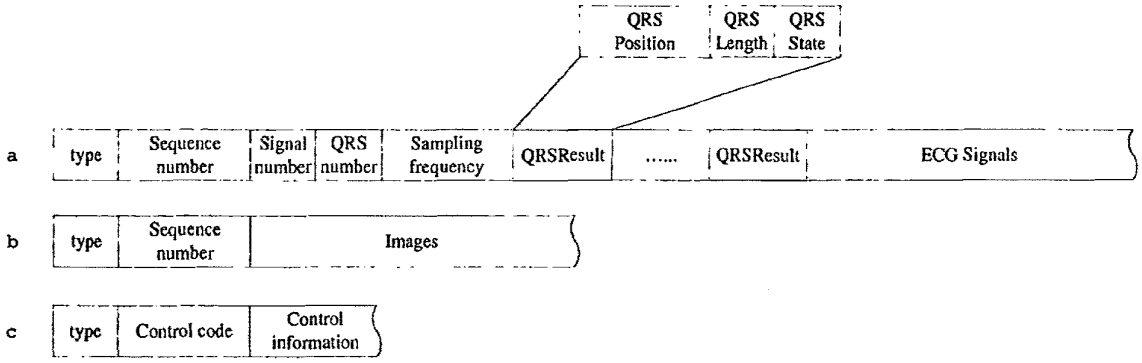


Fig. 42

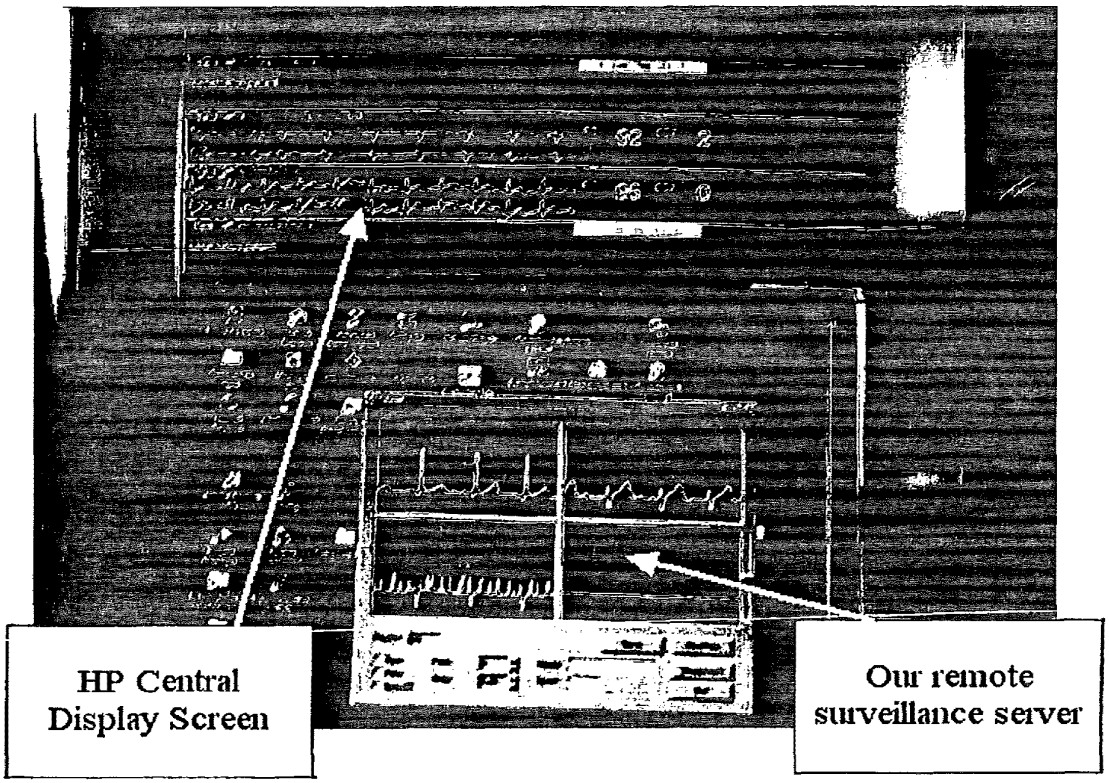


Fig. 43

Petitioner Ex-1004, 0362

BNSDOCID: <EP_____1724684A1_I_>

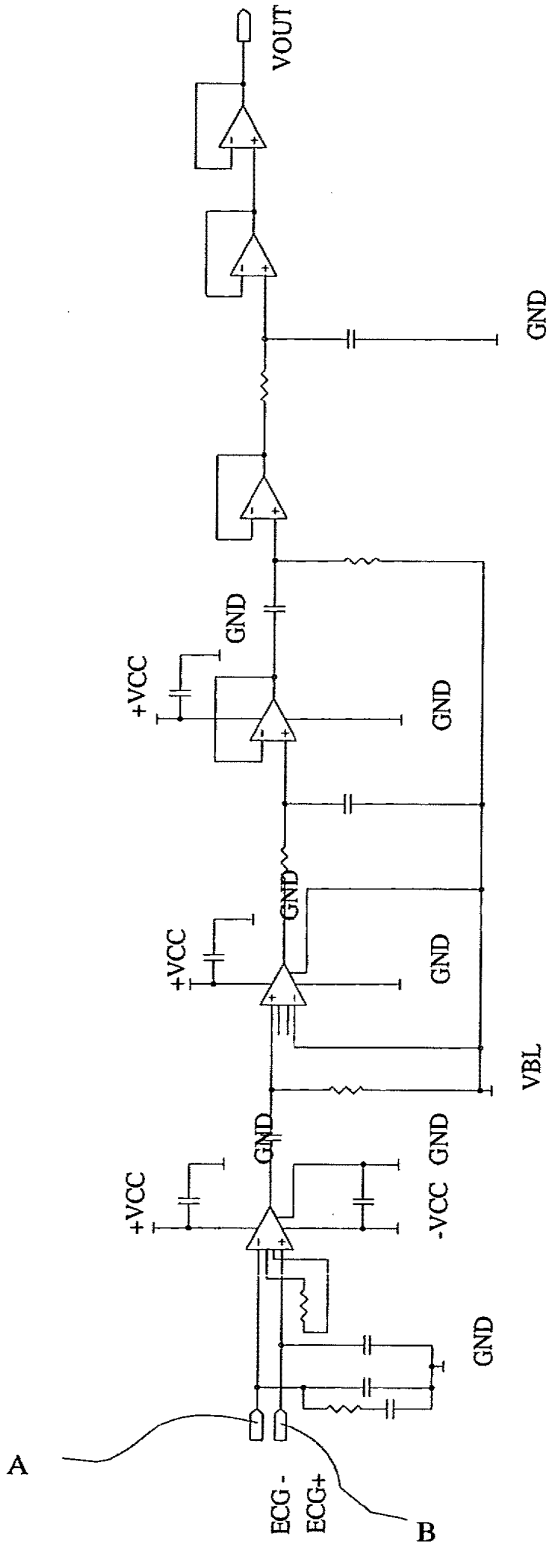


Fig. 44

Petitioner Ex-1004, 0363

BNSDOCID: <EP_____1724684A1_I_>

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 29 1064

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 02/054238 A (HONEYWELL INTERNATIONAL INC) 11 July 2002 (2002-07-11) * abstract * * page 8, line 9 - line 26 * * page 10, line 11 - page 11, line 4 * -----	1-5, 11-14, 37-46	G06F9/46
X	RIPOLL I ET AL: "AN OPTIMAL ALGORITHM FOR SCHEDULING SOFT APERIODIC TASKS IN DYNAMIC-PRIORITY PREEMPTIVE SYSTEMS" IEEE TRANSACTIONS ON SOFTWARE ENGINEERING, IEEE SERVICE CENTER, LOS ALAMITOS, CA, US, vol. 23, no. 6, June 1997 (1997-06), pages 388-399, XP000727454 ISSN: 0098-5589	1-3,13, 14,37-46	
A	* abstract * * page 388, left-hand column, line 1 - line 9 * * page 388, right-hand column, line 11 - line 16 * * page 389, left-hand column, line 14 - line 32 * * page 393, right-hand column, line 13 - line 18 * * page 395, right-hand column, line 5 - last line * -----	4,5,11, 12	TECHNICAL FIELDS SEARCHED (IPC) G06F A61B A61N

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	8 February 2006	Archontopoulos, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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& : member of the same patent family, corresponding document

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Petitioner Ex-1004, 0364

BNSDOCID: <EP_____1724684A1_I_>

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EUROPEAN SEARCH REPORT

Application Number
EP 05 29 1064

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	KANEKO H ET AL: "INTEGRATED SCHEDULING OF MULTIMEDIA AND HARD REAL-TIME TASKS" 17TH IEEE REAL-TIME SYSTEMS SYMPOSIUM. WASHINGTON,DC, DEC. 4 - 6, 1996, PROCEEDINGS OF THE IEEE REAL-TIME SYSTEMS SYMPOSIUM, NEW YORK, IEEE, US, vol. SYMP. 17, 4 December 1996 (1996-12-04), pages 206-217, XP000659642 ISBN: 0-7803-3801-4 * abstract *	1-5, 11-14, 37-46	
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A	STEVE VESPAL: "MetaH Support for Real-Time Multi-Processor Avionics" WORKSHOP ON OBJECT-ORIENTED REAL-TIME DEPENDABLE SYSTEMS, 1 April 1997 (1997-04-01), pages 11-21, XP002153417 * abstract * * page 14, left-hand column, line 27 - line 34 *	1-5, 11-14, 37-46	

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	8 February 2006	Archontopoulos, E

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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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EPO FORM 1503 03.82 (P04C01)

Petitioner Ex-1004, 0365

BNSDOCID: <EP_____1724684A1_I_>

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 29 1064

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	JIA YU ET AL: "A Novel Architecture for Realizing Grid Workflow using Tuple Spaces" GRID COMPUTING, 2004. PROCEEDINGS. FIFTH IEEE/ACM INTERNATIONAL WORKSHOP ON PITTSBURGH, PA, USA 08-08 NOV. 2004, PISCATAWAY, NJ, USA,IEEE, 8 November 2004 (2004-11-08), pages 119-128, XP010769490 ISBN: 0-7695-2256-4 * abstract * * paragraph [6.2.2] *	6-8	
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-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	8 February 2006	Archontopoulos, E

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4

Petitioner Ex-1004, 0366

BNSDOCID: <EP_____1724684A1_I_>

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 29 1064

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	TOMBROFF M ET AL: "OFFEN, VERTEILT UND VERNTZT. ECHTZEITANWENDUNGEN IN UNIX-NETZWERKEN" ELEKTRONIK, WEKA FACHZEITSCHRIFTENVERLAG, POING, DE, vol. 43, no. 21, 18 October 1994 (1994-10-18), pages 110-119, XP000469307 ISSN: 0013-5658 * page 111, left-hand column, line 9 - line 27 * * page 113, left-hand column, line 14 - line 25 *	9,10	
X	US 2005/004481 A1 (XUE JOEL Q ET AL) 6 January 2005 (2005-01-06) * abstract *	15-36	
X	US 5 951 483 A (JOO ET AL) 14 September 1999 (1999-09-14) * abstract; figures 2A,2B *	15-36	TECHNICAL FIELDS SEARCHED (IPC)
X	WO 2004/008960 A (NEW YORK UNIVERSITY; AXEL, LEON) 29 January 2004 (2004-01-29) * abstract *	15-36	
X	US 3 742 938 A (STERN T,US) 3 July 1973 (1973-07-03) * abstract *	47-50	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	8 February 2006	Archontopoulos, E

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
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D : document cited in the application
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& : member of the same patent family, corresponding document

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Petitioner Ex-1004, 0367

BNSDOCID: <EP_____1724684A1_I_>

European Patent Office

Application Number
EP 05 29 1064

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☒ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

Petitioner Ex-1004, 0368

BNSDOCID: <EP_____1724684A1_I_>

European Patent Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 05 29 1064

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-5,11-14,37-46

   Scheduling of two classes of tasks.
   ---

2. claims: 6-8

   Tuple based messaging system.
   ---

3. claims: 9,10

   Primitives defined by a meta language.
   ---

4. claims: 15-36

   Method of analysis of a signal.
   ---

5. claims: 47-50

   Method for the diagnosis of cardiac arrhythmia.

Petitioner Ex-1004, 0369

BNSDOCID: <EP_____1724684A1_I_>

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 29 1064

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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08-02-2006

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US 5951483 A	14-09-1999	NONE	
WO 2004008960 A	29-01-2004	AU 2003261272 A1	09-02-2004
US 3742938 A	03-07-1973	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Petitioner Ex-1004, 0370

BNSDOCID: <EP_____1724684A1_I_>

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 July 2012 (26.07.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/100175 A1

(51) International Patent Classification:
A61B 5/02 (2006.01) *A61B 5/1455* (2006.01)
A61B 5/0452 (2006.01) *H04B 7/24* (2006.01)

(21) International Application Number:
PCT/US2012/022049

(22) International Filing Date:
20 January 2012 (20.01.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/434,862	21 January 2011 (21.01.2011)	US
61/434,856	21 January 2011 (21.01.2011)	US
61/512,199	27 July 2011 (27.07.2011)	US
61/566,329	2 December 2011 (02.12.2011)	US

(71) Applicant *(for all designated States except US)*: **WORCESTER POLYTECHNIC INSTITUTE** [US/US]; 100 Institute Road, Worcester, Massachusetts 01609 (US).

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(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, 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, 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, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, 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, MD, 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, ML, MR, NE, SN, TD, TG).

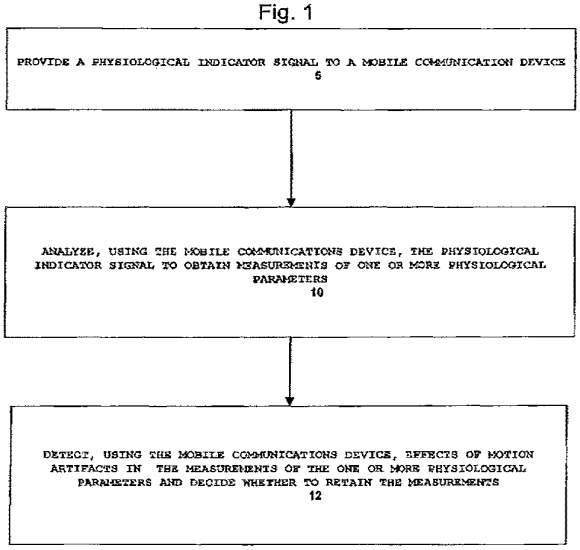
Published:

— *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**: PHYSIOLOGICAL PARAMETER MONITORING WITH A MOBILE COMMUNICATION DEVICE

Fig. 1



(57) **Abstract**: Systems and methods that enable physiological monitoring with a mobile communication device and that allow detection of motion artifacts so that the results reported are of acceptable quality are disclosed.

WO 2012/100175 A1

BNSDOCID: <WO_____2012100175A1_I_>

PHYSIOLOGICAL PARAMETER MONITORING WITH A MOBILE COMMUNICATION DEVICE

BACKGROUND

These teachings relate generally to physiological parameter monitoring, and, more particularly, to physiological parameter monitoring with a mobile communication device.

There is a need for low-cost physiological monitoring solutions that are easy to use, accurate, and can be used in the home or in ambulatory situations. Smart phones are becoming more popular, more powerful and have a variety of sensors available to capture information from the outside world, process in real-time, and transfer information remotely using wireless communications. This makes them an ideal option as a 'take-anywhere' physiological monitor without the need for additional hardware, and their potential has been explored for many medical telemonitoring applications.

Optical video monitoring of the skin with a digital camera contains information related to the subtle color changes caused by the cardiac signal and can be seen to contain a pulsatile signal. Given illumination of the area with a white LED mobile phone flash, this type of imaging can be described as reflection photoplethysmographic (PPG) imaging. The dynamics of the HR signal that can be captured by PPG contain information that can be used to detect other physiological conditions.

Motion artifacts can affect the results of standard PPG. In the case of a mobile device and where there is no physical device ensuring a stable connection as is the case with pulse-oximeter clips or EKG electrodes, motion artifacts can be of more concern. There is a need for systems and methods for physiological monitoring with a mobile communication device that allow detection of motion artifacts.

Petitioner Ex-1004, 0372

BNSDOCID: <WO____2012100175A1_I_>

BRIEF SUMMARY

The teachings described herein disclose systems and methods that enable physiological monitoring with a mobile communication device and that allow detection of motion artifacts so that the results reported are of acceptable quality are disclosed.

In one or more embodiments, the method of these teachings for physiological parameter monitoring includes providing a physiological indicator signal to a mobile communication device analyzing, using the mobile communications device, the physiological indicator signal to obtain measurements of one or more physiological parameters and detecting, using the mobile communications device, effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements.

Other embodiments and instances of the method of these teachings are also disclosed.

In one or more embodiments of the system of these teachings, the system includes a physiological indicator signal sensing component (sensor) and a mobile communication device having an analysis component analyzing the physiological indicator signal to obtain measurements of one or more physiological parameters and a motion artifact detection component detecting effects of motion artifacts in the measurements of the one or more physiological parameters.

Other embodiments and instances of the system of these teachings are also disclosed.

Embodiments and instances of computer usable media having computer readable code embodied therein, where the computer readable code causes one or more processors to implement the embodiments of the method of these teachings are also disclosed.

For a better understanding of the present teachings, together with other and further objects thereof, reference is

Petitioner Ex-1004, 0373

BNSDOCID: <WO_____2012100175A1_I_>

made to the accompanying drawings and detailed description and its scope will be pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a flowchart representation of one embodiment of the method of these teachings;

Figure 1a is a schematic flowchart representations of components of one embodiment of the method of these teachings;

Figure 1b is a schematic flowchart representations of components of another embodiment of the method of these teachings;

Figures 2a-2c are schematic graphical representations of results for one exemplary embodiment of the method of these teachings;

Figures 3a-3c are schematic graphical representations of results for another exemplary embodiment of the method of these teachings;

Figures 4a-4b are schematic graphical representations of results for yet another exemplary embodiment of the method of these teachings;

Figure 5 illustrates a schematic graphical representation of a resultant Time-Varying Coherence Function (TVCF) in a further exemplary embodiment of the method of these teachings;

Figures 6a and 6b are schematic graphical representations of the TVCF at different frequencies in the further exemplary embodiment of the method of these teachings;

Figures 7a-7c illustrate schematic graphical representations of true AF annotation and the values of frequency variations (FV) for different databases in the further exemplary embodiment of the method of these teachings; and

Figure 8 represents a schematic block diagram representation of one embodiment of the system of these teachings.

Petitioner Ex-1004, 0374

BNSDOCID: <WO____2012100175A1_I_>

DETAILED DESCRIPTION

The following detailed description is of the best currently contemplated modes of carrying out these teachings. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of these teachings, since the scope of these teachings is best defined by the appended claims. Although the teachings have been described with respect to various embodiments, it should be realized these teachings are also capable of a wide variety of further and other embodiments within the spirit and scope of the appended claims.

As used herein, the singular forms "a,""an," and "the" include the plural reference unless the context clearly dictates otherwise.

Except where otherwise indicated, all numbers expressing quantities of ingredients, reaction conditions, and so forth used in the specification and claims are to be understood as being modified in all instances by the term "about."

To assist in the understanding of the present teachings the following definitions are presented.

A "mobile communication device," as used herein, refers to a device capable of executing applications, and which is portable. In one instance, the mobile communication device has one or more processors and memory capability. Examples of mobile communication devices, these teachings not being limited to only these examples, include mobile phones, smart mobile phones, digital personal assistants, etc.

A "physiological indicator signal," as used herein, refers to a signal that can be used to obtain measurements of one or more physiological parameters. Examples of physiological indicator signals, these teachings not being limited only those examples, include photoplethysmograph (PPG) sig-

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Petitioner Ex-1004, 0375

electrocardiogram (EKG) signals and color video images obtained from a portion of a subject's body (for example, but not limited to, obtained using the camera in a mobile communication device), which behave as reflection PPG images.

"Volatility," as used herein, refers to a measure of the probability of obtaining an extreme value in the future , such as measured by kurtosis and other statistical measures.

"Detrending," as used herein, refers to the process of finding a best polynomial fit to a time series and subtracting that best polynomial fit from the time series.

"SpO2," as used herein, refers to a measurement of the amount of oxygen being carried by the red blood cell in the blood. SpO2 is usually given in as a percentage and measures oxygen saturation.

In one or more embodiments, the method of these teachings for physiological parameter monitoring includes providing a physiological indicator signal to a mobile communication device (step 5, Fig. 1), analyzing, using the mobile communications device, the physiological indicator signal to obtain measurements of one or more physiological parameters (step 10, Fig. 1) and detecting, using the mobile communications device, effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements (step 12, Fig. 1).

The physiological indicator signal can, in one instance, be provided by placing a portion of a subject's body over an objective lens of a camera in a mobile communication device and obtaining video images of the portion of the subject's body. In another instance, the physiological indicator signal can be provided by a physiological monitoring sensor, for example, an external photoplethysmographic (PPG) sensor or an external electrocardiogram sensor. It should be noted that other manners

Petitioner Ex-1004, 0376

of providing the physiological indicator signal are within the scope of these teachings.

Motion artifacts

One embodiment of the method for detecting effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements is disclosed hereinbelow. It should be noted that other embodiments are within the scope of these teachings.

In the embodiment shown in Fig. 1a, the method for detecting effects of motion artifacts includes preprocessing a segment of a signal (15, Fig. 1a) from a physiological measurement (20, Fig. 1a), obtaining a value of one or more indicators of volatility for the preprocessed segment (25, Fig. 1a) and determining from comparison of the value of the one or more indicators of volatility with a predetermined threshold whether or not noise/motion artifacts are not present. If noise/motion artifacts are not present, the segment is included in calculations quantities of interest (40, Fig. 1a) and the method proceeds to another segment (50, Fig. 1a), if another segment is available. If noise/motion artifacts are present, for most physiological parameters, the segment is discarded (45, Fig. 1a) and the method proceeds to another segment (50, Fig. 1a), if another segment is available. For the measurement of an indication of blood loss, as shown in Fig. 1b, a time-frequency spectrum analysis is performed for the preprocessed segment (30, Fig. 1b) and a predetermined measure of the time-frequency spectrum analysis is compared to a predetermined measure's threshold (35, Fig. 1b). If the predetermined measure is within limits determined by the predetermined measure's threshold, the segment is included in calculations quantities of interest (40, Fig. 1b) and the method proceeds to another segment, if another segment is available (50, Fig. 1b). If the predetermined measure is not within the limits

Petitioner Ex-1004, 0377

BNSDOCID: <WO____2012100175A1_I_>

determined by the predetermined measure's threshold, the segment is discarded (45, Fig. 1b) and the method proceeds to another segment (50, Fig. 1b), if another segment is available.

In one instance, the measure of volatility used in the above disclosed embodiment includes kurtosis. In another instance, the measure of volatility includes Shannon entropy. In a further instance, the measure of volatility uses both kurtosis and Shannon entropy.

An exemplary embodiment of the application of the method for detecting motion artifacts is described herein below in order to further elucidate these teachings. However it should be noted that these teachings are not limited to only that exemplary embodiments.

Experimental protocol for one exemplary embodiment

The algorithm has been tested on PPG signals obtained from two distinct scenarios as follows.

1. Involuntary movements: Multi-site PPG signals recorded from 10 healthy volunteers under supine resting conditions for 5 to 20 minutes in clinical settings were used for our analysis. The data analyzed were a part of simulated blood loss experiments which consisted of baseline and lower body negative pressure application where the data from only the former condition was used for this study. Three identical reflective infrared PPG-probes (MLT1020; ADI Instruments, CO Springs, CO, USA) were placed at the finger, forehead and ear. While the finger and ear PPG probes were attached with a clip, the forehead probe was securely covered by a clear dressing. The PPG signals were recorded at 100 Hz with a Powerlab/16SPdata acquisition system equipped with a Quad Bridge Amp (ML795 & ML112; ADI Instruments) and a high-pass filter cut-off of 0.01 Hz. The subjects were not restricted from making any sort of movements during the recording procedure.

Petitioner Ex-1004, 0378

BNSDOCID: <WO____2012100175A1_i_>

2. Voluntary movements: Finger-PPG signals were obtained from 14 healthy volunteers in an upright sitting posture using an infrared reflection type PPG transducer (TSD200) and a biopotential amplifier (PPG100) with a gain of 100 and cut-off frequencies of 0.05-10 Hz. The MP100 (BIOPAC Systems Inc., CA, USA) was used to acquire finger PPG signals at 100 Hz. After baseline recording for 5 minutes without any movements (i.e. clean data), motion artifacts were induced in the PPG data by left-right movements of the index finger with the pulse oximeter on it. The subjects were directed to produce the motions for time intervals that determined the percentage of noise within each 1 minute segment, varying from 10 to 50 %. For example, if a subject was instructed to make left-right movements for 6seconds, that segment of data would contain 10% noise. Such controlled movements were carried out 5 times for each level of noise. In this protocol, we used the left-right movement of the index finger having the PPG clamp to induce movement artifacts since left-right movement was perpendicular to the plane of the PPG sensor orientation and thus generated significant noise as compared to up-down or arbitrary movements of the finger. The recorded PPG signals from both protocols were analyzed offline using Matlab®.

B. Data Preprocessing:

The PPG data were partitioned into 60s segments and shifted every 10s for the entire data. Each 60s PPG segment was subjected to a finite impulse response (FIR) band pass filter of order 64 with cut-off frequencies of 0.1 Hz and 10 Hz. To account for the time-dependent low-frequency trends associated with the PPG signal and depending on the type of data analysis, either a low- or high-order polynomial detrending was used. For the purpose of artifact detection, we used in some cases as high as the 32nd-order polynomial fit to eliminate nonstationary dynamics in the

Petitioner Ex-1004, 0379

BNSDOCID: <WO_____2012100175A1_I_>

PPG signal. The use of a high-order polynomial detrend is important to an effective classification between clean and artifact-containing signals. For the time-frequency-spectral analysis during the second stage to determine usable data, a standard 2nd order polynomial detrend was used on the original PPG data (not on the data with a high-order polynomial detrend). Following detrend with either a low- or high-order polynomial fit, the PPG signal was zero-meaned. Before a computational analysis is conducted, the PPG waveforms in each data segment are visually examined and classified them into clean vs. corrupted segments. Any sort of disruption in the pulse characteristics was labeled as corrupted segments. This was done in order to later determine the accuracy of the method.

C. Computational measures for artifact detection

Following the preprocessing of each PPG data segment, our approach for the detection of artifacts involves the computation of the following two parameters.

Kurtosis: Kurtosis is a statistical measure used to describe the distribution of observed data around the mean. It represents a heavy tail and peakedness or a light tail and flatness of a distribution relative to the normal distribution. The kurtosis of a normal distribution is 3. Distributions that are more outlier-prone than the normal distribution have kurtosis greater than 3; distributions that are less outlier-prone have kurtosis less than 3. The kurtosis is defined as:

$$k = \frac{E(x-\mu)^4}{\sigma^4} \qquad (1)$$

Where μ is the mean of x, σ is the standard deviation of x, and $E(t)$ represents the expected value of the quantity t.

Petitioner Ex-1004, 0380

BNSDOCID: <WO____2012100175A1_I_>

Shannon entropy: SE quantifies how much the probability density function (PDF) of the signal is different from a uniform distribution and thus provides a quantitative measure of the uncertainty present in the signal. SE can be calculated as

$$SE = -\sum_{i=1}^{k} \frac{p(i)\times\log(p(i))}{\log(\frac{1}{k})} \qquad (2)$$

Where i represents the bin number, and $p(i)$ is the probability distribution of the signal amplitude. Presently, 16 bins $(k = 16)$ have been used to obtain a reasonably accurate measure of SE.

D. Statistical analysis of computational measures:

The nonparametric Mann Whitney test was conducted on data from the involuntary motion protocol to find the significance levels ($p<0.05$) for the SE and kurtosis measures between clean vs. corrupted PPG segments. Meanwhile, the nonparametric Kruskal-Wallis test with Dunn's multiple comparison post test was conducted on data from the voluntary motion protocol to find the significance ($p<0.05$) between clean vs. noise-corrupted PPG segments for the two measures.

E. Detection of motion/noise artifacts:

By varying kurtosis values from 0 to 10 with an increment of 0.1, and SE values from 0.5 to 1.0 with an increment of 0.01, receiver-operator characteristic (ROC) analysis were conducted for the population of SE and kurtosis values obtained from the respective pool of clean and corrupted PPG segments of both protocols. The substantially optimal threshold values for kurtosis and SE that produced the substantially optimal sensitivity and specificity for the detection of artifacts. (see, for example, S. H. Park et. al., Receiver Operating Characteristic (ROC) Curve: Practical Review for Radiologists,

Petitioner Ex-1004, 0381

BNSDOCID: <WO____2012100175A1_I_>

Korean J Radiol. 2004 Jan-Mar; 5(1): 11-18, which is Incorporated by reference herein is entirety for all purposes) where evaluated.

The decision rules for the detection of artifacts were formulated as follows:

$$DK_i = \begin{cases} 1 & if\ K_i \le K_{Th} \\ 0 & if\ K_i > K_{Th} \end{cases} \qquad (3)$$

where DK_i refers to the decision for artifact detection based on K_i, kurtosis for the ith segment. '1' represents clean data, whereas '0' represents corrupted data. K_{Th} refers to the Kurtosis threshold.

$$DS_i = \begin{cases} 1 & if\ SE_i \ge SE_{Th} \\ 0 & if\ SE_i < SE_{Th} \end{cases} \qquad (4)$$

where DS_i refers to the decision for artifact detection based on SE_i, SE for the ith segment. '1' represents clean data whereas '0' represents corrupted data. SE_{Th} refers to the SE threshold.

The fusion of kurtosis and SE metrics with their substantially optimal threshold values for the artifact detection was further consider and the sensitivity and specificity for the fusion of these two metrics was quantified. The decision rule for the detection of artifacts using a fusion of kurtosis and SE is:

$$FD_i = \begin{cases} 1 & if\ DK_i + DS_i = 2 \\ 0 & if\ DK_i + DS_i \ne 2 \end{cases} \qquad (5)$$

Petitioner Ex-1004, 0382

BNSDOCID: <WO____2012100175A1_I_>

where FD_i refers to the fusion decision for artifact detection based on both DK_i and DS_i for the ith segment. '1' represents clean data whereas '0' represents corrupted data.

Time-frequency spectral analysis for the assessment of severity of noise

In the second stage of this embodiment of the motion/Noise Artifact algorithm, where blood loss is being detected, how severe the noise must be to affect the dynamics of the signal in the HR frequency range is assessed (shown in Fig. 1b). Specifically, this second stage determines if some of the segments that were deemed to contain artifacts can be used for noninvasive blood loss detection, as these data may not be heavily contaminated.

This step first requires the computation of time-frequency analysis so that the amplitude modulations at each time point within the heart rate band can be obtained. This extracted amplitude modulation information is subsequently used to determine the state of usable data as detailed in the proceeding section. A time-frequency method known as the variable frequency complex demodulation method (VFCDM) to be described hereafter is used because it has been shown to provide one of the highest time-frequency resolutions.

VFCDM Analysis: The development of the VFCDM algorithm has been previously disclosed in K. H. Chon, S. Dash, and K. Ju, "Estimation of respiratory rate from photoplethysmogram data using time-frequency spectral estimation," IEEE Trans Biomed Eng, vol. 56, no. 8, pp. 2054-63, Aug, 2009 and in U.S. Patent Application Publication 20080287815, published on November 20, 2008, corresponding to U.S. Patent Application No. 11/803,770, filed on May 16, 2007, both of which are incorporated by reference herein in their entirety for all purposes. Thus the VFCDM algorithm will be only briefly summarized hereinbelow.

Petitioner Ex-1004, 0383

BNSDOCID: <WO____2012100175A1_I_>

Consider a sinusoidal signal x(t) to be a narrow band oscillation with a center frequency f0, instantaneous amplitude A(t), phase $\phi(t)$, and the direct current component dc(t):

$$x(t) = dc(t) + A(t)\cos(2\pi f_0 t + \phi(t)) \quad (6)$$

For a given center frequency, the instantaneous amplitude information A(t) and phase information $\phi(t)$ can be extracted by multiplying (6) by $e^{-j2\pi f_0 t}$, which results in the following:

$$z(t) = x(t)e^{-j2\pi f_0 t} = dc(t)e^{-j2\pi f_0 t} + \left(\frac{A(t)}{2}\right)e^{j\phi(t)} + \left(\frac{A(t)}{2}\right)e^{-j(4\pi f_0 t + \phi(t))} \quad (7)$$

A leftward shift by $e^{-j2\pi f_0 t}$ results in moving the center frequency f0 to zero frequency in the spectrum of z(t). If z(t) in (7) is subjected to an ideal low-pass filter (LPF) with a cut-off frequency $f_c < f_0$, then the filtered signal $z_{lp}(t)$ will contain only the components of interest and the following can be extracted:

$$z_{lp}(t) = \frac{A(t)}{2}e^{j\phi(t)} \quad (8)$$

$$A(t) = 2|z_{lp}(t)| \quad (9)$$

$$\phi(t) = tan^{-1}\frac{imag(z_{lp}(t))}{real(z_{lp}(t))} \quad (10)$$

The method can easily be extended to the variable frequency case, where the modulating frequency is expressed as $\int_0^t 2\pi f(\tau)d\tau$ and the negative exponential term used for the demodulation is $e^{-j\int_0^t 2\pi f(\tau)d\tau}$. The instantaneous frequency can be obtained using the familiar differentiation of the phase information as follows:

Petitioner Ex-1004, 0384

BNSDOCID: <WO____2012100175A1_I_>

$$f(t) = f_0 + \frac{1}{2\pi}\frac{d\phi(t)}{d(t)} \qquad (11)$$

Thus, the VFCDM method involves a two-step procedure. At first, the fixed frequency complex demodulation technique identifies the signal's dominant frequencies, shifts each dominant frequency to a center frequency, and applies a low-pass filter (LPF) to each of the center frequencies. The LPF has a cutoff frequency less than that of the original center frequency and is applied to each dominant frequency. This generates a series of band-limited signals. The instantaneous amplitude, phase and frequency information are obtained for each band-limited signal using the Hilbert transform and are combined to generate a time-frequency series (TFS). Finally, the second step of the VFCDM method is to select only the dominant frequencies and produce a high-resolution TFS.

Once the TFS of the PPG signal is obtained via the VFCDM method, the largest instantaneous amplitude at each time point within the HR band (HR±0.2Hz) of the TFS of the VFCDM are extracted as the so-called AMHR components of the PPG that reflect the time varying amplitude modulation (AM) of the HR frequency. The initial and final 5s of the TFS were not considered for the AMHR extraction because time frequency series have an inherent end effect that could produce false variability of the spectral power. The median value of the AMHR components was evaluated for each corrupted PPG segment.

Determination of usable PPG segments corrupted with insignificant artifacts:

The AMHR median values were computed separately for clean PPG segments of each probe site for involuntary artifacts as well as for the voluntary artifact protocols as described above. The mean ± 2*SD of the AMHR median population were determined as

Petitioner Ex-1004, 0385

BNSDOCID: <WO_____2012100175A1_I_>

their respective 95% statistical limits for each clean PPG data set. If the AMHR median value of the corrupted PPG segment lies within the statistical limits of the clean data, the respective corrupted PPG segment was considered as usable data; otherwise it was rejected. Thus, the model of our algorithm outlined in Fig. 1 has been designed to function in two separate stages for the detection and quantification of usable data among those that contain artifacts in PPG signals. Referring to Fig. 1a, a segment of a signal (15, Fig. 1) from PPG is preprocessed (filtered) (55, Fig. 1a), one or more indicators of volatility for the preprocessed segment are evaluated (60, Fig. 1a) to determine from comparison of the value of the one or more indicators of volatility with a predetermined threshold whether or not noise/motion artifacts are not present. If noise/motion artifacts are not present, the segment is included in calculations quantities of interest (65, Fig. 1) and the method proceeds to another segment, if another segment is available. If noise/motion artifacts are present, a time-frequency spectrum analysis is performed for the preprocessed segment and a predetermined measure of the time-frequency spectrum analysis, AMHR, is compared to a predetermined measure's threshold, the mean ± 2*Standard deviations (SD) of the AMHR median population of a clean sample. If the predetermined measure is within limits determined by the predetermined measure's threshold, the segment is included in calculations quantities of interest and the method proceeds to another segment, if another segment is available). If the predetermined measure is not within the limits determined by the predetermined measure's threshold, the segment is discarded and the method proceeds to another segment, if another segment is available.

Heart Rate And Heart Rate Variability Detection

Petitioner Ex-1004, 0386

BNSDOCID: <WO_____2012100175A1_I_>

In one instance, the physiological measurements are heart rate and heart rate variability. In one embodiment, the method of these teachings for obtaining measurements of heart rate and heart rate variability includes determining beats for the physiological indicator signal (examples of beat detection algorithm, these teachings not be limited to those examples, can be found in Beat Detection Algorithms, available at http://www.flipcode.com/misc/BeatDetectionAlgorithms.pdf and accessed on January 17, 2012), determining beat to beat intervals and applying a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.

The method for detection of beat to beat variability disclosed in United States Patent Application No. 20110166466, entitled RR INTERVAL MONITORING METHOD AND BLOOD PRESSURE CUFF UTILIZING SAME, published on July 7, 2011, which is incorporated by reference herein is entirety for all purposes, could be applied. Also, the methods for detection of the autonomous system imbalance disclosed in United States Patent Application 20090318983, entitled Method And Apparatus For Detection And Treatment Of Autonomic System Imbalance, published on December 24, 2009, which is Incorporated by reference herein is entirety for all purposes, could be applied.

In another instance, the physiological measurement is respiratory rate. One embodiment of the method for obtaining measurements of respiratory rate includes obtaining time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM) and obtaining respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.

An exemplary embodiment of the measurement of heart rate and heart rate variability and respiratory rate is presented

Petitioner Ex-1004, 0387

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hereinbelow in order to further elucidate these teachings. It should be noted that these teachings are not limited to the exemplary embodiment.

In order to compare the exemplary embodiment of the present teachings to conventional methods, experiments were performed to measure the heart rate, heart rate variability and respiratory rate using conventional techniques. Electrocardiogram (EKG) recordings were made with an HP 78354A acquisition system using the standard 5-lead electrode configuration. A respiration belt was attached around the subject's chest to monitor breathing rate (Respitrace Systems, Ambulatory Monitoring Inc.). Respiratory and EKG recordings were saved using LabChart software (ADInstruments) at a sampling rate of 400 Hz.

Data were recorded during spontaneous breathing for a single subject. Data collection was initiated as follows: (1) initiate mobile phone video recording, (2) start recordings of EKG and respiration trace 10 seconds after initiation of mobile phone recording, and (3) set mobile phone down and place subject's left index finger over camera lens. This procedure allowed for alignment of data files to within 1 second.

Metronome breathing experiments were performed on a single subject with rates set at 0.2, 0.3, and 0.4 Hz (12, 18, and 24 Beats per Minute (BPM)). The subject was asked to inhale with each beat of the metronome. Metronome recordings were made for 2 minutes for each section.

For the measurements using the exemplary embodiment of these teachings, color changes of the finger were recorded using a Motorola Droid® (Motorola Mobility, Inc.) mobile phone. The palmar side of the left index finger was placed over the camera lens with the flash turned on. Subjects were instructed to rest their finger on the camera lens without pressing down with additional force, and to keep their finger still to reduce any

Petitioner Ex-1004, 0388

BNSDOCID: <WO____2012100175A1_I_>

motion artifacts. Videos were recorded with 720x480 pixel resolution at a sampling rate of 24.99 fps in .3gpp file format. The .3gpp videos were converted to Audio-Video Interleave (AVI) format at 720x480 pixel resolution and 25 fps using Pazera Free 3gp to AVI Converter 1.3 (http://www.pazera-software.com/). All further analysis was performed on the AVI videos in Matlab R2010b (The Mathworks Inc.)

For experiments assessing HR, heart rate variability (HRV), and respiration rate, only the green band from the video recordings was used. A 50x50 pixel average of a region on the video signal at each frame was made for the green band. This signal is from herein referred to as GREEN.

R-wave peak detection was performed for the EKG signal using a custom peak detection algorithm. Beats were detected for the GREEN signal using a conventional algorithm. Beat-beat intervals were computed, and cubic splined to 4 Hz to obtain the continuous HR for each signal (HREKG and HRGREEN). The power spectral density (PSD) of HR was computed using Welch periodogram method.

A section 105 of an exemplary GREEN signal obtained during spontaneous breathing is shown in Fig. 2a. The pulse signal is similar to a traditional PPG signal obtained from a pulse-oximeter. Peak detection was performed to identify the HR signal, shown in Fig. 2b along with that obtained from an EKG after R-wave peak detection. The mean±SD was 92.2±5.3 for HREKG and 92.3±5.9 for HRGREEN.

The dynamics of the HR signals- HRGREEN 110, HREKG 120 shown in Fig. 2b were assessed by frequency analysis (Fig. 2c). The dominant peak on both signals is seen to be at a low frequency <0.1 Hz. A second peak is seen on both signals in the sympathetic range (0.04 - 0.15 Hz), and a third peak at approximately 0.2 Hz is representative of the respiration rate. Additional high frequency components are seen in HRGREEN 112 compared to HREKG,

Petitioner Ex-1004, 0389

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possibly from the suboptimal low sampling frequency of the mobile phone recording.

Respiration Rate Detection

Frequency modulation (FM) and amplitude modulation (AM) sequences were extracted as described in K. H. Chon, S. Dash, and K. Ju, "Estimation of respiratory rate from photoplethysmogram data using time-frequency spectral estimation," IEEE Trans Biomed Eng, vol. 56, no. 8, pp. 2054-63, Aug, 2009 and in U.S. Patent Application Publication 20080287815, published on November 20, 2008, corresponding to U.S. Patent Application No. 11/803,770, filed on May 16, 2007, both of which are incorporated by reference herein in their entirety for all purposes, and used to estimate the breathing rate (Fig. 3a&b). Breathing rates were confirmed by taking the PSD of the respiration trace during 3 periods of metronome breathing recorded with the metronome set at 0.2, 0.3, and 0.4 Hz. Breathing rates from the respiration trace and GREEN signal using the FM sequence were estimated at the three metronome rates as 0.18 and 0.16, 0.30 and 0.32, and 0.40 and 0.38 Hz, respectively. The PSDs of the FM sequence 210, 220, 232 and respiration trace 212, 222, 230 for the three breathing rates are shown in Fig. 3c.

Oxygen Saturation Detection

In yet another instance, the physiological measurement is a measure of oxygen saturation. In one embodiment, the physiological indicator signal is acquired by placing a portion of a subject's body over an objective lens of a camera in a mobile communication device and obtaining video images of the portion of the subject's body. In that embodiment, the method of these teachings for obtaining a measure of oxygen saturation includes obtaining an average intensity of a red component and a blue component of the video images of the portion of the subject's body, the average intensity of the red component and

Petitioner Ex-1004, 0390

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the average intensity of the blue component constituting DCRED and DCBLUE respectively, obtaining a standard deviation of the red component and the blue component, the standard deviation of the red component and the blue component constituting ACRED and ACBLUE respectively, and obtaining the measure of oxygen saturation (SpO2) by

$$SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}.$$

An exemplary embodiment of the measure of oxygen saturation is presented hereinbelow in order to further elucidate these teachings. It should be noted that these teachings are not limited to the exemplary embodiment.

In order to compare the exemplary embodiment of the present teachings to conventional methods, experiments were performed to measure oxygen saturation.

Breath holding experiments were performed to assess the impact of reduced oxygen saturation on the optical recordings on two subjects. A commercial reflectance pulse-oximeter (Radical SETTM, Masimo) was placed on the left ring finger to record 1 sec measurements of SpO2. The mobile phone camera lens was placed underneath the subjects' left index fingertip. A black cloth was placed around the finger on the camera lens to isolate the sensor from light emanating from the commercial pulse-oximeter. The data files were aligned by starting the data logging of the pulse-oximeter by verbal command after the mobile phone recording started, and using the audio file to determine the initiation time point.

Subjects were asked to breathe normally for approximately 30 seconds, exhale, and then to hold their breath till they felt

Petitioner Ex-1004, 0391

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discomfort. Two consecutive breath holding periods were recorded for each subject.

Oxygen Saturation Monitoring

The ratio of RED and BLUE in the equation for SpO provided hereinabove was computed and the A and B parameters were estimated for each subject using the commercial pulse-oximeter SpO2 values as a reference. For the subject shown in Fig. 4a, A and B in $SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}$ were determined to be 154.5 and 220.3, respectively, and for the subject in Fig. 4b, A and B were determined to be 155.7 and 265.5. (In Figs. 4a and 4b, measurements from the pulse oxymeter are labeled 310, 312, while measurements from these teachings are labeled 320, 322. It can be observed in Fig. 4a, 4b that SpO_2 decreases monitored with the commercial pulse-oximeter appear to cause decreases in our computed SpO_2 value obtained from the mobile phone recording. For the subject in Fig. 4a, a minimum SpO_2 level of 84% was recorded from the commercial pulse-oximeter and a minimum of 81% was computed with

$$SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}.$$

It should be noted that, although offline analysis we performed in the above exemplary embodiments, given the current processing power available in mobile phones (currently 1GHz dual-core processors available), performing the analysis directly on a mobile phone is within the scope of these teachings.

Blood Loss Detection

Petitioner Ex-1004, 0392

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In a further instance, the physiological measurement is a measure of blood loss. One embodiment of the method for obtaining a measure of blood loss includes obtaining time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM), obtaining the amplitude modulation (AM) series from a set of the largest instantaneous amplitude at each time sample within the heart rate frequency band of the time-frequency spectrum and determining whether the amplitude modulation decreases, a decrease in the amplitude modulation indicating blood volume loss in the subject.

An exemplary embodiment of the method for obtaining a measure of blood loss is disclosed in U.S. Provisional Application Ser. No. 61/434,856, filed January 21, 2011, entitled, SYSTEM AND METHOD FOR THE DETECTION OF BLOOD VOLUME LOSS" and in Nandakumar Selvaraj, Christopher G. Scully, Kirk H. Shelley, David G. Silverman, and Ki H. Chon, Early Detection of Spontaneous Blood Loss using Amplitude Modulation of Photoplethysmogram, 33rd Annual International Conference of the IEEE EMBS Boston, Massachusetts USA, August 30 - September 3, 2011, both of which are incorporated by reference herein in their entirety for all purposes.

Other embodiments of the method for obtaining a measure of blood loss are disclosed in WIPO International Publication No. WO 2011/050066 A2, entitled "Apparatus And Method For Respiratory Rate Detection And Early Detection Of Blood Loss Volume," published on April 28, 2011, which is incorporated by reference herein in its entirety for all purposes.

Atrial Fibrillation Detection

In a further instance, the physiological measurement is a measure of atrial fibrillation. One embodiment of the method for obtaining a measure of atrial fibrillation includes obtaining a time-varying coherence function by multiplying two time-varying

Petitioner Ex-1004, 0393

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transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments with one data segment as input signal and the other data segment as output to produce the first TVTF, the second TVTF is produced by reversing the input and output signals and determining whether the time-varying coherence function (TVCF) is less than a predetermined quantity. In another embodiment, determining whether the time-varying coherence function is less than the predetermined quantity includes obtaining one or more indicators of atrial fibrillation and determining whether the one or more indicators of atrial fibrillation exceed predetermined thresholds. In one instance, the one or more indicators of atrial fibrillation include a variance of the time-varying coherence function. In another instance, the one or more indicators of atrial fibrillation also include Shannon entropy. In yet another instance, the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.

In the embodiment of the method for obtaining a measure of atrial fibrillation disclosed hereinabove, the TVCF is estimated by the multiplication of two time-varying transfer functions (TVTFs). The two TVTFs are obtained using two adjacent data segments with one data segment as the input signal and the other data segment as the output to produce the first TVTF; the second TVTF is produced by reversing the input and output signals. It has been found that the resultant TVCF between two adjacent normal sinus rhythm segments show high coherence values (near 1) throughout the entire frequency range. However, if either or both segments partially or fully contain AF, the resultant TVCF is significantly lower than 1. When TVCF was combined with Shannon entropy (SE), even more accurate AF detection rate of 97.9% are obtained for the MIT-BIH Atrial Fibrillation (AF) database (n=23) with 128 beat segments.

Petitioner Ex-1004, 0394

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In the embodiment disclosed herein above, the TVCF is obtained by the multiplication of the two time-varying transfer functions. To demonstrate the use of the TVTF in obtaining the TVCF, the TVCF is first defined via the nonparametric time-frequency spectra as

$$|\gamma(t,f)|^4 = \frac{|S_{xy}(t,f)|^2}{S_{xx}(t,f)S_{yy}(t,f)} \frac{|S_{yx}(t,f)|^2}{S_{yy}(t,f)S_{xx}(t,f)} \qquad (12)$$

where $S_{xy}(t,f)$ and $S_{yx}(t,f)$ represent the time-frequency cross-spectrum, and $S_{xx}(t,f)$ and $S_{yy}(t,f)$ represent the auto spectra of the two signals x and y, respectively. Specifically, the first term in Eq. (12) is the coherence function when x is considered as the input and y as the output. Similarly, the second term in Eq. (12) is the coherence function when y is considered as the input and x as the output. For a linear time varying (TV) system with x as the input and y as the output, the TVTF in terms of time-frequency spectra can be obtained as

$$H_{x\to y}(t,f) = \frac{S_{xy}(t,f)}{S_{xx}(t,f)} \qquad (13)$$

where $H_{x\to y}(t,f)$ is the TVTF from the input x to the output y signal. Similarly, for a linear TV system with y as the input and x as the output, the TVTF can be obtained as

$$H_{y\to x}(t,f) = \frac{S_{yx}(t,f)}{S_{yy}(t,f)} \qquad (14)$$

Thus, the time-varying magnitude $|\gamma(t,f)|^2$ is obtained by multiplying the two transfer functions,

$$\left|H_{x\to y}(t,f)H_{y\to x}(t,f)\right| \qquad (15)$$

Petitioner Ex-1004, 0395

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Given the relationship of (15), a high resolution TVCF can be obtained from ARMA models:

$$y(n) = -\sum_{i=1}^{P_1} a(n,i)y(n-i) + \sum_{j=0}^{Q_1} b(n,j)x(n- \qquad (16\text{-}1)$$

$$x(n) = -\sum_{i=1}^{P_2} \alpha(n,i)x(n-i) + \sum_{j=0}^{Q_2} \beta(n,j)y(n-j) \qquad (16\text{-}2)$$

where (16-1) represents $y(n)$ as the output and $x(n)$ as the input. Similarly, (16-2) represents $x(n)$ as the output and $y(n)$ as the input. Given the ARMA models of (16), the two transfer functions of (15) can be obtained as

$$H_{x\to y}(n,e^{j\omega}) = \frac{B(n,e^{j\omega})}{A(n,e^{j\omega})} = \frac{\sum_{i=0}^{Q_1} b(n,j)e^{-j\omega i}}{1+\sum_{i=1}^{P_1} a(n,i)e^{-j\omega i}}$$

$$H_{y\to x}(n,e^{j\omega}) = \frac{\beta(n,e^{j\omega})}{\alpha(n,e^{j\omega})} = \frac{\sum_{i=0}^{Q_2} \beta(n,j)e^{-j\omega i}}{1+\sum_{i=1}^{P_2} \alpha(n,i)e^{-j\omega i}} \qquad (17)$$

Finally, the TVCF can be obtained by multiplying the two transfer functions as described in (17). For the parameter estimation, the time-varying optimal parameter search (TVOPS) criterion can be used, which has been shown to be accurate when applied to many diverse physiological signals. For the physiological signals considered, the TVOPS has been shown to be more accurate than the AIC, minimum description length (MDL) and the fast orthogonal search criterion. For TVOPS, time-varying coefficients are expanded onto a set of basis functions. It has been previously demonstrated that Legendre polynomials are a good choice for capturing dynamics that are smoothly changing with time.

AF Detection: Variance of TVCF

Petitioner Ex-1004, 0396

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For AF detection, two adjacent beat segments with the length denoted as seg has been formulated using the following ARMA models:

$$S_{i+1:i+seg}(n) = -\sum_{i=1}^{P_1} a(n,i)S_{i+1:i+seg}(n-i) + \sum_{j=0}^{Q_1} b(n,j)S_{i+seg+1:i+2\cdot seg}(n-j)$$
$$S_{i+seg+1:i+2\cdot seg}(n) = -\sum_{i=1}^{P_1} \alpha(n,i)S_{i+seg+1:i+2\cdot seg}(n-i) + \sum_{j=0}^{Q_1} \beta(n,j)S_{i+1:i+seg}(n-j) \quad (18)$$

where $S_{i+1:i+seg}(n)$ and $S_{i+seg+1:i+2\cdot seg}(n)$ are two adjacent RR interval time series from the $(i+1)^{th}$ to the $(i+seg)^{th}$ and from the $(i+seg+1)^{th}$ to the $(i+2\cdot seg)^{th}$, respectively. By substituting (18) into (17), the two transfer functions are obtained, and the TVCF is obtained by multiplication of the two TVCFs.

An exemplary embodiment of the measure of atrial fibrillation is presented hereinbelow in order to further elucidate these teachings. It should be noted that these teachings are not limited to the exemplary embodiment.

The detection algorithm was tested on four databases using 128 beat segments: the MIT-BIH AF database, the MIT-BIH normal sinus rhythm (NSR) database (n=18), the MIT-BIH Arrhythmia database (n=48), and a clinical 24-hour Holter AF database (n=15).

In order to illustrate AF detection, the TVCF are calculated using ARMA (P1=5,Q1=5) with the first order Legendre function for subject 8455 of the MIT-BIH AF database. The first order of Legendre polynomials was used as this choice resulted in the best accuracy for the MIT-BIH AF database (N=23). The optimal ARMA model order was found to be P1=5 and Q1=5 with seg=128, which will be explained in detail in the proceeding section. A 128 beat segment was used which was then shifted by 128 beats. A 64 point FFT was used, which resulted in a frequency resolution of

Petitioner Ex-1004, 0397

BNSDOCID: <WO_____2012100175A1_I_>

0.0156 Hz. Figure 5 shows the resultant TVCFs according to each beat and normalized frequency (assuming a Nyquist frequency of 0.5 Hz). As shown in Figure 5, the TVCF values are close to one throughout the entire frequency range for the two adjacent normal sinus rhythm (NSR) data segments. However, the TVCF values significantly decreased when either or both segments partially or fully contained AF.

As shown in Figure 5, it is observed that the TVCF values are highly varying for different frequencies when the patient is in AF. That is, high frequencies tend to have lower coherence values than lower frequencies, in AF (see Figures 6a, 6b). To illustrate this phenomenon in more detail, some of the TVCF values are shown selected at various frequencies from Figure 5 as a function of time in Figure 6(a). Figure 6(b) shows the corresponding average values of TVCF according to each normalized frequency and each 128-beat segment for both the AF and NSR databases. It is noted that for AF data, TVCF values start close to one at low frequencies but they drop to low values quickly as the frequency increases. However, for NSR data, the TVCFs are nearly constant (slightly decreasing) at near unit values for all frequencies. This can be explained by the fact that the selected ARMA model terms for AF include largely self and its delay of one lag terms (e.g. x(n), x(n-1), y(n) and y(n-1)), as expected, thus, TVCF values will be high only at the low frequencies and become lower as frequencies increase. Also note in the left panel of Figure 6, it is observed that the variance of TVCF values is significantly high for AF but nearly constant for NSR.

Based on the latter observation as described above, AF detection is performed by examining the variance of TVCF through the entire frequency range. For each beat, the variance of TVCF values, termed the frequency variations (FV), is calculated

Petitioner Ex-1004, 0398

DID: <WO____2012100175A1_I_>

among all frequencies. Using FV-TVCF, the AF detection performance was investigated on the entire MIT-BIH AF database.

Referring now to Figures 7A and 3B, FV-TVCF values and true AF annotation for three representative subjects 4048, 735 and 7162 of the MIT-BIH AF database are shown. In Figure 7(a), the data set 4048 contains seven AF episodes with lengths of 206, 66, 37, 34, 388, 40 and 42 beats, and the values of FV-TVCF increase in the beats where AF occurs. In Figs. 7(b), the data set 735 contains one AF episode with a length of 332 beats whereas for the dataset 7162, AF episodes persist for the entire time segment shown. The FV-TVCF values reflect this by never returning to a value of zero.

Ectopic Beat Elimination and Shannon Entropy Combination

A NSR segment including premature or ectopic beats may also result in lower TVCF values. In order to reduce the effect of the premature and ectopic beats, we eliminated outliers and filtered ectopic beats. To summarize, premature or ectopic beats can be recognized by their signature short-long RR sequence between normal RR intervals. For each RR interval in the time series, the ratio RR(i)/RR(i-1) was computed, where RR(i) is the ith beat, and eliminated RR(i) and RR(i+1) when the following three conditions were satisfied: 1) RR(i)/RR(i-1)<perc1, 2) RR(i+1)/RR(i)>perc99 and 3) RR(i+1)/RR(i+2)>perc25, where perc1, perc25 and perc99 are the 1st, 25th and 99th percentiles based on a histogram of the RR interval values, respectively.

Shannon entropy (SE) as in (19) was also combined with FV-TVCF, to increase the accuracy of AF detection. SE has been shown to be a robust detector of AF and is estimated according to the following calculation:

Petitioner Ex-1004, 0399

BNSDOCID: <WO_____2012100175A1_I_>

$$SE = -\sum_{u=1}^{N_{bin}} p(u) \frac{log(p(u))}{log(\frac{1}{N_{bin}})} \qquad (19)$$

Note that N_{bin} was selected for the best accuracy according to segment lengths while $N_{bin} = 16$ was selected.

Detector Optimization

In one embodiment, the condition for AF detection can be given by a simple logical AND condition:

If (FV $\geq TH_{var}$) AND (SE $\geq TH_{SE}$), then classify it as AF.

Else classify it as non-AF.

TH_{var} and TH_{SE} are the threshold values of the variance and the Shannon entropy, respectively, and are selected based on the best accuracy; specifically, we used receiver operator characteristic (ROC) analyses. For each combination of TH_{var} and TH_{SE}, the number of True Positives (TP), True Negatives (TN), False Positives (FP) and False Negatives (FN) were found, and used the accuracy (TP+TN)/(TP+TN+FP+FN) on the MIT-BIH AF database. In addition, the sensitivity TP/(TP+FN) and specificity TN/(TN+FP) were calculated. The procedure was repeated by changing the order of ARMA model and the lengths of segments. Note that the ARMA model order was restricted by setting P1=Q1. After finding the values of TH_{var} and TH_{SE} with each different number of model orders and lengths of segments, the same parameters were applied to the databases from MIT-BIH and the clinical AF database.

In another embodiment of the method for obtaining a measure of atrial fibrillation, the method, using the Root Mean Square of Successive Differences (RMSSD), disclosed in United States Patent Application No. 20110166466, entitled RR INTERVAL MONITORING METHOD AND BLOOD PRESSURE CUFF UTILIZING SAME, published on July 7, 2011, which is incorporated by reference herein is entirety for all purposes, is applied.

Petitioner Ex-1004, 0400

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In one or more embodiments, the system of these teachings for physiological parameter monitoring includes a physiological indicator signal sensing component (sensor) and a mobile communication device having an analysis component analyzing the physiological indicator signal to obtain measurements of one or more physiological parameters and a motion artifact detection component detecting effects of motion artifacts in the measurements of the one or more physiological parameters.

In one instance, the mobile communication device includes one or more processors and one or more computer usable media, where the computer usable media has computer readable code embodied therein that causes the processor to analyze the physiological indicator signal to obtain measurements of one or more physiological parameters and to detect effects of motion artifacts in the measurements of the one or more physiological parameters. In one or more embodiments, the computer readable code causes the processor to implement the methods described hereinabove.

It should be noted that other embodiments of the mobile communication device, such as the use of ASICs or FPGAs in order to implement the analysis component and/or the motion artifact detection component are within the scope of these teachings.

Fig. 8 is a block diagram representation of one embodiment of the system of these teachings. Referring to Fig. 8, in the embodiment shown therein, a mobile communication system 280 includes a processor 250 and one or more memories 260. A physiological indicator signal sensing component (sensor) 270 supplies a physiological indicators signal to the mobile communication device 280. The sensor 270 can be a photoplethysmographic (PPG) sensor or an electrocardiogram (EKG) sensor. In the embodiment shown in Fig. 8, a camera 265, where the camera as an objective lens 267, can also supply the

Petitioner Ex-1004, 0401

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physiological indicators signal to the mobile communication device 280. The one or more memories 260 have computer usable code embodied therein that causes the processor 250 to that causes the processor to analyze the physiological indicator signal to obtain measurements of one or more physiological parameters and to detect effects of motion artifacts in the measurements of the one or more physiological parameters. In one or more instances, the computer readable code causes the processor 250 to perform the implement the methods described hereinabove.

The one or more memories 260 represent one embodiment of computer usable media having computer readable code embodied therein that causes a processor to implement the methods of these teachings. Embodiments of the method of these teachings are described hereinabove and the computer readable code can cause a processor to implement those embodiments.

In the embodiment shown in Fig. 8, the mobile communication device 280 also includes an antenna 265 that enables communications through one or more of a variety of wireless protocols or over wireless networks. It should be noted that, although the sensor 270 is shown as being directly connected to the mobile communication device 280, embodiments in which the sensor 270 provides the physiological indicators signal to the mobile communication device 280 through a wireless connection are also within the scope of these teachings.

For the purposes of describing and defining the present teachings, it is noted that the term "substantially" is utilized herein to represent the inherent degree of uncertainty that may be attributed to any quantitative comparison, value, measurement, or other representation. The term "substantially" is also utilized herein to represent the degree by which a quantitative

Petitioner Ex-1004, 0402

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representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

Elements and components described herein may be further divided into additional components or joined together to form fewer components for performing the same functions.

Each computer program may be implemented in any programming language, such as assembly language, machine language, a high-level procedural programming language, or an object-oriented programming language. The programming language may be a compiled or interpreted programming language.

Each computer program may be implemented in a computer program product tangibly embodied in a computer-readable storage device for execution by a computer processor. Method steps of the invention may be performed by a computer processor executing a program tangibly embodied on a computer-readable medium to perform functions of the invention by operating on input and generating output.

Common forms of computer-readable media include, for example, a floppy disk, a flexible disk, hard disk, magnetic tape, or any other magnetic medium, a CDROM, any other optical medium, any physical medium with patterns of holes, a RAM, a PROM, and EPROM, a FLASH-EPROM, any other memory chip or cartridge, all of which are non-transitory. As stated in the USPTO 2005 Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. Office 142 (Nov. 22, 2005), "On the other hand, from a technological standpoint, a signal encoded with functional descriptive material is similar to a computer-readable memory encoded with functional descriptive material, in that they both create a functional interrelationship with a computer. In other words, a computer is able to execute the encoded functions, regardless of whether the format is a disk or a signal."

Petitioner Ex-1004, 0403

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Although the invention has been described with respect to various embodiments, it should be realized these teachings are also capable of a wide variety of further and other embodiments within the spirit and scope of the appended claims.

What is claimed is:

Petitioner Ex-1004, 0404

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CLAIMS

1. A method for physiological parameter monitoring, the method comprising:

providing a physiological indicator signal to a mobile communication device;

analyzing, using the mobile communications device, the physiological indicator signal to obtain measurements of one or more physiological parameters; and

detecting, using the mobile communications device, effects of motion artifacts in the measurements of the one or more physiological parameters and deciding whether to retain the measurements.

2. The method of claim 1 wherein the step of detecting effects of motion artifacts in the measurements comprises:

a. preprocessing a segment from the measurement of one physiological parameter;

b. obtaining a value of at least one indicator of volatility for the preprocessed segment;

c. including the segment in analyses of physiological measurements, if comparison of the value of the at least one indicator of volatility with a predetermined threshold indicates noise/motion artifacts are not present; and

d. selecting another segment of the signal from the physiological measurement and proceeding to step (a), if the value of the at least one indicator of volatility is less than a predetermined threshold and another segment is available.

Petitioner Ex-1004, 0405

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3. The method of claim 2 wherein said at least one indicator of volatility comprises kurtosis.

4. The method of claim 2 wherein said at least one indicator of volatility comprises Shannon entropy.

5. The method of claim 2 wherein said at least one measure of volatility comprises kurtosis and Shannon entropy.

6. The method of claim 2 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.

7. The method of claim 1 wherein providing a physiological indicator signal comprises:
placing a portion of a subject's body over an objective lens of a camera in a mobile communication device; and

obtaining video images of the portion of the subject's body.

8. The method of claim 1 wherein providing a physiological indicator signal comprises obtaining a signal from a physiological monitoring sensor.

9. The method of claim 8 wherein the physiological monitoring sensor is a photoplethysmographic (PPG) sensor or an electrocardiogram sensor.

10. The method of claim 1 wherein the one or more physiological measurements comprise heart rate and heart rate variability.

Petitioner Ex-1004, 0406

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11. The method of claim 10 wherein obtaining measurements of heart rate and heart rate variability comprise:
determining beats for the physiological indicator signal;

determining beat to beat intervals; and

applying a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.

12. The method of claim 1 wherein the one or more physiological measurements comprise respiratory rate.

13. The method of claim 12 wherein measurement of respiratory rate comprises:
obtaining time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and

obtaining respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.

14. The method of claim 1 wherein the one or more physiological measurements comprise a measure of oxygen saturation.

15. The method of claim 14 wherein providing a physiological indicator signal comprises:
placing a portion of a subject's body over an objective lens of a camera in a mobile communication device; and

Petitioner Ex-1004, 0407

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obtaining video images of the portion of the subject's body, and

wherein obtaining the measure of oxygen saturation comprises:

obtaining an average intensity of a red component and a blue component of the video images of the portion of the subject's body; the average intensity of the red component and the average intensity of the blue component constituting DC_{RED} and DC_{BLUE} respectively;

obtaining a standard deviation of the red component and the blue component; the standard deviation of the red component and the blue component constituting AC_{RED} and AC_{BLUE} respectively; and

obtaining the measure of oxygen saturation (SpO2) by

$$SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}.$$

16. The method of claim 1 wherein the one or more physiological measurements comprise a measure of blood loss.

17. The method of claim 16 wherein obtaining the measure of blood loss comprises:

obtaining time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM);

Petitioner Ex-1004, 0408

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obtaining the amplitude modulation (AM) series from a set of the largest instantaneous amplitude at each time sample within the heart rate frequency band of the time-frequency spectrum; and

determining whether the amplitude modulation decreases; a decrease in the amplitude modulation indicating blood volume loss in subject.

18. The method of claim 1 wherein the one or more physiological measurements comprise a measure of atrial fibrillation.

19. The method of claim 18 wherein obtaining the measure of atrial fibrillation comprises:

obtaining a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments with one data segment as input signal and the other data segment as output to produce the first TVTF; the second TVTF is produced by reversing the input and output signals; and

determining whether the time-varying coherence function is less than a predetermined quantity.

20. The method of claim 19 wherein determining whether the time-varying coherence function is less than the predetermined quantity comprises:

obtaining one or more indicators of atrial fibrillation; and

Petitioner Ex-1004, 0409

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determining whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.

21. The method of claim 20 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.

22. The method of claim 21 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.

23. The method of claim 20 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.

24. A system for physiological parameter monitoring, the system comprising:
a physiological indicator signal sensing component; and a mobile communication device comprising:
an analysis component analyzing the physiological indicator signal to obtain measurements of one or more physiological parameters; and

a motion artifact detection component detecting effects of motion artifacts in the measurements of the one or more physiological parameters.

25. The system of claim 24 wherein the mobile communications device comprises:
at least one processor; and

at least one computer usable medium, the computer usable medium having computer readable code embodied therein, the

Petitioner Ex-1004, 0410

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computer readable code causing the at least one processor to:

analyze the physiological indicator signal to obtain measurements of one or more physiological parameters; and

detect effects of motion artifacts in the measurements of the one or more physiological parameters.

26. The system of claim 25 wherein the computer readable code, in causing the at least one processor to detect effects of motion artifacts, causes the at least one processor to:

a. preprocess a segment from the measurement of one physiological parameter;

b. obtain a value of at least one indicator of volatility for the preprocessed segment;

c. include the segment in analyses of physiological measurements, if comparison of the value of the at least one indicator of volatility with a predetermined threshold indicates noise/motion artifacts are not present;

d. select another segment of the signal from the physiological measurement and proceeding to step (a), if the value of the at least one indicator of volatility is less than a predetermined threshold and another segment is available.

27. The system of claim 26 wherein said at least one indicator of volatility comprises kurtosis.

28. The system of claim 26 wherein said at least one indicator of volatility comprises Shannon entropy.

Petitioner Ex-1004, 0411

BNSDOCID: <WO____2012100175A1_I_>

29. The system of claim 26 wherein said at least one measure of volatility comprises kurtosis and Shannon entropy.

30. The system of claim 26 wherein the predetermined threshold is determined using receiver operator characteristic (ROC) analysis.

31. The system of claim 24 wherein the physiological indicator signal sensing component comprises an image acquisition component, said acquisition component capable of acquiring a number of frames, each frame acquired at a predetermined time.

32. The system of claim 31 wherein the mobile communications device comprises said image acquisition component.

33. The system of claim 24 wherein the physiological indicator signal sensing component comprises a physiological monitoring sensor.

34. The system of claim 33 wherein the physiological monitoring sensor is a photoplethysmographic (PPG) sensor or an electrocardiogram sensor.

35. The system of claim 25 wherein the physiological indicator signal sensing component comprises an image acquisition component, said acquisition component capable of acquiring a number of frames, each frame acquired at a predetermined time; wherein said image acquisition component acquires a color image having red, green and blue components; wherein one or more physiological measurements comprise a measure

Petitioner Ex-1004, 0412

ID: <WO_____2012100175A1_I_>

of oxygen saturation; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain an average intensity of a red component and a blue component of the images of a portion of a subject's body; the average intensity of the red component and the average intensity of the blue component constituting DC_{RED} and DC_{BLUE} respectively;

obtain a standard deviation of the red component and the blue component; the standard deviation of the red component and the blue component constituting AC_{RED} and AC_{BLUE} respectively; and

obtain the measure of oxygen saturation by

$$SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}.$$

36. The system of claim 25 wherein the one or more physiological measurements comprise heart rate and heart rate variability; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

determine beats for the physiological indicator signal; determine beat to beat intervals; and

Petitioner Ex-1004, 0413

BNSDOCID: <WO____2012100175A1_I_>

apply a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.

37. The system of claim 25 wherein the one or more physiological measurements comprise respiratory rate; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and

obtain respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.

38. The system of claim 25 wherein the one or more physiological measurements comprise a measure of blood loss; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM);

obtain the amplitude modulation (AM) series from set of the largest instantaneous amplitude at each time sample within the heart rate frequency band of the time-frequency spectrum; and

Petitioner Ex-1004, 0414

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determine whether the amplitude modulation decreases; a decrease in the amplitude modulation indicating blood volume loss in subject.

39. The system of claim 25 wherein the one or more physiological measurements comprise a measure of atrial fibrillation; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments with one data segment as input signal and the other data segment as output to produce the first TVTF; the second TVTF is produced by reversing the input and output signals; and

determine whether the time-varying coherence function is less than a predetermined quantity.

40. The system of claim 39 wherein the computer readable code, in causing the at least one processor to determine whether the time-varying coherence function is less than the predetermined quantity, causes the at least one processor to:

obtain one or more indicators of atrial fibrillation; and determine whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.

Petitioner Ex-1004, 0415

BNSDOCID: <WO____2012100175A1_I_>

41. The system of claim 40 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.

42. The system of claim 41 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.

43. The system of claim 41 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.

44. A computer usable medium having computer readable code embodied therein, the computer readable code causing at least one processor to:

analyze a physiological indicator signal to obtain measurements of one or more physiological parameters; and

detect effects of motion artifacts in the measurements of the one or more physiological parameters.

45. The computer usable medium of claim 44 wherein the physiological indicator signal comprises a video color image having red, green and blue components, the video color image being an image obtained from of a portion of a subject's body; wherein the measurements of one or more physiological parameters comprise a measure of oxygen saturation; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

Petitioner Ex-1004, 0416

BNSDOCID: <WO____2012100175A1_I_>

obtain an average intensity of the red component and a blue component of the video color image of a portion of a subject's body; the average intensity of the red component and the average intensity of the blue component constituting DC_{RED} and DC_{BLUE} respectively;

obtain a standard deviation of the red component and the blue component; the standard deviation of the red component and the blue component constituting AC_{RED} and AC_{BLUE} respectively; and

obtain the measure of oxygen saturation by

$$SpO2 = A - B\frac{AC_{RED}/DC_{RED}}{AC_{BLUE}/DC_{BLUE}}.$$

46. The computer usable medium of claim 44 wherein the one or more physiological measurements comprise heart rate and heart rate variability; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

determine beats for the physiological indicator signal;

determine beat to beat intervals; and

apply a cubic spline algorithm to obtain a substantially continuous beat to beat interval signal indicative of heart rate.

Petitioner Ex-1004, 0417

BNSDOCID: <WO____2012100175A1_I_>

47. The computer usable medium of claim 44 wherein the one or more physiological measurements comprise respiratory rate; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM); and

obtain respiratory rates by extracting a frequency component that has a largest amplitude for each time point at a heart rate frequency band.

48. The computer usable medium of claim 44 wherein the one or more physiological measurements comprise a measure of blood loss; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain time-frequency spectrum of the physiological indicator signal utilizing variable frequency complex demodulation (VFCDM);

obtain the amplitude modulation (AM) series from set of the largest instantaneous amplitude at each time sample within the heart rate frequency band of the time-frequency spectrum; and

determine whether the amplitude modulation decreases; a decrease in the amplitude modulation indicating blood volume loss in subject.

Petitioner Ex-1004, 0418

SID: <WO 2012100175A1 >

49. The computer usable medium of claim 44 wherein the one or more physiological measurements comprise a measure of atrial fibrillation; and wherein the computer readable code, in causing the at least one processor to analyze the physiological indicator signal, causes the at least one processor to:

obtain a time-varying coherence function by multiplying two time-varying transfer functions (TVFTs), the two time-varying transfer functions obtained using two adjacent data segments with one data segment as input signal and the other data segment as output to produce the first TVTF; the second TVTF is produced by reversing the input and output signals; and

determine whether the time-varying coherence function is less than a predetermined quantity.

50. The computer usable medium of claim 44 wherein the computer readable code, in causing the at least one processor to determine whether the time-varying coherence function is less than the predetermined quantity, causes the at least one processor to:

obtain one or more indicators of atrial fibrillation; determine whether the one or more indicators of atrial fibrillation exceed predetermined thresholds.

51. The computer usable medium of claim 50 wherein the one or more indicators of atrial fibrillation comprise a variance of the time-varying coherence function.

Petitioner Ex-1004, 0419

BNSDOCID: <WO____2012100175A1_I_>

52. The computer usable medium of claim 51 wherein the one or more indicators of atrial fibrillation also comprise Shannon entropy.

53. The computer usable medium of claim 50 wherein the predetermined thresholds are determined using receiver operator characteristic (ROC) analysis.

Petitioner Ex-1004, 0420

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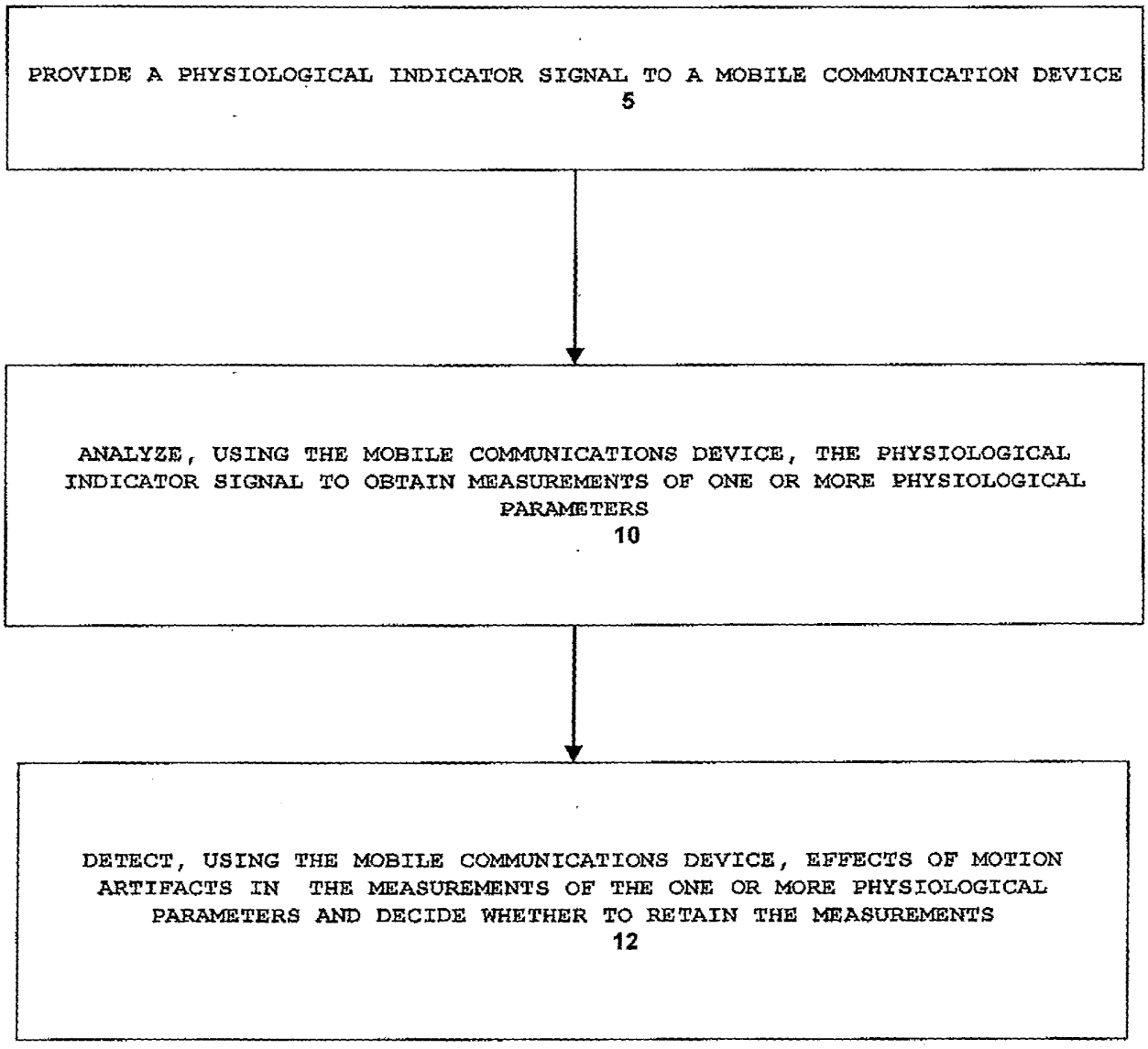

PROVIDE A PHYSIOLOGICAL INDICATOR SIGNAL TO A MOBILE COMMUNICATION DEVICE
5
ANALYZE, USING THE MOBILE COMMUNICATIONS DEVICE, THE PHYSIOLOGICAL INDICATOR SIGNAL TO OBTAIN MEASUREMENTS OF ONE OR MORE PHYSIOLOGICAL PARAMETERS
10
DETECT, USING THE MOBILE COMMUNICATIONS DEVICE, EFFECTS OF MOTION ARTIFACTS IN THE MEASUREMENTS OF THE ONE OR MORE PHYSIOLOGICAL PARAMETERS AND DECIDE WHETHER TO RETAIN THE MEASUREMENTS
12

Fig. 1

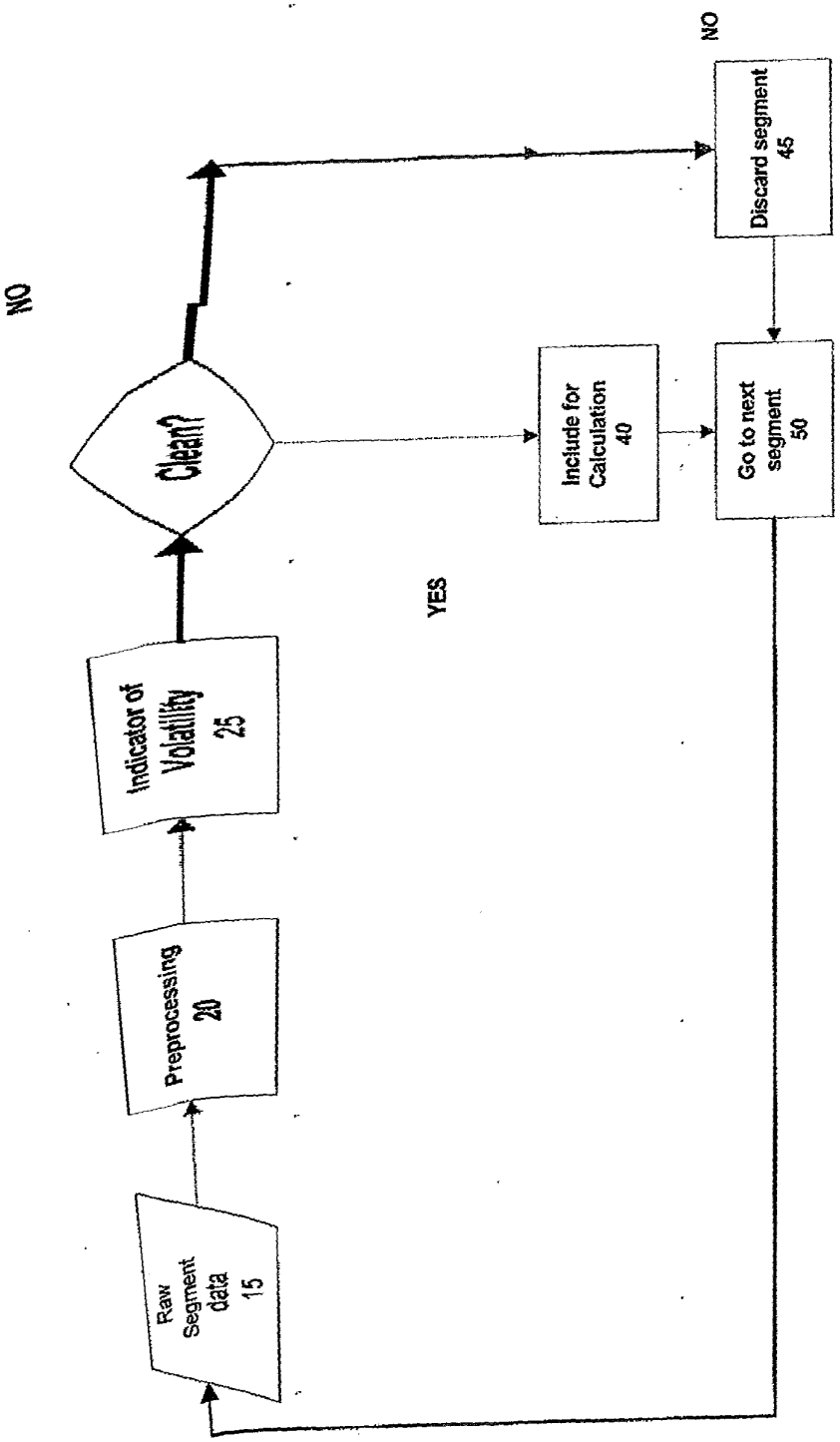

Raw Segment data 15
Preprocessing 20
Indicator of Volatility 25
Clean?
NO
YES
Include for Calculation 40
Discard segment 45
NO
Go to next segment 50

Fig. 1a

BNSDOCID: <WO_____2012100175A1_I_>

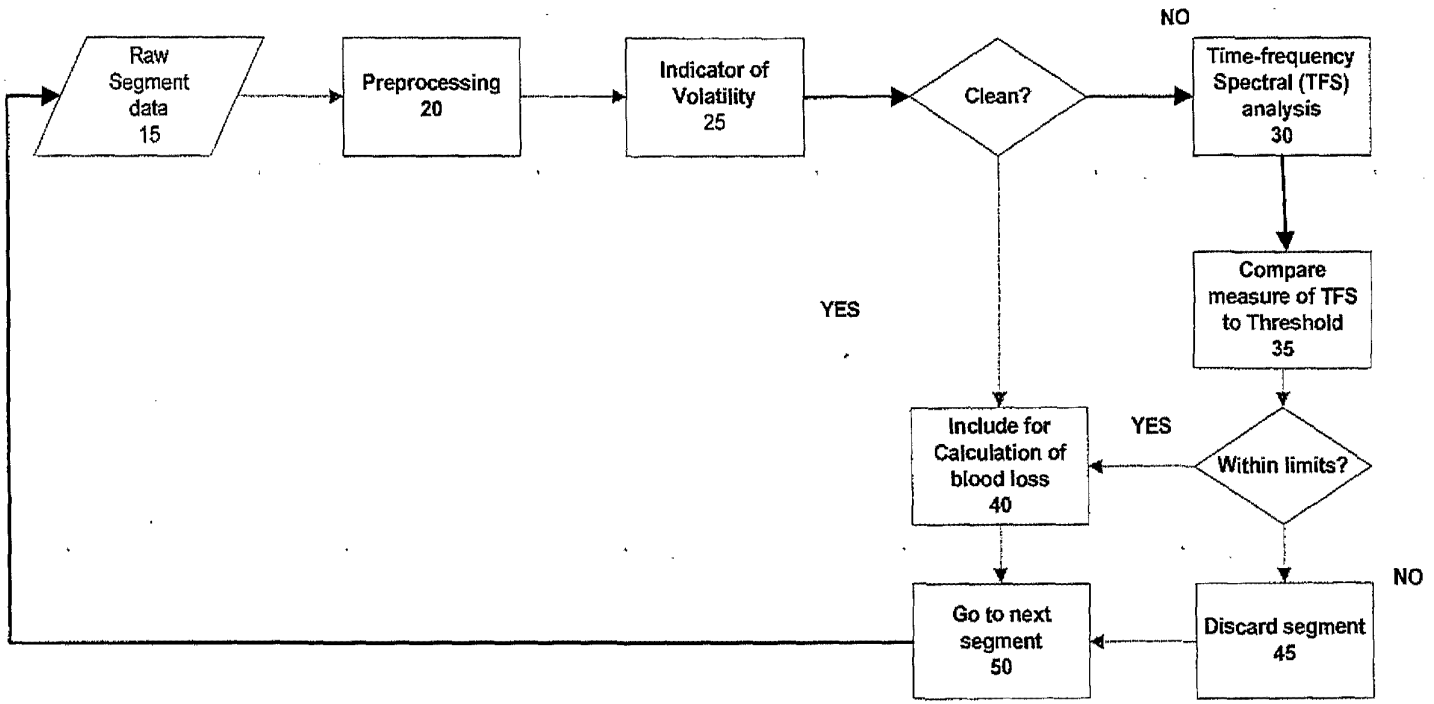
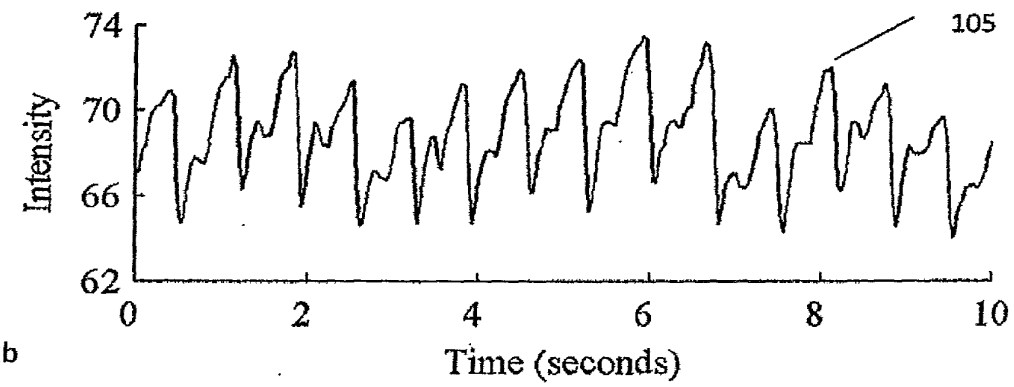
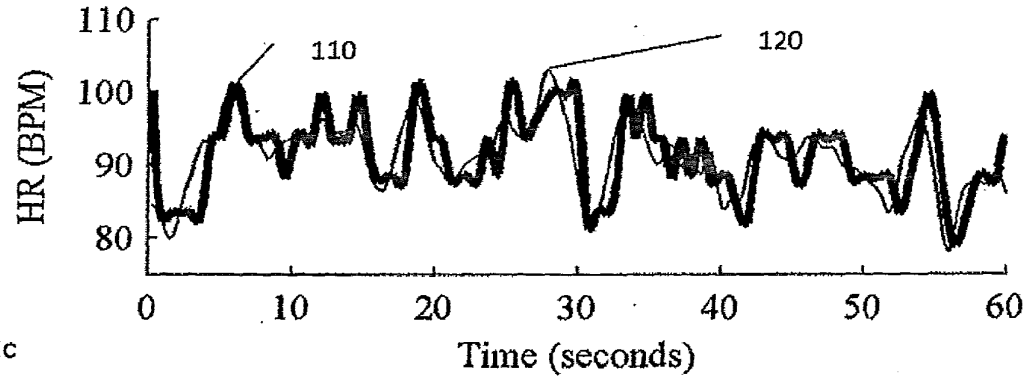


Fig. 1b

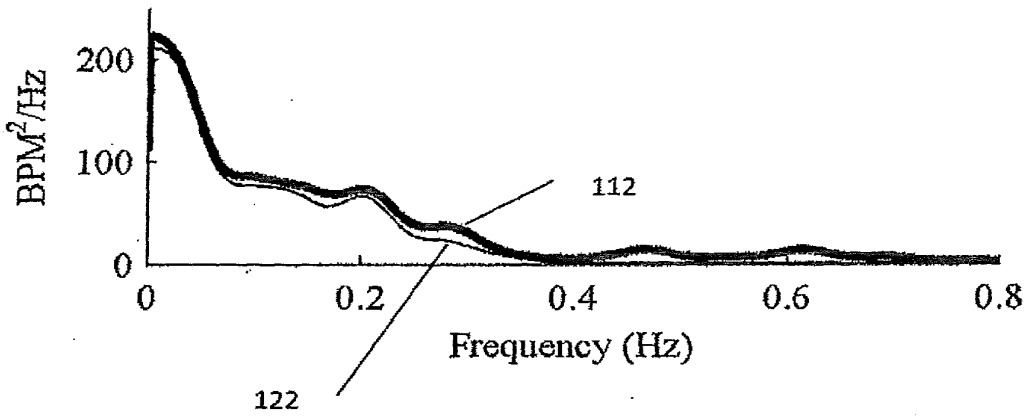
2a



2b

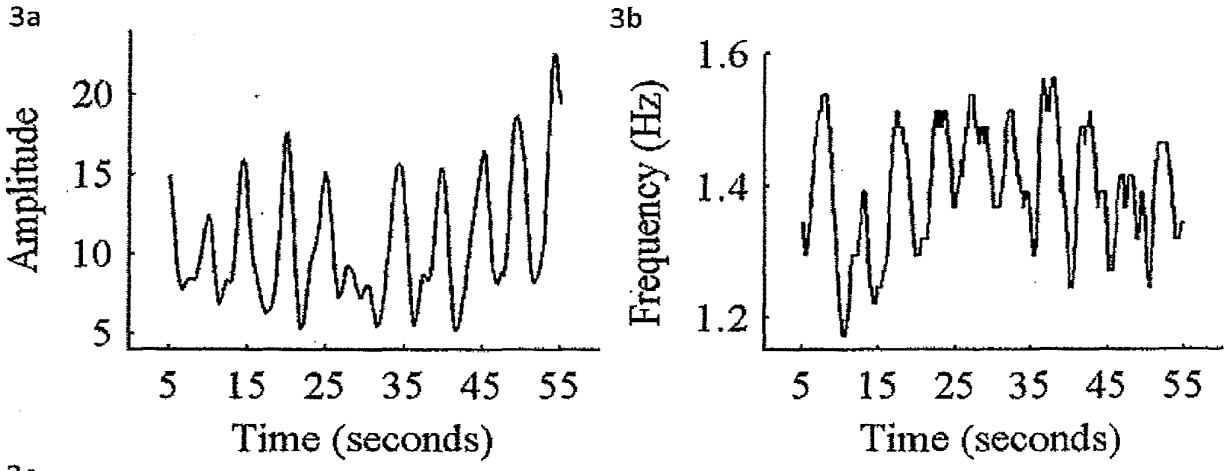


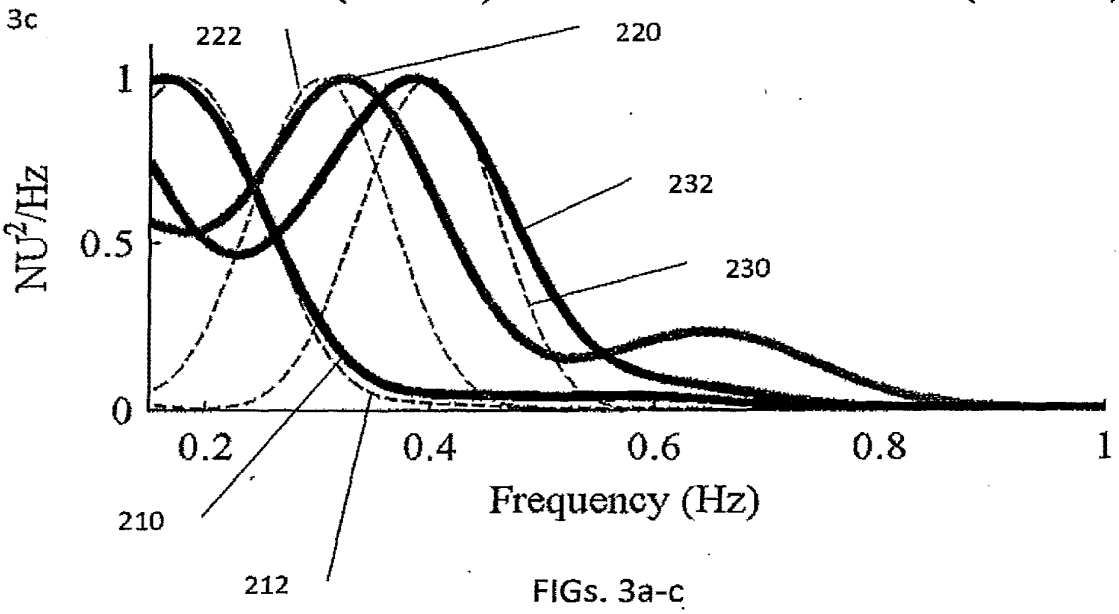
2c



Figs. 2a-c

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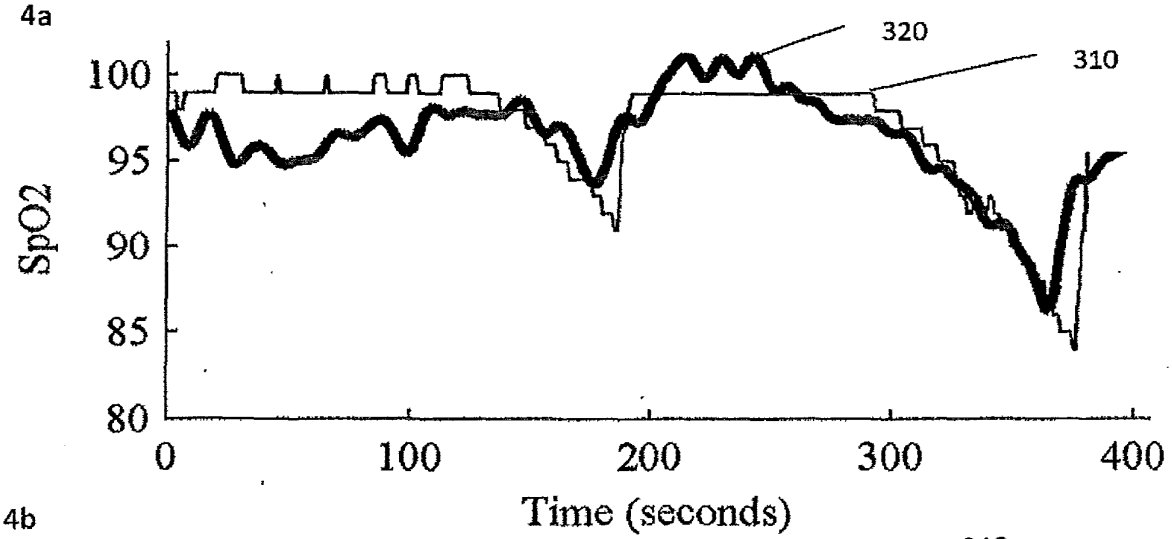




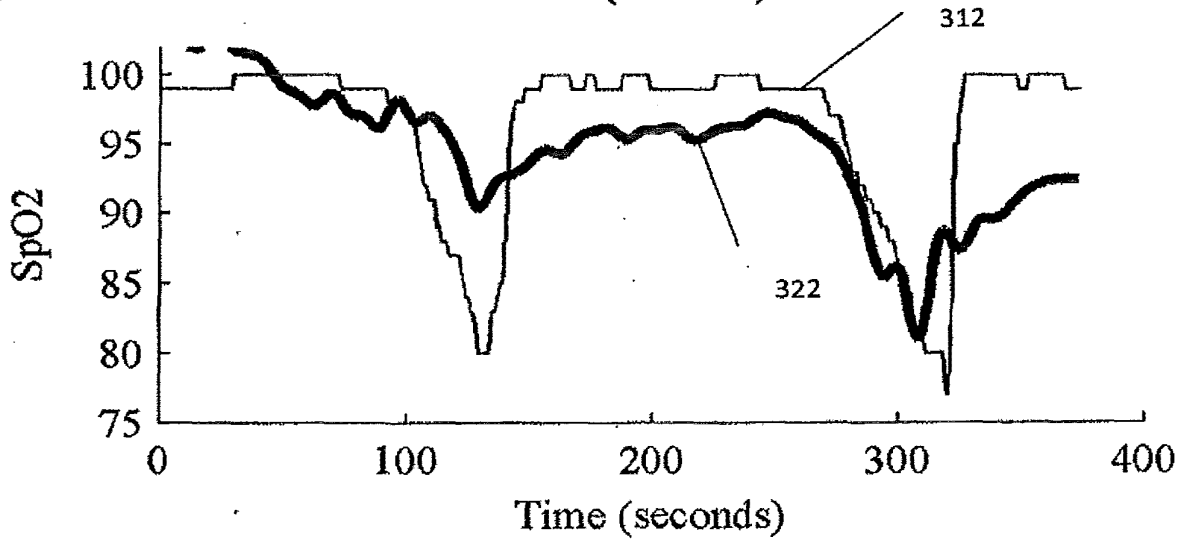
FIGs. 3a-c

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4a



4b



Figs. 4a-b

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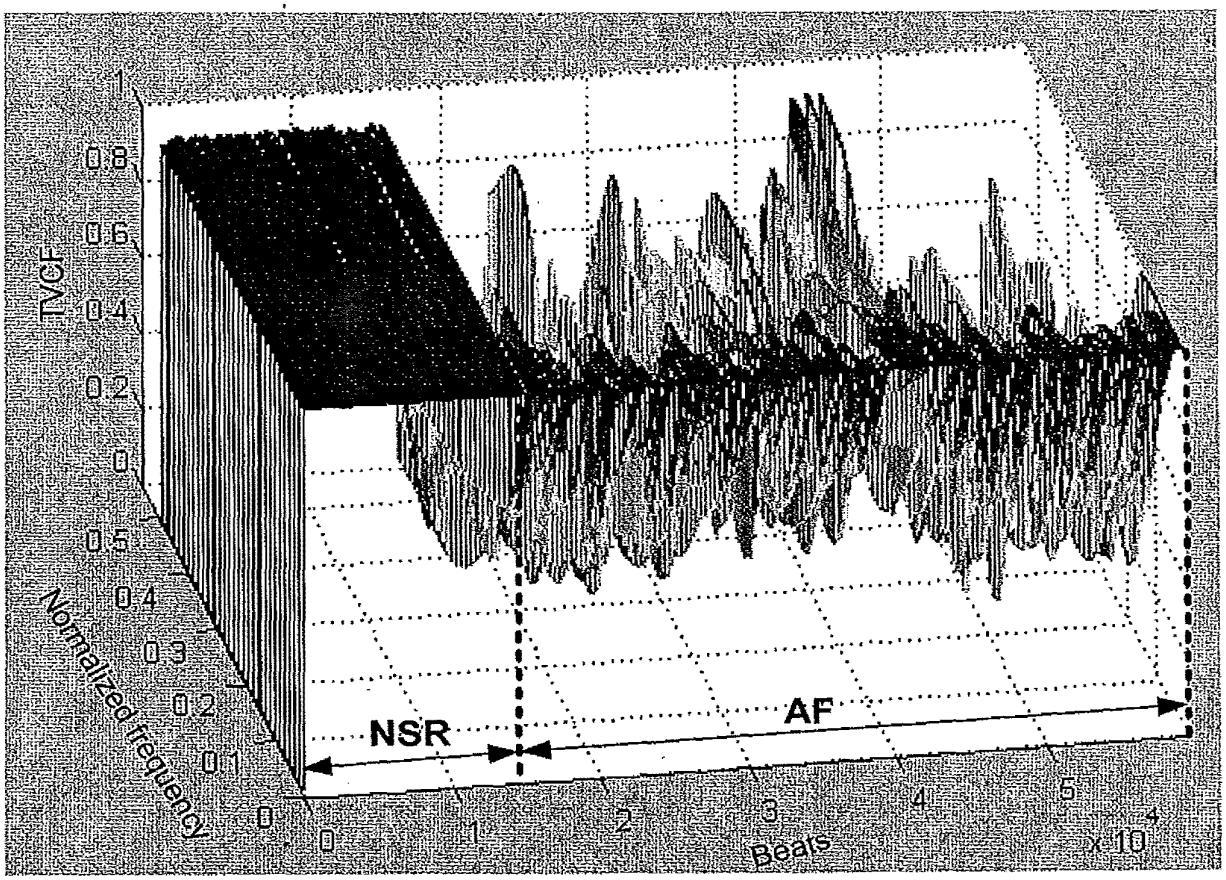


Fig. 5

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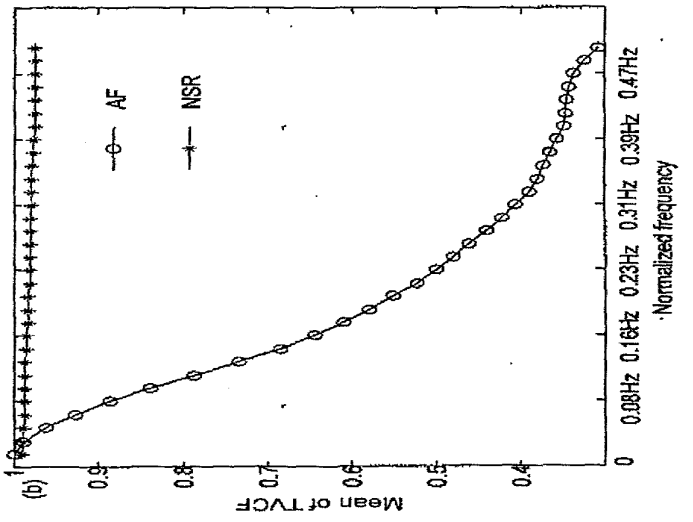


Fig. 6b

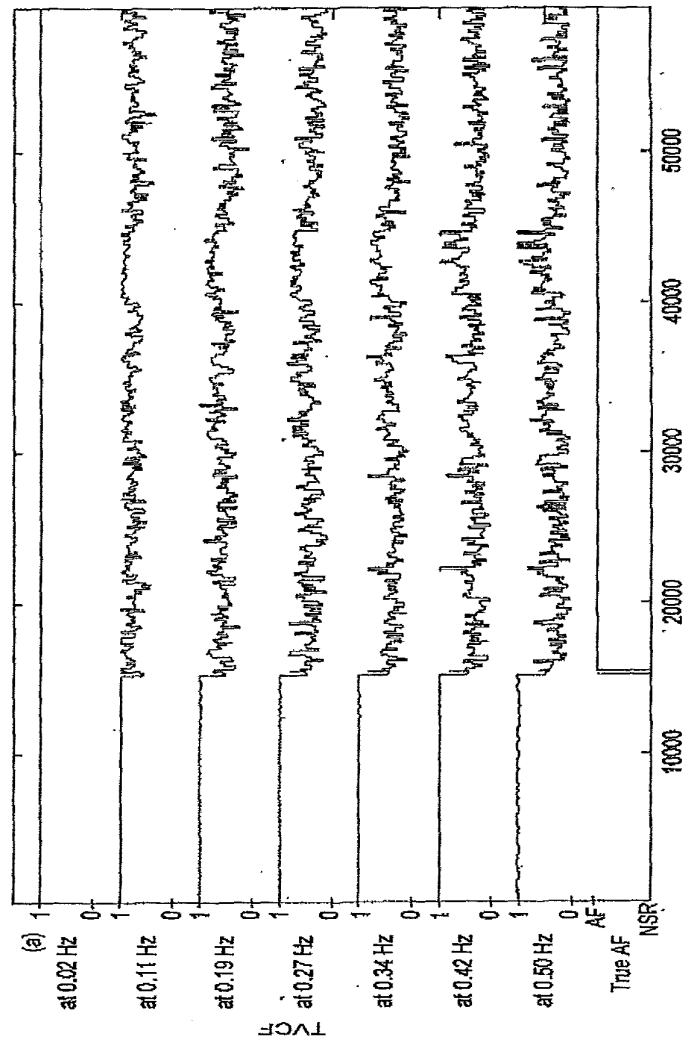
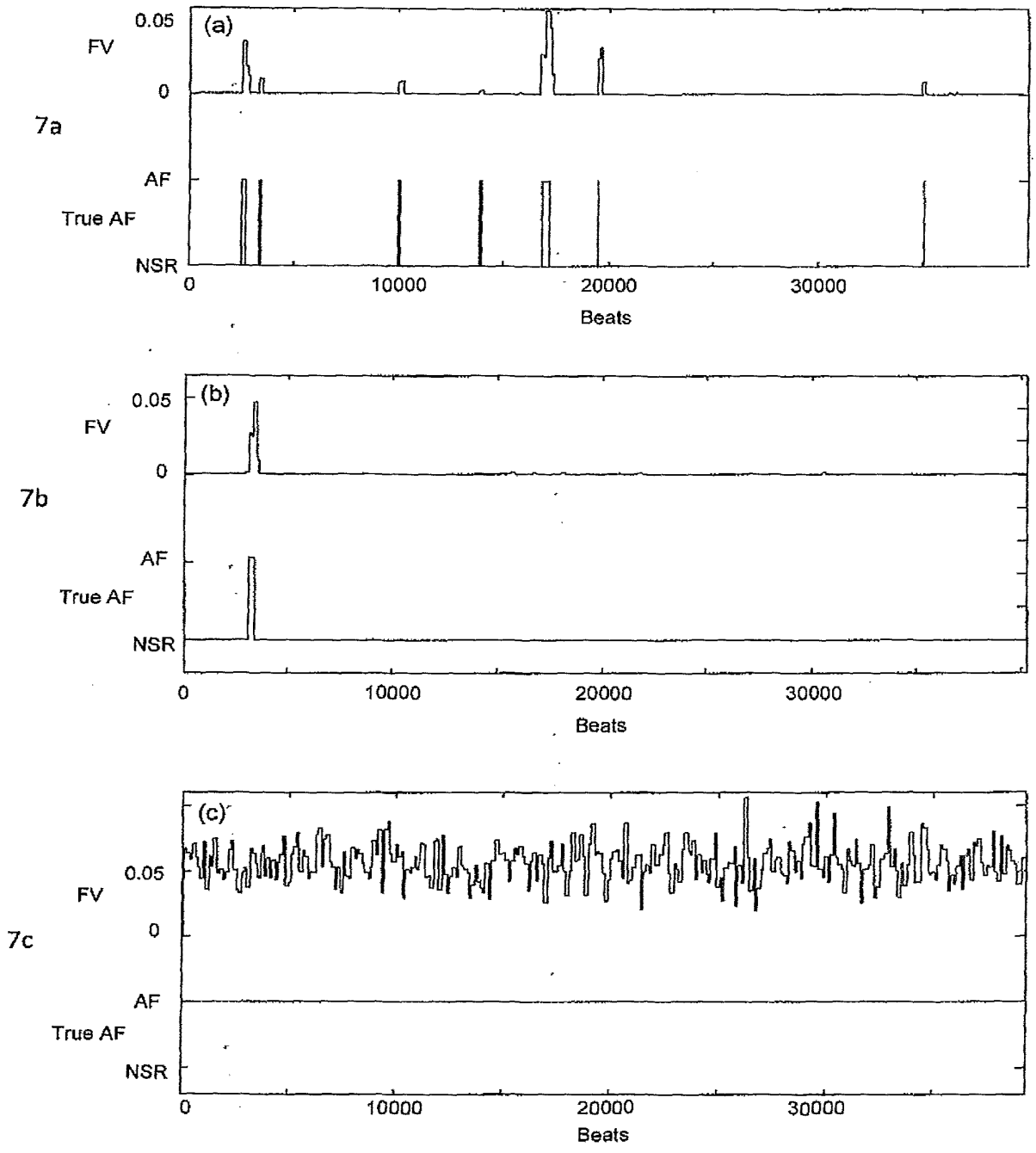


Fig. 6a

Petitioner Ex-1004, 0428

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Figs. 7a-c

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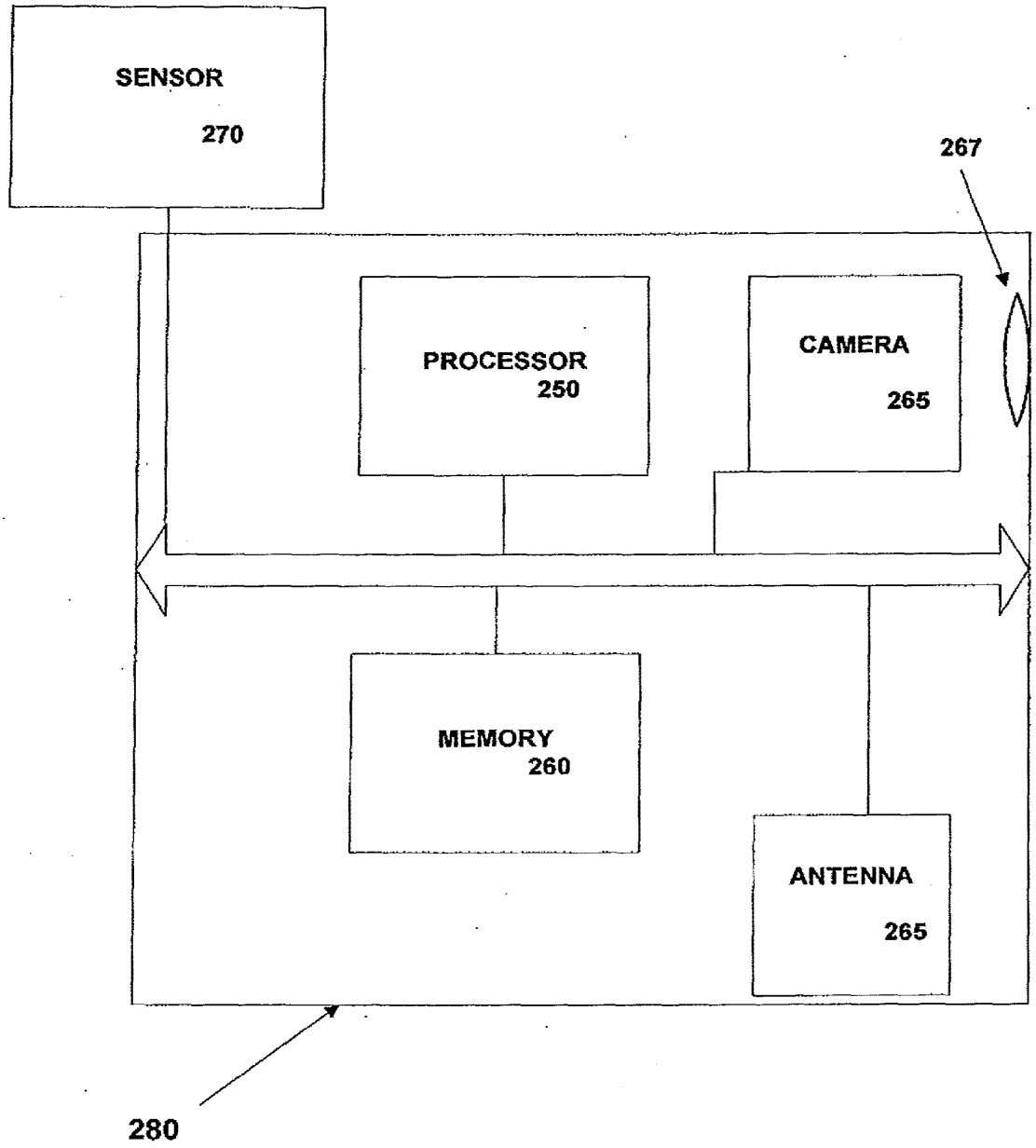


Fig. 8

BNSDOCID: <WO_____2012100175A1_I_>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/022049

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/02(2006.01)i, A61B 5/0452(2006.01)i, A61B 5/1455(2006.01)i, H04B 7/24(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/02; A61B 5/00

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: physiological, sensor, motion artifact, discard

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010-0030088 A1 (CARNEY JAMES KEVIN et al.) 04 February 2010	24,44
Y	See abstract, paragraphs [0028]-[0049],[0106]-[0121], claims 1-22,	1
A	and figures 1,8-10.	2-23,25-43,45-53
X	US 2006-0135860 A1 (CLARK BAKER et al.) 22 June 2006	44
Y	See abstract, paragraphs [0021]-[0028],[0043],[0057]-[0059], claims 1-28, and figures 1,2.	1
X	US 2007-0078316 A1 (HOARAU CARINE et al.) 05 April 2007 See abstract, paragraphs [0047]-[0052], claims 47,48, and figures 7-9.	44
X	US 7254425 B2 ((MICHAEL G. LOWERY et al.) 07 August 2007 See abstract, column 4, lines 51-67, and claims 1-12.	44

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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 citation or other special reason (as specified)
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"P" document published prior to the international filing date but later than the priority date claimed
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"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
27 JUNE 2012 (27.06.2012)	**28 JUNE 2012 (28.06.2012)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM Tae Hoon Telephone No. 82-42-481-5728

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

BNSDOCID: <WO_____2012100175A1_I_>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/022049

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BNSDOCID: <WO_____2012100175A1_I_>

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

(11) EP 2 792 297 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
22.10.2014 Bulletin 2014/43

(51) Int Cl.:
A61B 5/00 *(2006.01)* ***A61B 5/04*** *(2006.01)*

(21) Application number: **14164272.8**

(22) Date of filing: **10.04.2014**

(84) Designated Contracting States:
AL 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 RS SE SI SK SM TR
Designated Extension States:
BA ME

(30) Priority: **15.04.2013 EP 13163813**

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5656 AE Eindhoven (NL)

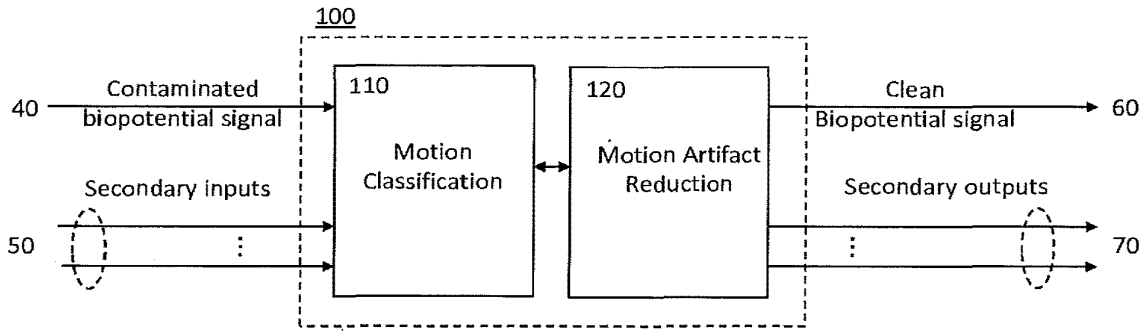
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- **Mihajlovic, Vojkan**
  3001 Leuven (BE)

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IP Department
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(54) System and method for the analysis of biopotential signals using motion artifact removal techniques

(57) The invention relates to a system (100) for the analysis of biopotential signals, comprising: a motion classification module (110) configured for receiving at least one biopotential signal (40) and at least one reference secondary input signal (50), performing motion artifact classification for determining motion information (MMI) comprising a type and/or severity indication about motion phenomena causing artifacts in the biopotential signal and communicating said motion information (MMI) to a motion artifact reduction module (120); the motion artifact reduction module (120) configured for performing motion artifact removal from the biopotential signal based on the information received from the motion classification module (110); wherein the system is further configured for evaluating the effectiveness of at least one algorithm used for motion artifact removal and generating feedback information (190) between the motion classification module (110) and the motion artifact reduction module (120) for optimizing the performance of the motion artifact classification.

Figure 1



EP 2 792 297 A1

Description

Technical Field

[0001] The present invention relates generally to the field of biopotentital signal analysis, e.g. detecting, monitoring and/or processing electrocardiogram (ECG), electroencephalogram (EEG) or electromyography (EMG) signals. More specifically the invention relates to a system and a method for the analysis of such biopotential signals using motion artifact removal techniques.

Background

[0002] In real life situations and ambulatory recordings of biopotential signals, motion artifacts result from relative movement of recording electrodes, cables, and acquisition system with respect to the skin and the environment. The most significant changes during motion are happening on the interface between the skin and the electrodes. These might be due to changes in the charge distribution along the contact surface or skin deformations and hence changes in conduction within the skin. However, different type of movements might induce distinct changes in the measured electrical activity.

[0003] A known system that proposes motion artifact removal from ECG signals is described in paper *"Motion Artifact Removal using Cascade Adaptive Filtering for Ambulatory ECG Monitoring System"*, Hyejung Kim et al., Proc. BioCAS 2012.

[0004] Another known technique for motion artifact removal from ECG signals is disclosed in paper "Implementation of Fuzzy-rule based Activity Classification and Optimized Adaptive Filter-set for Wearable ECG Recording", Yun-Hong Noh and Do-Un Jeong, International Journal of Multimedia and Ubiquitous Engineering, Vol.7, No.4, October 2012. The solution proposes the use of an adaptive filter with an optimal filter coefficient selection to remove motion artifacts. With the data obtained from a three-axis accelerometer, activity status can be classified into different states and optimal filter coefficients can then be selected to minimize the distortion of ECG signal.

[0005] US patent 5,513,649 describes an EEG (electroencephalogram) system that detects brain waves from a subject, and reduces the adverse effect of artifacts due to head, body and eye movements. A head and body movement reference signal can be provided by an accelerometer, motion detector or, alternatively, spatial average of EEG channels. Eye motion sensors are used as a reference for eye movement artifacts.

Summary

[0006] According to exemplary embodiments of the invention, there is provided a new and improved system and method for removing motion artifacts from biopotential signals.

[0007] Advantageously, according to embodiments of the invention, the proposed system and method adaptively and automatically determines and sets appropriate motion artifact reduction techniques based on the motion type and/or severity affecting the biopotencial signal.

[0008] According to some exemplary embodiments of the invention, the proposed system and method is particularly advantageous for wireless, low power data acquisition technology and/or ambulatory biopotential measurement applications.

[0009] It is also advantageous that the proposed system and method allows for reliable and high quality biosignal monitoring in ambulatory conditions.

[0010] According to some embodiments, it is important to focus on characterizing the effects of human motion on EEG but also other biopoential signals that can be monitored with low-power devices.

[0011] According to an exemplary embodiment, there is provided a system for the analysis of biopotential signals, comprising: a motion artifact reduction module configured for reducing or eliminating a motion artifact estimate from a recorded biopotential signal; and a motion classification module configured for determining information about the motion causing the artifacts and communicating said information to the motion artifact reduction module.

[0012] According to an exemplary embodiment, the determined information about the motion comprises an indication or classification of type and/or severity of the motion phenomena causing the artifacts in the recorded biopotential signal.

[0013] According to an exemplary embodiment, the motion classification module may be configured for determining information about the motion causing the artifacts based on information about one or a combination comprising contact impedance, contact force, motion acceleration, temperature or humidity sensor signals.

[0014] According to another exemplary embodiment, the motion classification module may be further configured for determining and communicating setting parameters for artifact removal to the motion artifact reduction module. Said setting parameters may comprise, for example, an artifact removal technique selection indication and/or coefficients related to a given artifact removal technique and/or signal selection indication for a given artifact removal technique.

Petitioner Ex-1004, 0434

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[0015] According to another exemplary embodiment, the motion artifact reduction module may be further configured for applying, configuring and/or optimizing a certain artifact removal technique based on information received from the motion classification module.

[0016] In another exemplary embodiment, the motion classification module and the motion artifact reduction module may be configured for performing one or a combination of classification, statistical analysis, spectral analysis, cross-signal analysis, PCA, ICA, CCA, AF, BF or EMD techniques.

[0017] According to still another embodiment, the system (100) may further comprise a pre-processing module configured for adapting the received signals in order to be processed by the motion classification module and/or a post-processing module configured for adapting the output signals provided by the motion classification module and/or the motion artifact reduction module.

[0018] According to another exemplary embodiment, there is provided a system for the analysis of biopotential signals, comprising: a motion classification module configured for receiving at least one biopotential signal and at least one reference secondary input signal, performing motion artifact classification for determining motion information comprising a type and/or severity indication about motion phenomena causing artifacts in the biopotential signal and communicating said motion information to a motion artifact reduction module; the motion artifact reduction module being configured for performing motion artifact removal from the biopotential signal based on the information received from the motion classification module; and wherein the system is further configured for evaluating the effectiveness of at least one algorithm used for motion artifact removal and generating feedback information between the motion classification module and the motion artifact reduction module for optimizing the performance of the motion artifact classification.

[0019] According to an exemplary embodiment, the system is further configured to store and process outputs of the a motion classification module and the motion artifact reduction module in different periods of time in order to generate said feedback information for optimizing the performance of the motion artifact classification.

[0020] According to another exemplary embodiment, evaluating the effectiveness of at least one algorithm used for motion artifact removal comprises comparing the clean biopotential signal after motion artifact removal with a reference baseline signal of such biopotential signal.

[0021] The invention also relates to an electronic device comprising a system for the analysis of biopotential signals according to any of the embodiments as herein described.

[0022] According to another exemplary embodiment there is also provided a method for the analysis of biopotential signals, comprising, in a system: receiving at least one biopotential signal; receiving at least one secondary input signal from a sensor providing direct or indirect information about electrode motion; determining a classification information of the kind of motion causing artifacts in the received biopotential signal; and using that classification information for reducing or eliminating a motion artifact affecting the received biopotential signal.

[0023] According to another exemplary embodiment, there is provided a method for the analysis of biopotential signals, comprising, in a system according to an embodiment of the invention: receiving at least one biopotential signal; receiving at least one secondary input signal; performing motion artifact classification for determining motion information comprising a type and/or severity indication about motion phenomena causing artifacts in the biopotential signal; performing removal of the motion artifact from the biopotential signal based on that motion artifact classification; and evaluating the effectiveness of the removal of the motion artifact from the biopotential signal and generating feedback information for optimizing the performance of the motion artifact classification.

[0024] Certain objects and advantages of various new and inventive aspects have been described above. It is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the present invention. Those skilled in the art will recognize that the solution of the present invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages without necessarily achieving other objects or advantages.

Brief description of the drawings

[0025] The above and other aspects of the system and a method according to the present invention will be shown and explained with reference to the non-restrictive example embodiments described hereinafter.

Figure 1 shows a general block diagram of a system for the analysis of biopotential signals according to a first exemplary embodiment.

Figure 2 shows a block diagram of a system for the analysis of biopotential signals according to a second exemplary embodiment.

Figure 3 shows a schematic block diagram of a system for the analysis of biopotential signals according to a third exemplary embodiment.

Figure 4A shows a flow diagram of a method for the analysis of an EEG signal according to a first exemplary embodiment.

Petitioner Ex-1004, 0435

BNSDOCID: <EP_____2792297A1_I_>

Figure 4B illustrates an exemplary graph of the standard deviation of measured electrode-to-skin impedance and 3-axis motion acceleration signals during EEG monitoring when applying the method shown in **Figure 4A.**
Figure 4C shows the skewness of the signals shown in **Figure 4B.**
Figure 4D shows the kurtosis of the signals shown in **Figure 4B.**
Figure 4E illustrates an exemplary graph of the magnitude of measured electrode-to-skin impedance and 3-axis motion acceleration signals during EEG analysis when applying a method as shown in **Figure 4A.**
Figure 5A shows a flow diagram of a method for the analysis of an EEG signal according to a second exemplary embodiment.
Figure 5B illustrates an exemplary graph of the deviation from the mean of measured force applied on the electrode and 3-axis motion acceleration signals during EEG monitoring when applying a method as shown in **Figure 5A.**
Figure 5C illustrates an exemplary graph of the magnitude of measured force and an EEG signal during EEG analysis when applying a method shown in **Figure 5A.**
Figure 6A shows a general block diagram of a system for the analysis of biopotential signals according to a fourth exemplary embodiment.
Figure 6B shows an exemplary block diagram of a system for the analysis of biopotential signals of **Figure 6A.**
Figure 6C shows a flow diagram of a method for the analysis of an EEG signal according to a third exemplary embodiment.
Figure 7A shows a flow diagram of a method for the analysis of an EEG signal according to a fourth exemplary embodiment.
Figure 7B illustrates an exemplary graph of EEG spectral contents for a baseline EEG and the EEG obtained after application of different types of motion artifact removal during EEG analysis when applying a method as shown in **Figure 7A.**
Figure 7C illustrates an exemplary graph of a distribution of the data points for a reference, input and cleaned EEG signal during EEG analysis when applying a method as shown in **Figure 7A.**

Detailed description

[0026] In the following, in the description of exemplary embodiments, various features may be grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This is however not to be interpreted as the invention requiring more features than the ones expressly recited in the main claim. Furthermore, combinations of features of different embodiments are meant to be within the scope of the invention, as would be clearly understood by those skilled in the art. Additionally, in other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of the description.

[0027] **Figure 1** shows a general block diagram of an exemplary system **100** for the analysis of biopotential signals. The system **100** comprises a motion classification module **110** configured for analyzing the input signals **40, 50,** extracting meta-information about the motion, determining the type of motion causing the artifacts and communicating settings for artifact removal to a motion artifact reduction module **120.** According to one exemplary embodiment, the motion artifact reduction module **120** is configured for receiving information from the motion classification module **110** and performing artifact removal based on available signal input and information received. According to another exemplary embodiment, the motion artifact reduction module **120** may also provide information or data to the motion classification module **110,** for example for updating some parameters.

[0028] The system **100** may receive at least one biopotential signal **40** which may be contaminated by a motion artifact and one or more secondary inputs **50** related to the subject or electrode motion and/or direct or indirect artifact distortion causes. The system **100** may provide as output: at least one cleaned biopotential signal **60** which is the result of applying some motion artifact reduction technique(s) to the received contaminated biopotential signal **40** and secondary outputs **70** with motion meta-information about the type and features of the motion detected.

[0029] According to an exemplary embodiment, extraction of a clean EEG signal from the contaminated one may be performed in the system **100** based on the meta-information extracted from one or more reference secondary input signals **50,** such as, but not limited to, electrode-to-tissue impedance, applied or contact force or acceleration of/on the electrode. The meta-information extracted from those reference secondary inputs **50** may comprise, but is not limited to, signal properties, such as standard deviation, slope and/or higher-order statistics. From such extracted meta-information, certain optimized filtering methods and parameters may be automatically selected. According to an exemplary embodiment, the system **100** is configured for selecting the most appropriate filtering technique for a determined type and severity of motion that affects the biopotential signal and to adjust certain filter or other motion artifact reduction settings to be applied to the contaminated biopotential signal. Such filtering techniques may include, but are not limited to, adaptive filtering, ICA, and/or wavelet decomposition.

[0030] **Figure 2** shows another block diagram of an exemplary system **100** for the analysis of biopotential signals.

Petitioner Ex-1004, 0436

BNSDOCID: <EP_ 2792297A1 | >

The system **100** may comprise a pre-processing module **105** configured for performing basic signal preprocessing required before motion classification and/or artifact handling. The pre-processing module **105** may comprise simple linear filtering (e.g. for removing power line noise), resampling, etc. The system **100** further comprises a motion classification module **110** configured for analyzing the input signals, estimating the kind of motion that causes the artifacts, extracting meta information about the motion, and/or communicating optimized settings for artifact removal to the motion artifact reduction module **120**. According to one exemplary embodiment, the motion artifact reduction module **120** is configured for receiving information from the motion classification module **110** and performing artifact reduction based on available signal input. According to another exemplary embodiment, the motion artifact reduction module **120** may also provide input information or data **190** for the motion classification module **110**, for example for updating some parameters. After the motion artifact reduction module **120**, a post-processing module **125** may be provided for formatting the output information or signals, along with the raw input received by the system. According to an exemplary embodiment, the post-processing module **125** may be configured also for combining the outputs of different artifact removal methods.

[0031] The system **100** may receive: a) biopotential input signals **X1 to Xn** consisting of n biopotential channels/electrodes measuring biopotential of interest at different locations. Biopotential signals may be, but are not limited to, EEG, ECG or EMG signals; b) auxiliary sensor input signals **AUX** such as, but not limited to, contact impedance, contact force and/or acceleration of the sensors. Said sensors may be, but not necessarily, located at the electrodes; and/or c) contextual sensor input signals **CON** such as, but not limited to, acceleration, temperature and/or humidity.

[0032] The system **100** may provide, as output: a) motion meta information **MMI** about the type and features of the motion detected. This can be, for example, a type of motion (e.g., walking, running), or the severity of the impact of motion on the biopotential signal of interest; b) artifact meta information **AMI** about the artifact removal method(s) used, along with the additional information that might be useful; and/or c) cleaned biopotential signals **Cleaned BioP** which are the result of applying artifact reduction techniques on the biopotential input signals. The cleaned biopotential signals are signals in which the artifact contamination has been totally or partially removed.

[0033] **Figure 3** shows another schematic block diagram of an exemplary system **100** for the analysis of biopotential signals. According to an exemplary embodiment, the motion classification module **110** and the motion artifact reduction module **120** may share methods and algorithms used for signal analysis and classification.

[0034] According to an exemplary embodiment, the motion classification module **110** may be configured for carrying out some classification techniques in combination with statistical analysis, spectral analysis, cross-signal analysis, and/or wavelet analysis methods. A list of such possible methods can be found, for example, in paper "Introduction to Applied Statistical Signal Analysis", by Richard Shiavi, Elsevier Inc., 3rd edition, San Diego, 2006, but it may also include higher (than 4) order statistics, and/or non-linear signal analysis methods. According to another exemplary embodiment, the motion classification module **110** may be also configured for performing some artifact handling functions, such as, for example, PCA, ICA and/or CCA. According to another exemplary embodiment the motion classification module **110** may be also configured for carrying out some classification algorithms, such as KNN, LDA, SVM, BN, NN. A description of such algorithms can be found in the literature and are known for the person skilled in the art.

[0035] According to an exemplary embodiment, the motion artifact reduction module **120** may be configured for carrying out procedures such as, for example, PCA, ICA, CCA, AF, BF, and/or EMD. A recent review of such methods is disclosed in paper "Artifact Removal in Physiological Signals-Practices and Possibilities", by Kevin T. Sweeney et al., IEEE Transactions on Information Technology in Biomedicine, Vol. 16, Issue 3, pages 488-500, 2012. According to another exemplary embodiment, the motion artifact reduction module **120** may be also configured for performing cross-signal analysis, wavelet analysis, etc., and/or may also perform some of the classification methods.

[0036] It shall be understood, for a person skilled in the art, that the above introduced list of methods and techniques, individually or in combinations, is not exhaustive.

[0037] **Figure 4A** shows a flow diagram of a method for the analysis of an EEG signal according to a first exemplary embodiment. The method is based on the usage of information about electrode-to-skin impedance **Z**, electrode (3-axis) acceleration motion **A**, and the EEG as the biopotential signal of interest **EEG**. According to an exemplary embodiment, the motion classification module **110** may be configured for determining and analyzing the standard deviation, skewness and kurtosis of the impedance magnitude **|Z|** and acceleration signals **A**. Based on the output of the motion classification module **110**, the motion artifact reduction module **120** may either perform CCA or ICA techniques.

[0038] The method may comprise the following steps:

- in step 1, if standard deviation of impedance magnitude and (or) acceleration in all (or a subset of) directions is larger than predetermined threshold, then go to step2. Otherwise provide the clean EEG signal (and eventually information about the impedance and acceleration signals). **Figure 4B** illustrates, for example, the standard deviation of those signals during an EEG recording that contains artifacts between seconds 35 and 105. According to an exemplary embodiment, the threshold values can be set to 1kΩ for impedance magnitude and 0.025g for acceleration;
- in step 2, if skewness and (or) kurtosis **HOS** of impedance magnitude and (or) acceleration in all (or a subset of) directions is larger than the predefined threshold, then go to step 3. Otherwise go to step 4. As an example, **Figures**

Petitioner Ex-1004, 0437

BNSDOCID: <EP_____2792297A1_I_>

4C and **4D** illustrate, respectively, the skewness and kurtosis of the impedance magnitude and acceleration for the same segment as depicted in **Figure 4B.**

- in step 3, use the ICA method to extract the components from the EEG (and other signals), since ICA uses higher order statistics (e.g., skewness and kurtosis) in the analysis and then go to step 5;
- in step 4, use the CCA method to extract the components from the EEG (and other signals), since CCA uses only first and second order statistics (e.g., mean and standard deviation) in the analysis and then go to step 5;
- in step 5, correlate the identified components from the EEG signal(s) with the impedance magnitude and acceleration signals, select the component that has the highest correlation and then go to step 6. As an example, **Figure 4E** illustrates an EEG signal along impedance magnitude and acceleration signals, for the same segment as in **Figures 4B to 4D.** They can be used to select the component in the EEG that represent the artifact and that is extracted using the ICA or CCA method;
- in step 6, remove the identified component from the EEG signal and reconstruct the 'clean EEG' **(Cleaned BioP** in **Figure 2).**

[0039] In case the artifact is not identified, the clean EEG will be the same as the input EEG.

[0040] **Figure 5A** shows a flow diagram of another exemplary method for the analysis of an EEG signal. The method is based on the usage of information about the force applied to an electrode **F**, electrode (3-axis) acceleration motion **A**, and the EEG as the biopotential signal of interest **EEG.** According to an exemplary embodiment, the motion classification module **110** may be configured for determining and analyzing the deviation from the mean and optionally based on a well-tested classifier. Based on the output of the motion classification module **110,** the motion artifact reduction module **120** may perform an adaptive filtering method that uses either force or the acceleration signal with the largest deviation from the mean as a reference signal. The selection of the reference signal is also provided by the system as a motion meta Information indicating whether there is a force (pressure) change in one or more electrodes, or there is a head and/or body movement.

[0041] The method may comprise the following steps:

- in step 1, if deviation from the mean of the force in all (or a subset of) electrodes is larger than deviation from the mean of acceleration in all (or a subset) of electrodes and in all (or a subset) of directions, then go to step 2. Otherwise go to step 3. As an example, **Figure 5B** illustrates the deviation from the mean during the recording that contains artifacts between second 40 and 360. In the example of the figure, it can be observed that the deviation from the mean for force is much larger than the deviation from the mean for acceleration (in all directions). In case this step is not so obvious, more advanced techniques can be used for making an adequate choice in this step, e.g., using LDA, or KNN classification methods;
- in step 2, use the AF method with force signal as a reference signal to estimate the filter coefficients and then go to step 4. The sample data that can be used in this step is illustrated in **Figure 5C.** For a person skilled in the art it is known how AF can be used to remove artifacts from the EEG recording;
- in step 3, use the AF method with acceleration signal in the direction of the largest deviation from the mean as a reference signal to estimate the filter coefficients and then go to step 4;
- in step 4, use filter coefficient to filter the EEG signal and obtain a clean EEG **(Cleaned BioP** in **Figure 2)** and forward information as the motion meta data that either force was applied on all (or a subset) of electrodes or there is a head/body movement.

[0042] **Figure 6A** shows a general block diagram of another exemplary system for the analysis of biopotential signals. The system uses all available information that may include biopotential signal(s) (for example, EEG signals), auxiliary signal(s), and contextual information, as an input for the motion classification module **110.** The system **100** shows the usage of a neural network (NN), but the embodiment can be based on classifiers other than NN. The usage of such classifier requires training. Training should be performed on the data set that has sufficient samples of the signals obtained during artifact and non-artifact (clean) segments, such that these segments are labeled as e.g., moderate artifact segments, severe artifact segments, and clean segments. Another more detailed exemplary embodiment of the system is illustrated in **Figure 6B.** The output of motion classification module **110** during training are the coefficients that will be used for real time operation of the NN as well as data statistics, such as probability density function of different input signals for artifact and clean data segments.

[0043] According to another exemplary embodiment, in real-time operation, the motion classification module **110** uses coefficients which are the output of the training stage and the motion artifact reduction module **120** uses data distribution information obtained in the training stage.

[0044] **Figure 6C** shows a flow diagram of another exemplary method for the analysis of an EEG signal. The method may comprise the following steps:

Petitioner Ex-1004, 0438

BNSDOCID: <EP_____2792297A1_I_>

- in step 1, use the Neural Network to classify the input signal(s) **(EEG, |Z|, A, F, pdf(EEG), pdf(|Z|), pdf(A), pdf(F))** and in case it is classified as segment with moderate artifacts then go to step 2. Otherwise go to step 4. The NN is used to distinguish between segments that do not require artifact removal, ones that require, and ones that are too noisy for the artifact removal technique to be effective;
- in step 2, the information about the data distribution of the clean and contaminated segments (e.g., probability density function) is used as an input for Wiener filtering (or other filtering method that uses information about data distribution **pdf(EEG), pdf(|Z|), pdf(A), pdf(F)**), resulting in the Wiener filter coefficients (as can be seen in **Figure 6B**). After obtaining the coefficients go to step 3;
- in step 3, use a Wiener filtering method and obtain a clean EEG **(Cleaned BioP** in **Figure 2)** based on all available input signals, update the artifact data distribution information **pdf(EEG), pdf(|Z|), pdf(A), pdf(F),** and go to step 5;
- in step 4, if the NN classifies the segment as a clean data segment, then update the clean data distribution information **pdf(EEG), pdf(|Z|), pdf(A), pdf(F)** and go to step 5.
- in step 5, output motion meta information based on the output of the classification step, i.e., whether it is a segment with no artifacts, segment with too much artifacts, or a segment where artifact reduction is applied.

It is understood that all the above described embodiments may be implemented by hardware and/or software means, for example, in a microprocessor or microcomputer environment.

[0045] **Figure 7A** shows a flow diagram of a method for the analysis of an EEG signal according to a fourth exemplary embodiment. The method uses all available information that may include biopotential signal(s) (for example, EEG signals), auxiliary signal(s), and contextual information, as an input **(EEG, |Z|, A, F, pdf(EEG), pdf(|Z|), pdf(A), pdf(F))** for the motion classification module **110.** The motion classification module **110** may use a motion classification approach, but not limited to, as implemented in the exemplary embodiments of **Figures 4A, 5A and 6A.** The output of the motion classification module **110** is then assigned to a segment (i.e., epoch) of biopotential data, denoting what type of motion artifact is present in the signal **Type 1 MA to Type n MA.** Several motion artifact reduction algorithms may be available and applied in the motion artifact reduction module **120** and the output of this motion artifact removal algorithms is then evaluated with respect to the expected signal properties and the estimated effectiveness of each of the algorithms is used to build the knowledge on how to optimize motion classification as well as motion artifact reduction.

[0046] The method may comprise the following steps:

- in step 1, use one or a combination of motion classification algorithms to determine one or more types of motion artifact **Type 1 MA to Type n MA.** The algorithm(s) used may be pre-defined but may also be based on a built knowledge about the effectiveness of the algorithms for motion artifact handling performed in step 3 and accumulated in step 4. The input signals used in the classification may be predefined but may also be based on the evaluation performed in steps 3 and 4. The knowledge on the optimal algorithm for motion artifact types extracted in step 4 may be used for, but not limited to: adjusting the parameters of the motion artifact classification algorithms (e.g., the thresholds used, the size of the neural network, etc.) to achieve better classification; and/or selecting which algorithm to use (including the selection of parameters for that motion artifact reduction algorithm) to achieve better classification;
- in step 2 several implementation of motion artifact reduction algorithms (and/or their combinations) are applied to the input signals. The algorithm(s) used can be pre-defined but can also be based on a built knowledge about the effectiveness of the algorithms for motion artifact handling performed in step 3 and accumulated in step 4. The input signals used in the classification can be predefined but may also be based on the evaluation performed in steps 3 and 4. The result is a clean EEG (**Cleaned BioP in Figure 2**) based on all (or a subset) of available input signals. The knowledge on the optimal algorithm for motion artifact types extracted in step 4 can be used for, but not limited to: adjusting the parameters of the motion artifact reduction algorithms (e.g., the number of filter coefficients for adaptive filtering, type of the wavelets used for wavelet transform, etc.) to achieve better motion artifact reduction; and/or selecting which algorithm to use for a specific motion artifact type (including the selection of parameters for that motion artifact reduction algorithm) to achieve better motion artifact reduction; and/or selecting the optimal combination of algorithms to be used (e.g., adaptive filtering and discrete wavelet transform, Wiener filtering and ICA, etc.) to achieve better motion artifact reduction;
- in step 3 an evaluation of the motion artifact handling algorithm may be done based on comparing the obtained clean EEG signal and the expected signal. In case of an EEG this may be done, for example, by comparing the spectral content of the baseline EEG (without artifact contamination) and the one(s) obtained after application of the artifact removal algorithm(s) (e.g. sagittal, coronal, standing, walking, jumping). Such signals are illustrated in **Figure 7B.** Another option for evaluating would be to look at the distribution of the data points between the baseline and the artifact-contaminated signal. Such signals, for an EEG biopotential signal, are illustrated in **Figure 7C.** Similarly, in case of an ECG biopotential signal, the obtained clean ECG signal can be compared with a template ECG signal or a baseline one. Other evaluation metrics (or a combination of those) may be used in a similar way;

Petitioner Ex-1004, 0439

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- in step 4, based on the evaluation of a) the output of one or more motion artifact reduction algorithm(s) from the motion artifact reduction module **120**, b) the output of one or more motion artifact classification algorithm(s) from the motion classification module **110**, and, when available, c) previous outputs of these modules on the data segments already processed, feedback information is generated to optimize the performance of the motion artifact classification described in step 1, and motion artifact reduction described in step 2;
- in step 5, the method may output motion meta-information **MMI** based on the output of the classification step (step 1), i.e., whether it is a segment with no artifacts, a segment with too much artifacts, or a segment where artifact reduction is applied, which classification algorithm(s) is(are) used and what parameters. Also the information from step 4 is used, describing the optimal setup for motion artifact reduction approach for a certain type of motion artifact.

[0047] Further advantageous embodiments and background information of the invention will be described below. For example, according to an exemplary embodiment of the invention, extraction of a clean biopotential signal from the contaminated one is performed in two stages. Based on the meta information extracted from one or more reference signals (such as electrode to tissue impedance, force on the electrode or acceleration of the electrode) the proper filtering method and parameters are automatically selected. This is performed by a 'motion classifier' (using signal properties, such as standard deviation, slope, higher-order statistics) which performs the selection of the filtering technique. Hence, the motion classifier will be used to select the most appropriate filtering technique for the type and severity of motion at hand and to adjust filter settings. Filtering techniques can include adaptive filtering, ICA, wavelet decomposition, etc.

[0048] Data supporting the proposed invention is at least based on the experiment performed with a number of participants where EEG, force, impedance and acceleration were continuously monitored while applying force on dry EEG electrode or performing various movements. The **Table** given below illustrates the changes that are observed in each of the signals.

Petitioner Ex-1004, 0440

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		Con	Rep	Imp	Nod	Til	Sta	Wal	Jum
EEG(*mV*)	mean	-1.7±0.17	-1.7±0.09	-1.7±0.20	-0.17±0.22	-1.7±0.23	-1.7±0.28	-1.6±0.29	-1.4±0.61
	max-min	3.1±2.41	3.0±3.39	4.2±1.91	2.6±1.25	3.8±2.99	3.3±2.93	11.8±4.77	11.9±3.88
	stdev	0.1±0.06	0.1±0.11	0.2±0.15	0.1±0.11	0.2±0.11	1.5±0.13	1.0±0.67	1.0±0.85
Imp(*kΩ*)	mean	39±21	35±12	41±20	57±23	53±24	52±25	56±27	59±20
	max-min	32±21	23±24	35±21	36±33	28±42	14±12	36±27	94±26
	stdev	8.7±6.5	5.1±3.5	5.9±5.6	7.5±6.8	3.9±5.1	1.5±1	5.3±5.2	7.4±2.5
For(*N*)	mean	1.5±0.28	1.2±0.25	1.0±0.39	0.8±0.29	0.9±0.26	0.8±0.52	0.9±0.48	0.9±0.53
	max-min	4.5±0.73	3.2±0.89	4.0±1.03	1.1±0.49	1.1±0.38	1.0±0.31	1.5±0.55	3.1±1.18
	stdev	1.0±0.19	0.7±0.18	0.3±0.11	0.3±0.16	0.2±0.06	0.1±0.03	1.6±0.08	0.2±0.06
Acc(*g*)	mean	0.7±0.06	0.7±0.05	0.7±0.06	0.7±0.05	0.7±0.07	0.7±0.05	0.7±0.05	0.7±0.05
	max-min	0.2±0.07	0.16±0.2	0.3±0.18	0.4±0.12	0.6±0.08	0.5±0.11	0.6±0.17	1.2+0.33
	stdev	0.0±0.00	0.0±0.00	0.0±0.00	0.1±0.02	0.1±0.01	0.0±0.01	0.0±0.01	0.1±0.02

Petitioner Ex-1004, 0441

[0049] The columns represent different force applications (continuous, repetitive, impact) or different movements (head nodding, head tilting, standing up/sitting down, walking and jumping). There is a difference between the values of EEG, impedance, force and acceleration across different conditions.

[0050] Different conditions also result in different correlation between the signals in question. For example, large correlation coefficient values between the EEG and impedance can be observed for short-term large amplitude changes due to external force (impact force). The correlation of segments containing large changes in force or large changes in acceleration can be characterized. High correlation can be observed (to a lesser degree) for head movements (sagittal and coronal), stand up/sit down movements, force application and release in case of continuous force application, and particularly in the correlation values for jumping segments. Similar outcomes can be observed when looking into correlation of EEG with other signals.

[0051] Such results demonstrate that the system can extract information on the type and dynamics of motion based on the signal properties. According to an exemplary embodiment of the invention, such information may be used in the motion classifier module to select which filtering to apply, what parameters to use in the filtering, as well as which signals to use for removing artifacts. Numerous methods exist in the literature that can be used for artifacts removal that can be part of the system, namely, adaptive filtering, blind source separation methods, wavelet transform, etc. Furthermore, the motion classifier can select a number of them to be applied in sequence or in parallel to have more efficient artifact removal.

Claims

1. A system (100) for the analysis of biopotential signals, comprising:

   a motion classification module (110) configured for receiving at least one biopotential signal (40) and at least one reference secondary input signal (50), performing motion artifact classification for determining motion information (MMI) comprising a type and/or severity indication about motion phenomena causing artifacts in the biopotential signal and communicating said motion information (MMI) to a motion artifact reduction module (120);
   the motion artifact reduction module (120) configured for performing motion artifact removal from the biopotential signal based on the information received from the motion classification module (110);
   characterized in that
   the system is further configured for evaluating the effectiveness of at least one algorithm used for motion artifact removal and generating feedback information (190) between the motion classification module (110) and the motion artifact reduction module (120) for optimizing the performance of the motion artifact classification.

2. A system (100) according to claim 1 wherein the system is further configured to store and process outputs of the a motion classification module (110) and the motion artifact reduction module (120) in different periods of time in order to generate said feedback information (190) for optimizing the performance of the motion artifact classification.

3. A system (100) according to any of the previous claims wherein evaluating the effectiveness of at least one algorithm used for motion artifact removal comprises comparing the clean biopotential signal after motion artifact removal with a reference baseline signal of such biopotential signal.

4. A system (100) according to any of the previous claims wherein the at least one reference secondary input signal (50) is a signal comprising information about one or a combination of contact impedance, contact force, motion acceleration, temperature or humidity.

5. A system (100) according to any of the previous claims wherein the motion classification module (110) is further configured for determining and communicating setting parameters for artifact removal to the motion artifact reduction module (120).

6. A system (100) according to claim 5 wherein said setting parameters comprise an artifact removal technique selection indication and/or coefficients related to a given artifact removal technique and/or signal selection indication for a given artifact removal technique.

7. A system (100) according to any of the previous claims wherein the motion artifact reduction module (120) is further configured for applying, configuring and/or optimizing a certain artifact removal technique based on information received from the motion classification module (110).

Petitioner Ex-1004, 0442

BNSDOCID: <EP_____2792297A1_I_>

8. A system (100) according to any of the previous claims wherein the motion classification module (110) and the motion artifact reduction module (120) are configured for performing one or a combination of classification, statistical analysis, spectral analysis, cross-signal analysis, PCA, ICA, CCA, AF, BF or EMD techniques.

9. A system (100) according to any of the previous claims further comprising a pre-processing module (105) configured for adapting the received signals in order to be processed by the motion classification module (110) and/or a post-processing module (125) configured for adapting the output signals provided by the motion classification module (110) and/or the motion artifact reduction module (120).

10. An electronic device comprising a system (100) for the analysis of biopotential signals according to any one of claims 1 to 9.

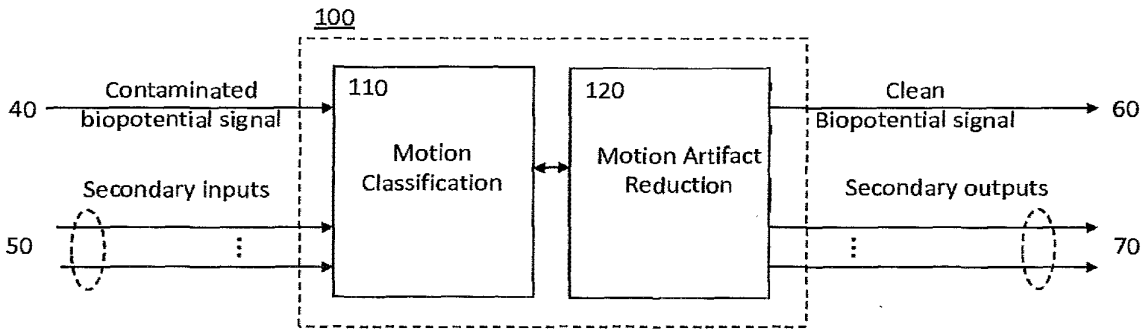
11. A method for the analysis of biopotential signals, comprising, in a system (100) according to claim 1:

- receiving at least one biopotential signal (40);
- receiving at least one secondary input signal (50);
- performing motion artifact classification for determining motion information (MMI) comprising a type and/or severity indication about motion phenomena causing artifacts in the biopotential signal;
- performing removal of the motion artifact from the biopotential signal based on that motion artifact classification;
- evaluating the effectiveness of the removal of the motion artifact from the biopotential signal and generating feedback information (190) for optimizing the performance of the motion artifact classification.

Petitioner Ex-1004, 0443

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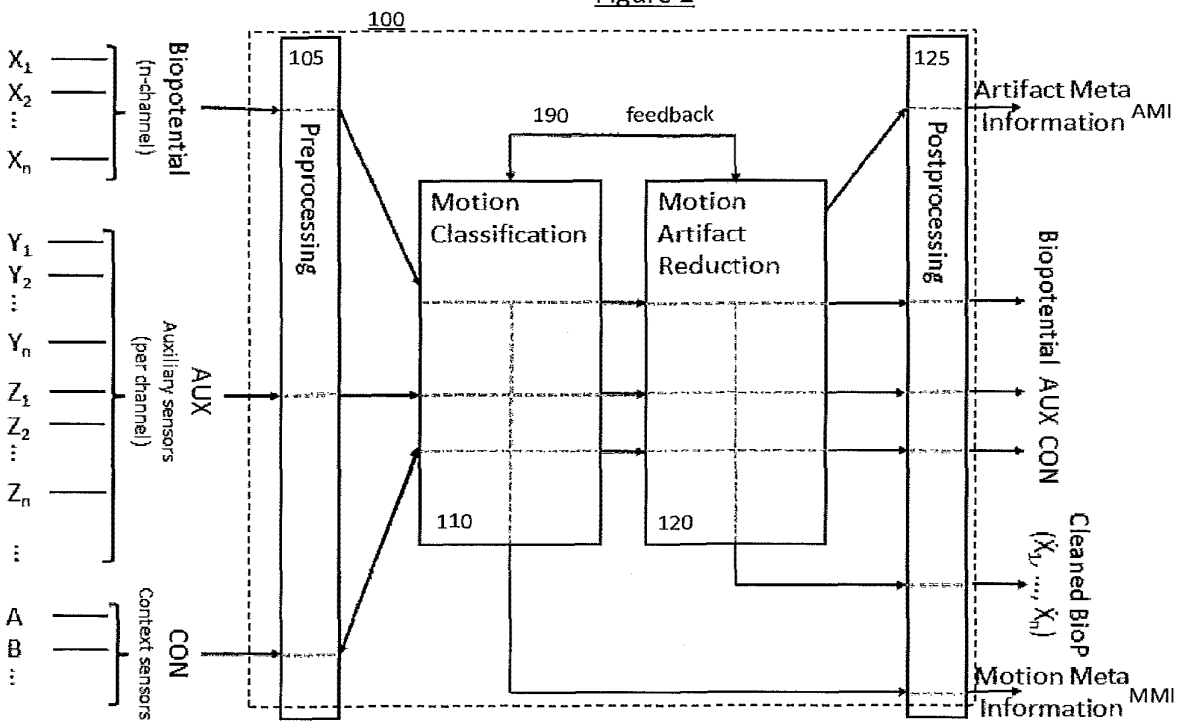
Figure 1



Petitioner Ex-1004, 0444

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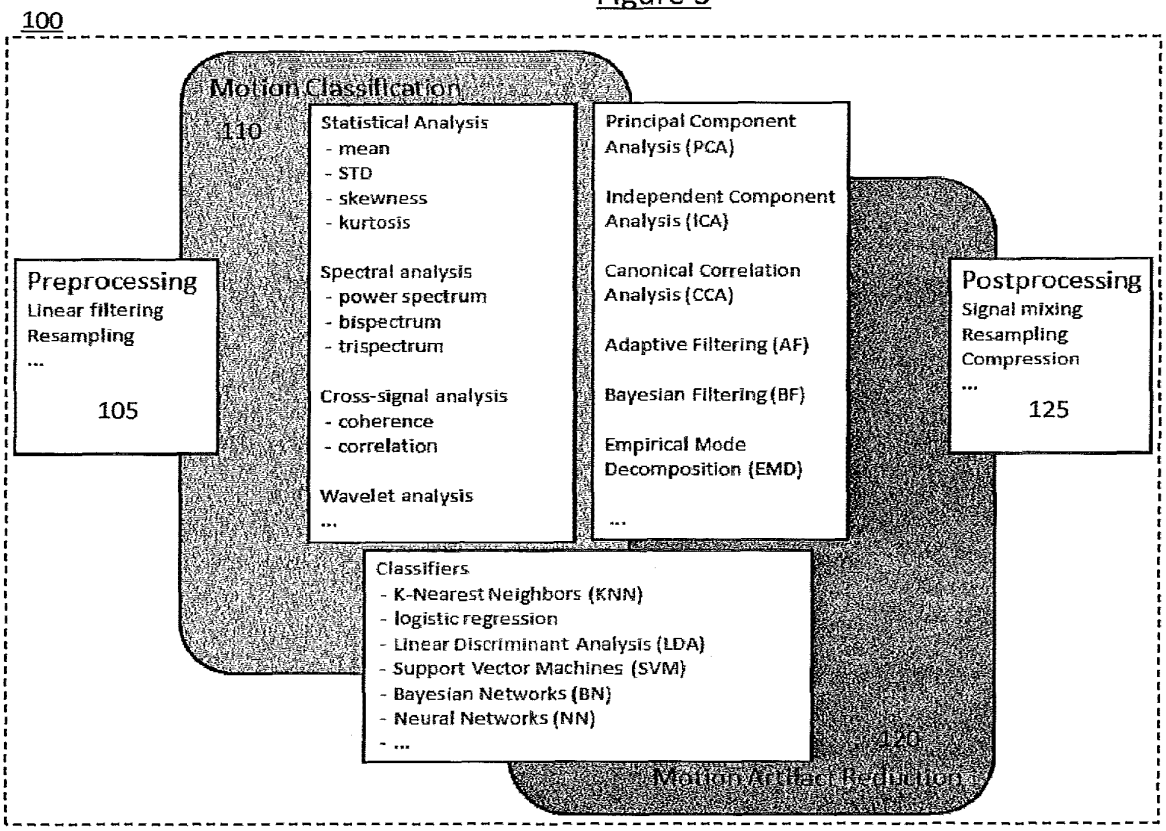
Figure 2



Petitioner Ex-1004, 0445

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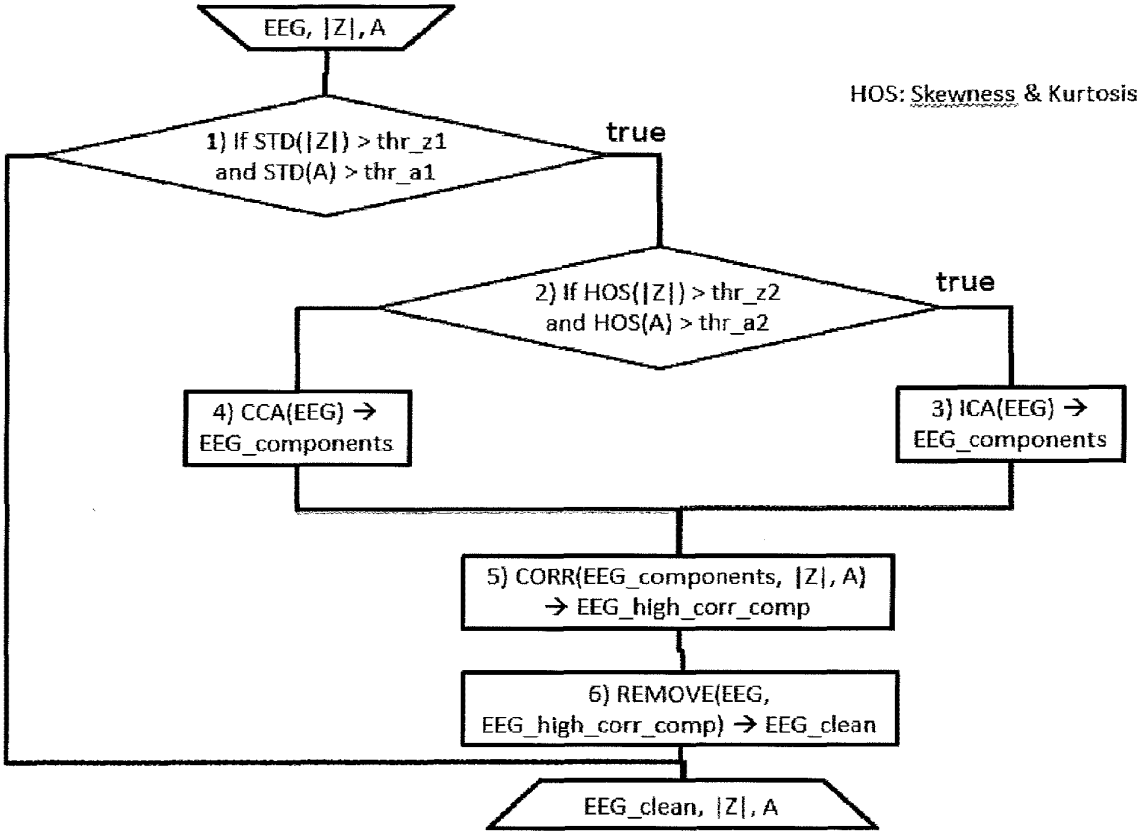
Figure 3



Petitioner Ex-1004, 0446

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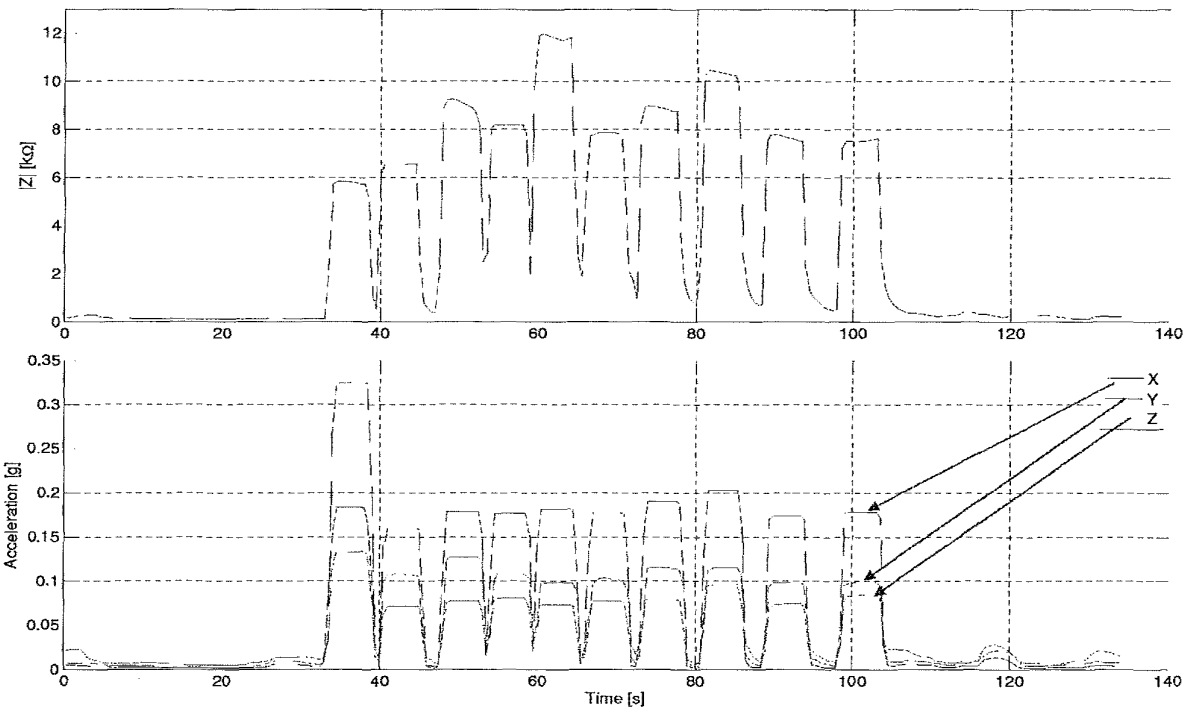
Figure 4A



Petitioner Ex-1004, 0447

BNSDOCID: <EP_____2792297A1_I_>

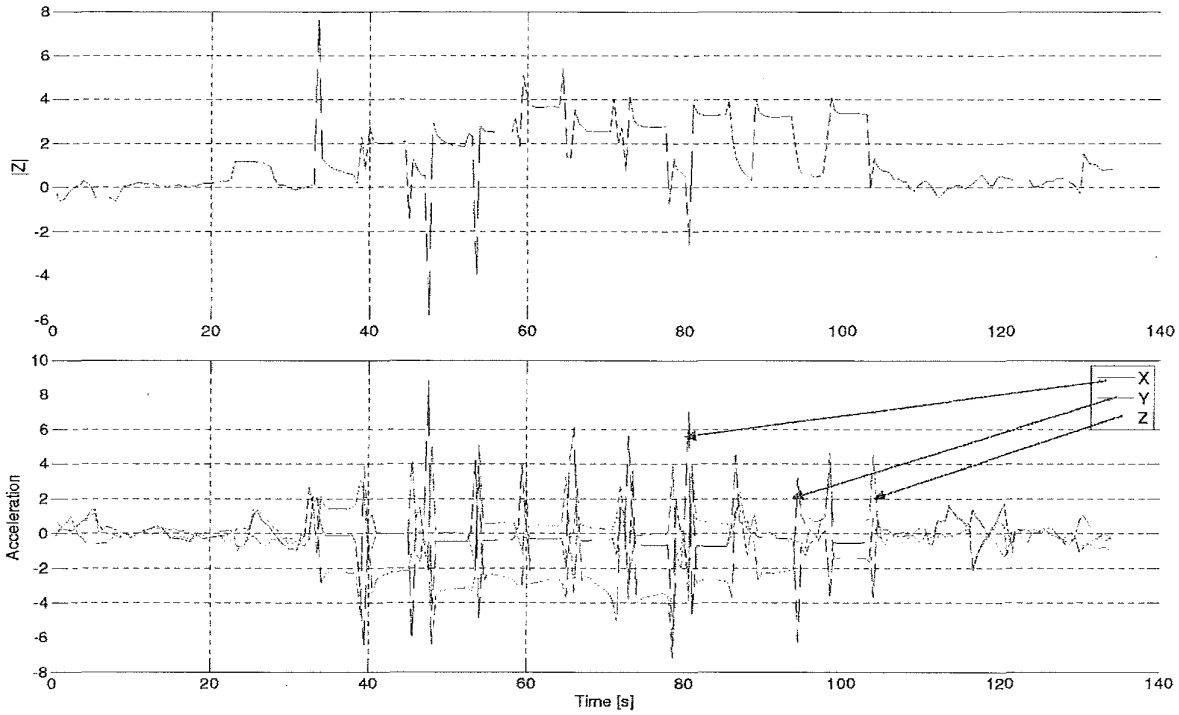
Figure 4B



Petitioner Ex-1004, 0448

BNSDOCID: <EP_____2792297A1_I_>

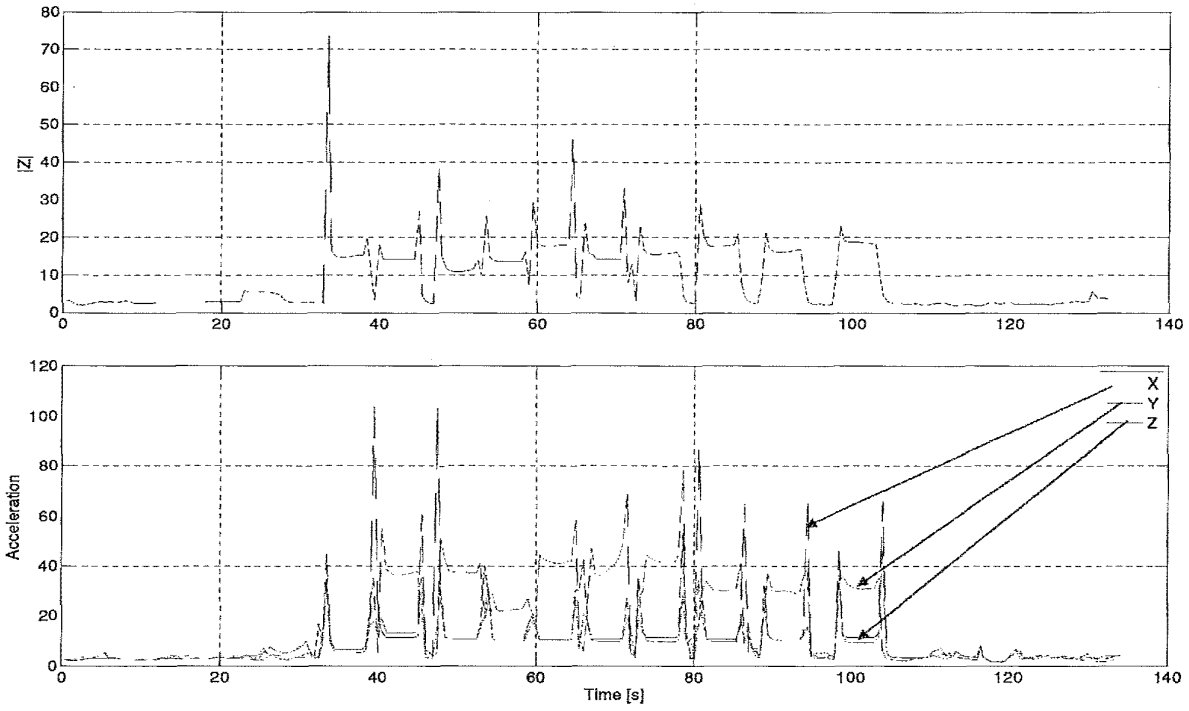
Figure 4C



Petitioner Ex-1004, 0449

BNSDOCID: <EP_____2792297A1_I_>

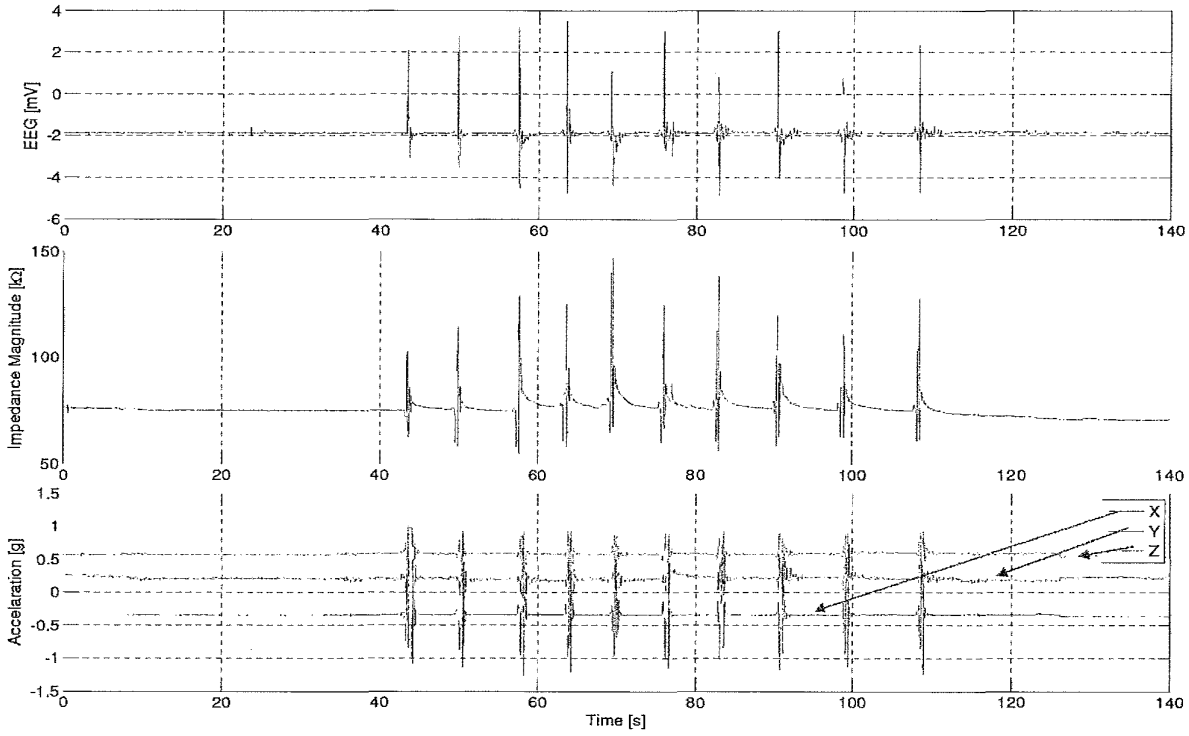
Figure 4D



Petitioner Ex-1004, 0450

BNSDOCID: <EP_____2792297A1_I_>

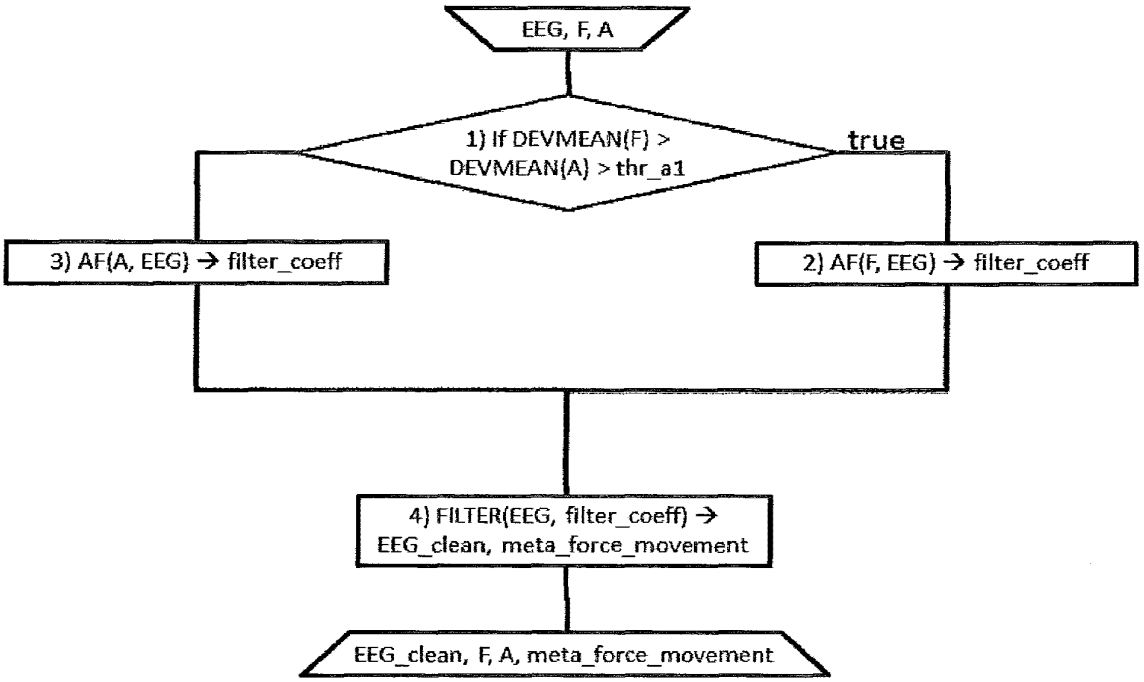
Figure 4E



Petitioner Ex-1004, 0451

BNSDOCID: <EP_____2792297A1_I_>

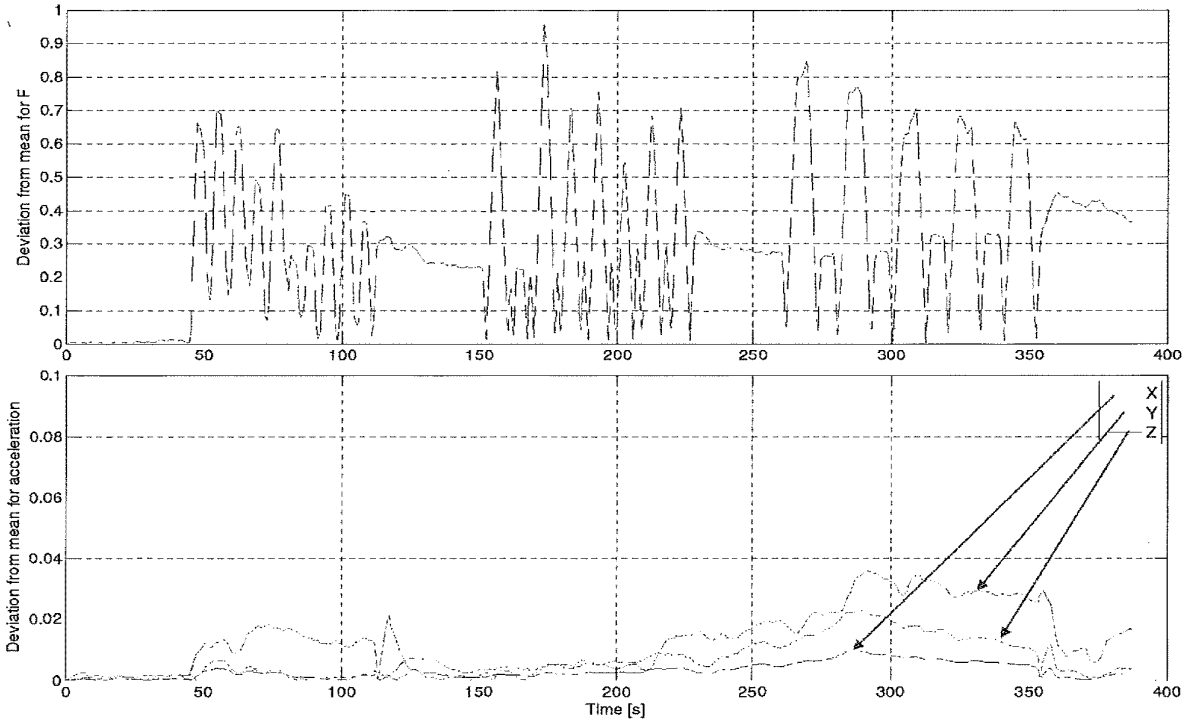
Figure 5A



Petitioner Ex-1004, 0452

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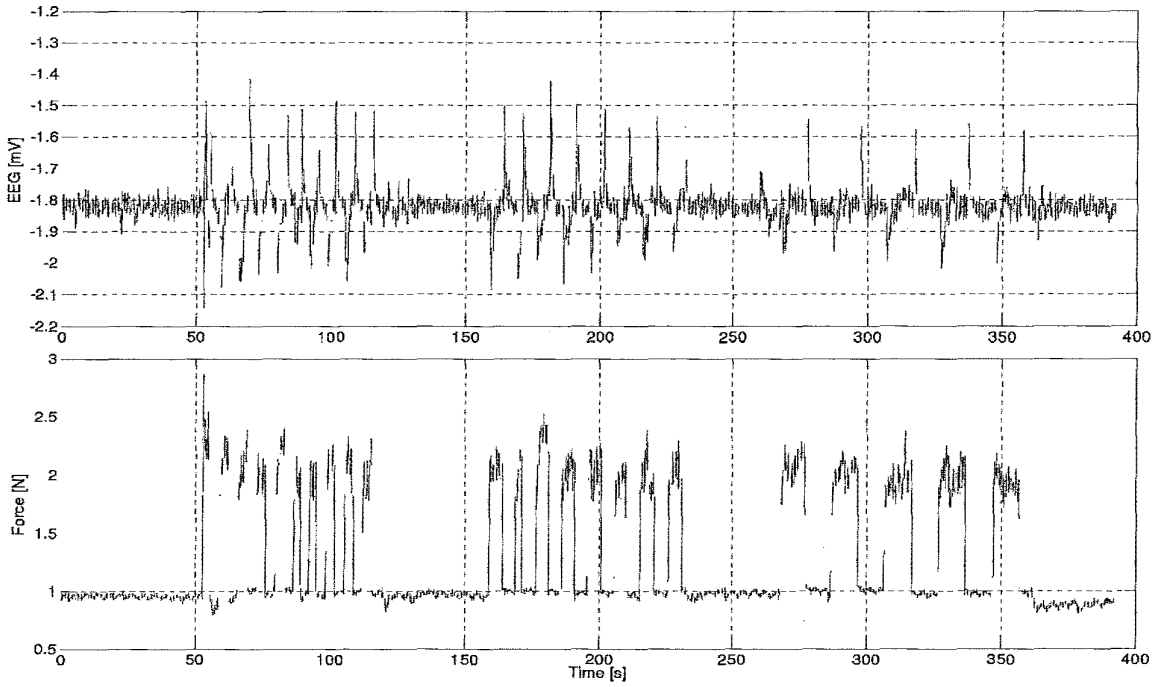
Figure 5B



Petitioner Ex-1004, 0453

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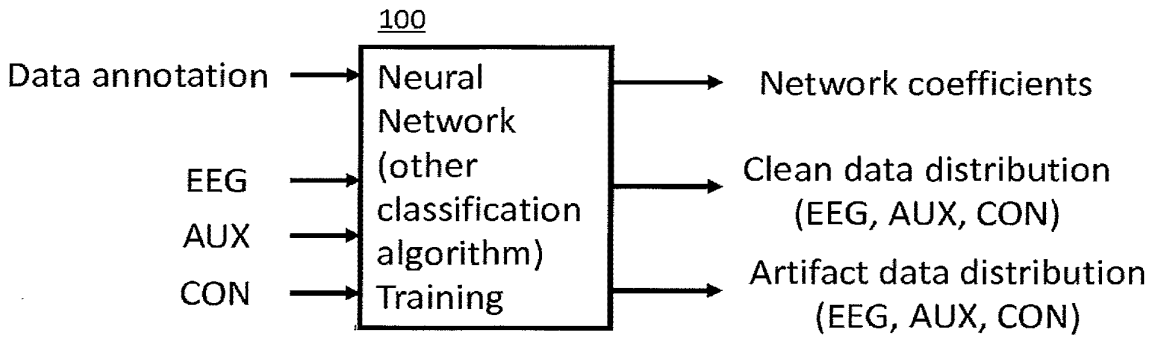
Figure 5C



Petitioner Ex-1004, 0454

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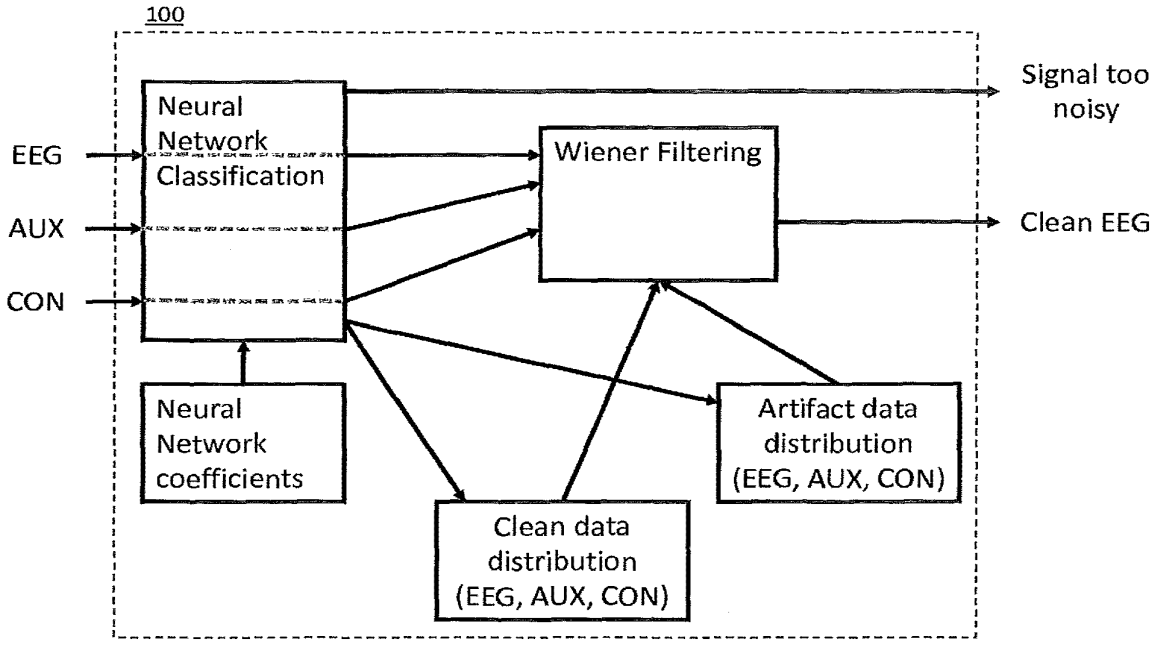
Figure 6A



Petitioner Ex-1004, 0455

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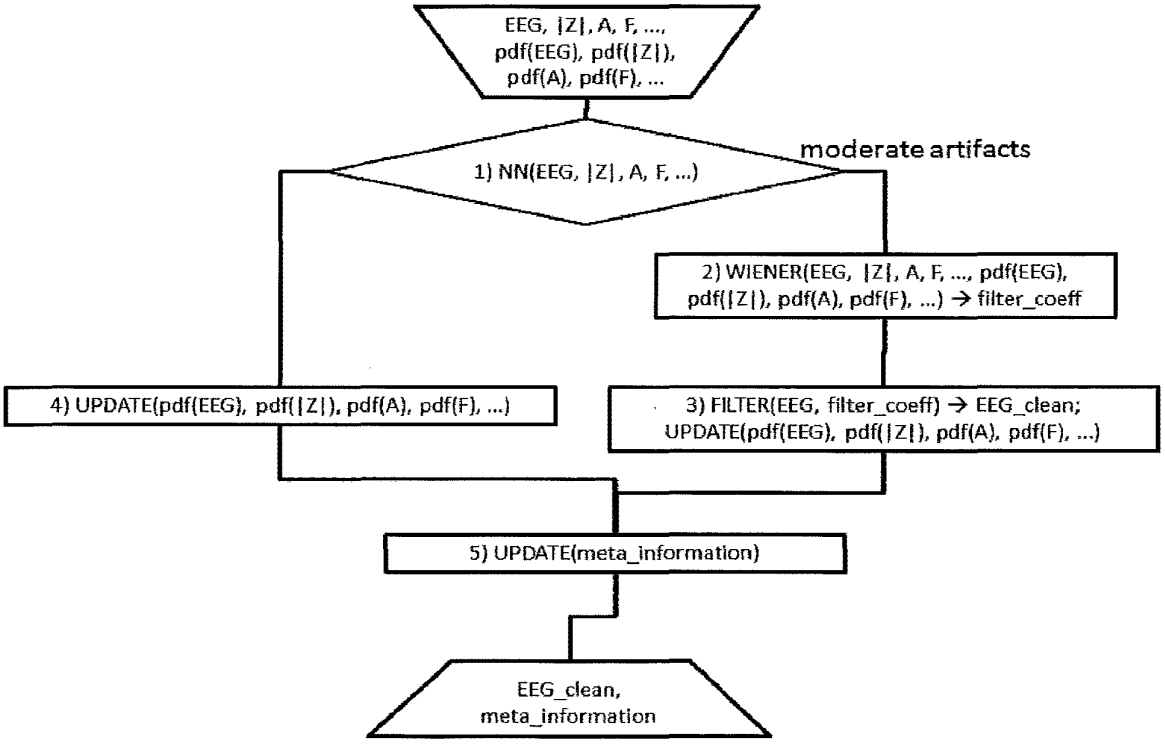
Figure 6B



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BNSDOCID: <EP_____2792297A1_I_>

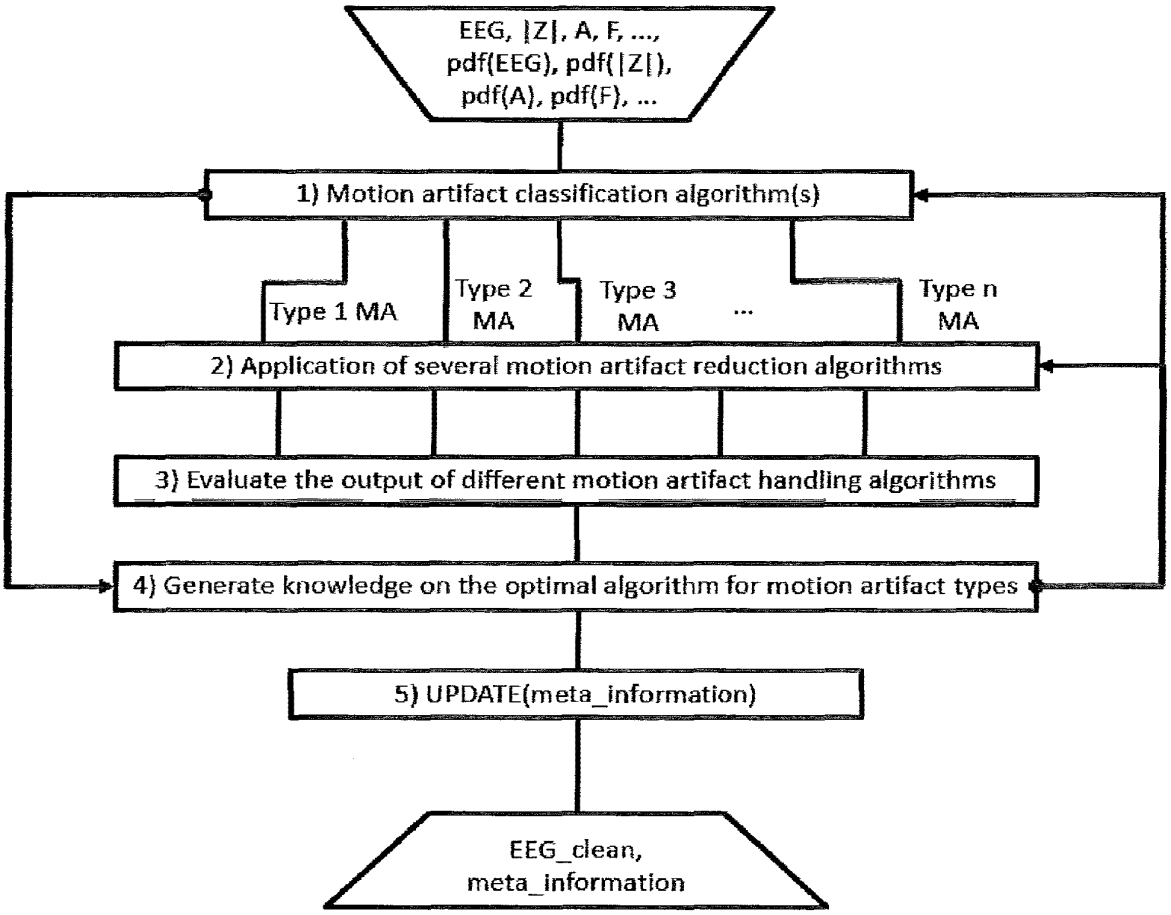
Figure 6C



Petitioner Ex-1004, 0457

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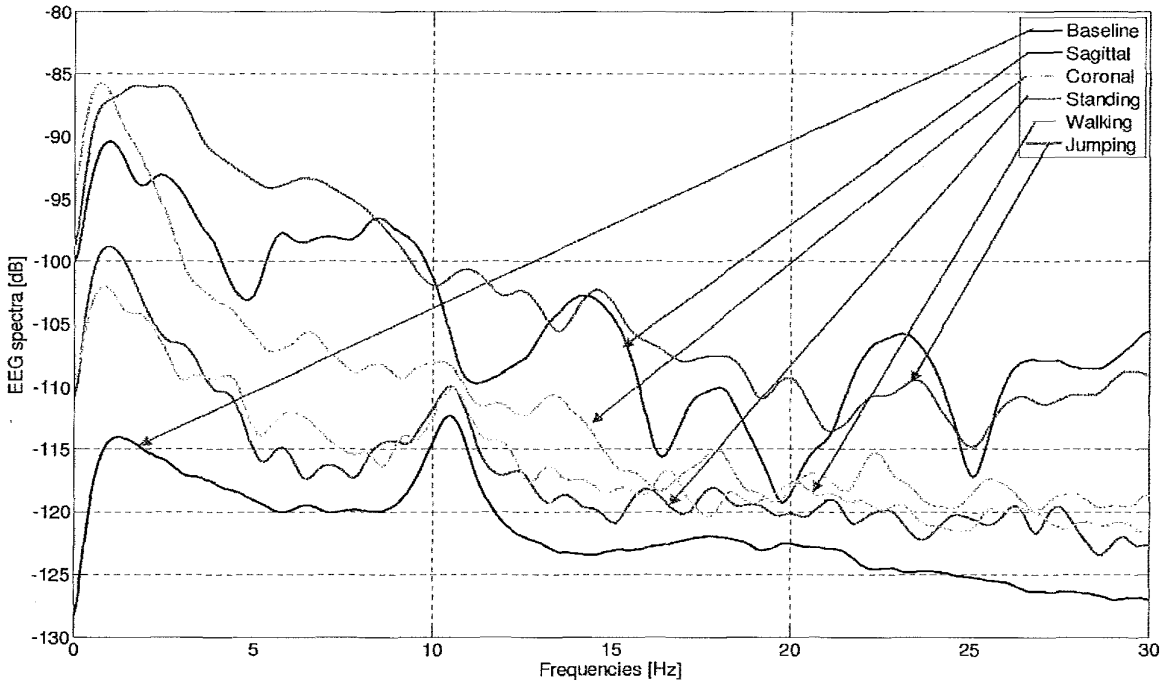
Figure 7A



Petitioner Ex-1004, 0458

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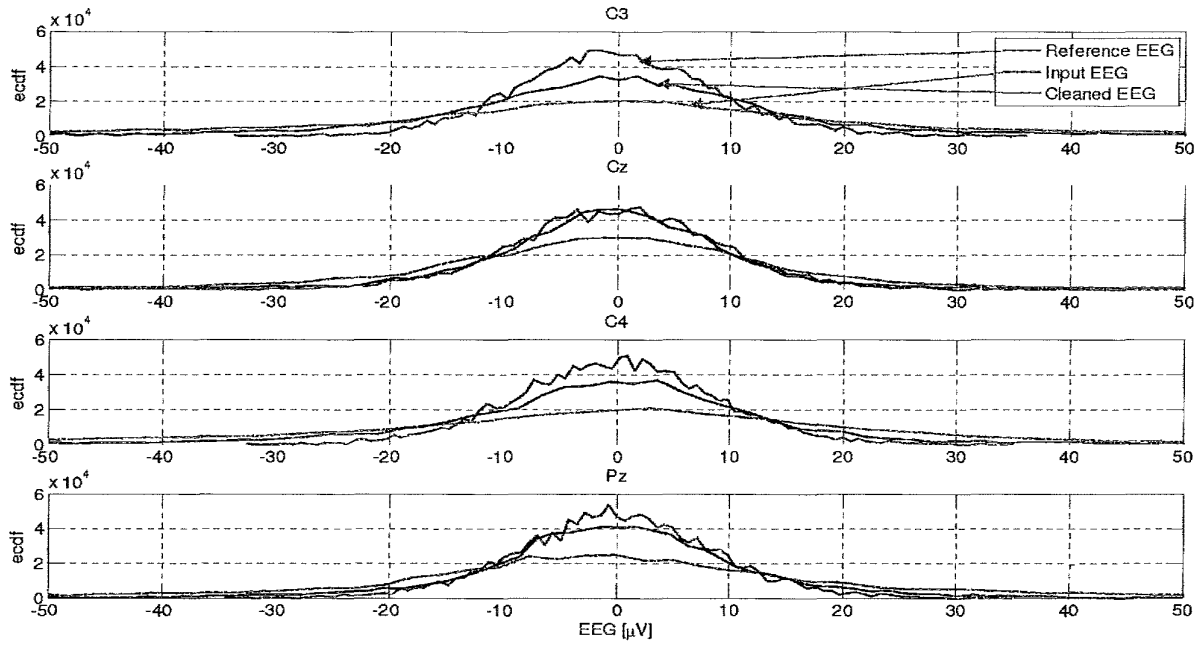
Figure 7B



Petitioner Ex-1004, 0459

BNSDOCID: <EP_____2792297A1_I_>

Figure 7C



BNSDOCID: <EP_____2792297A1_I_>

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EUROPEAN SEARCH REPORT

Application Number
EP 14 16 4272

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	WO 2011/149752 A1 (NEUROWAVE SYSTEMS INC [US]) 1 December 2011 (2011-12-01) * abstract; figure 3 * * page 4, line 1 - page 5, line 1 * * page 6, line 3 - line 9 * * page 16, line 23 - page 20, line 3 *	1-11	INV. A61B5/00 A61B5/04
A	NEISHA A CHADWICK ET AL: "Classifying eye and head movement artifacts in EEG signals", DIGITAL ECOSYSTEMS AND TECHNOLOGIES CONFERENCE (DEST), 2011 PROCEEDINGS OF THE 5TH IEEE INTERNATIONAL CONFERENCE ON, IEEE, 31 May 2011 (2011-05-31), pages 285-291, XP031953764, DOI: 10.1109/DEST.2011.5936640 ISBN: 978-1-4577-0871-8 * abstract * * page 285, column 2, paragraph 2 - page 285, column 2, paragraph 4 *	1-11	
			TECHNICAL FIELDS SEARCHED (IPC)
A	US 2005/049470 A1 (TERRY ALVIN MARK [US]) 3 March 2005 (2005-03-03) * paragraph [0002]; figure 2 * * paragraph [0007] - paragraph [0011] * * paragraph [0043] - paragraph [0044] * * paragraph [0046] - paragraph [0050] *	1-11	A61B G06F
A	LARS KOTTHOFF ET AL: "An Evaluation of Machine Learning in Algorithm Selection for Search Problems", AI COMMUNICATIONS, vol. 25, no. 3, 1 August 2012 (2012-08-01), pages 257-270, XP055127031, * abstract * * Section 1. Introduction * * Section 2. Background *	1-11	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	7 July 2014	Furlan, Stéphane

CATEGORY OF CITED DOCUMENTS

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EPO FORM 1503 03.82 (P04C01)

Petitioner Ex-1004, 0461

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EUROPEAN SEARCH REPORT

Application Number
EP 14 16 4272

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A,D	US 5 513 649 A (GEVINS ALAN S [US] ET AL) 7 May 1996 (1996-05-07) * abstract; figure 1 * * the whole document * -----	1-11	

TECHNICAL FIELDS SEARCHED (IPC)

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	7 July 2014	Furlan, Stéphane

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 14 16 4272

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07-07-2014

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011149752 A1	01-12-2011	EP 2575608 A1	10-04-2013
		US 2011295142 A1	01-12-2011
		WO 2011149752 A1	01-12-2011
US 2005049470 A1	03-03-2005	US 2005049470 A1	03-03-2005
		WO 2005020798 A2	10-03-2005
US 5513649 A	07-05-1996	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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BNSDOCID: <EP_____2792297A1_I_>

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 5513649 A **[0005]**

Non-patent literature cited in the description

- **YUN-HONG NOH ; DO-UN JEONG.** Implementation of Fuzzy-rule based Activity Classification and Optimized Adaptive Filter-set for Wearable ECG Recording. *International Journal of Multimedia and Ubiquitous Engineering,* October 2012, vol. 7 (4 **[0004]**
- **RICHARD SHIAVI.** Introduction to Applied Statistical Signal Analysis. Elsevier Inc, 2006 **[0034]**
- **KEVIN T. SWEENEY et al.** Artifact Removal in Physiological Signals-Practices and Possibilities. *IEEE Transactions on Information Technology in Biomedicine,* 2012, vol. 16 (3), 488-500 **[0035]**

Petitioner Ex-1004, 0464

BNSDOCID: <EP_____2792297A1_I_>

Electronic Acknowledgement Receipt

EFS ID:	27283819
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	21-OCT-2016
Filing Date:	09-JUN-2016
Time Stamp:	14:39:14
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	Transmittal Letter	41471020002IDSTrans.pdf	91146 2baff0cf7cb1c1cc93c26d5dfca768256d4844f2	no	3

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	41471020002LOR.pdf	118537 82d1544c65598b382fff607fddf3e176345f5a92	no	3
Warnings:					
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3	Foreign Reference	WO03000125A1.pdf	1551541 065154ffae9825ec46dba578730d4f4b091c165a	no	68
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4	Foreign Reference	EP1724684A1.pdf	2085211 441736f1bd8eba7dbbd08ed824736abd9deaa917	no	122
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Information:					
6	Foreign Reference	EP2792297A1.pdf	487408 72f39213915506cfc308165378ff36197543ed25	no	32
Warnings:					
Information:					
7	Non Patent Literature	Zhang_NovelQRSDetectionbyCWT.pdf	113781 74838c357e2135456a685c738a18f6d46cffac4b	no	4
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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

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	Not yet assigned
Confirmation No.:	7605		
For:	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals		

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Commissioner:

This Information Disclosure Statement is submitted:

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits; or before the mailing of a first office action after the filing of a Request for Continued Examination)

☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before any of a final action, notice of allowance, or an action that closes prosecution, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(Filed after final action, notice of allowance, or an action that otherwise closes prosecution, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee) [Consider QPIDS Pilot]

No aspect of this submission constitutes a disclaimer of claim scope.

Statement Under 37 CFR 1.97(e)

☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)
Applies to original applications (other than design) filed on or after May 29, 2000

☐ (1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

☐ (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

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☒ Enclosed herewith is a Listing of References. Copies of the cited references are enclosed except as indicated below or in the attached Listing of References.

☐ Copies of the cited references submitted with an Information Disclosure Statement in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed, are not required under 37 CFR 1.98(d)(1) and (2) and are thus not provided.

☐ The listed references were cited in the enclosed Search Report in counterpart foreign application [ ], which is listed in the attached Listing of References.

☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

Method of payment:

☐ Authorization is NOT granted to charge any fees which may be due in this matter to our Deposit Account.

☐ Please charge Deposit Account 08-0380 in the amount of $[ ].

☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By /Mark B. Solomon, Reg. No. 44348/
Mark B. Solomon
Registration No. 44,348
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: 10/21/2016

DOCKET NO. 4147.1020-002 (15-089)

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/178,089 filed on June 9, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims.

I acknowledge the duty to disclose to the Patent Office all information known to me to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Seyed M. A. Salehizadeh Date (Optional): 10/16/2016

Signature: S. M. A. Salehizadeh

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 (or equivalent) form for each additional inventor.

2381732.v1

DOCKET NO. 4147.1020-002(15-089)

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 15/178,089 filed on June 9, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims.

I acknowledge the duty to disclose to the Patent Office all information known to me to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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LEGAL NAME OF INVENTOR

Inventor: Ki H. Chon Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 (or equivalent) form for each additional inventor.

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LEGAL NAME OF INVENTOR

Inventor: Yeonsik Noh Date (Optional): _____

Signature: _____

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2381732.v1

Electronic Acknowledgement Receipt

EFS ID:	27526196
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	16-NOV-2016
Filing Date:	09-JUN-2016
Time Stamp:	14:32:08
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	Oath or Declaration filed	41471020002Declaration.PDF	116549 233f5c4a1660c73ae6f80da96c96079bffeb7442	no	3

Warnings:

Information:	
Total Files Size (in bytes):	116549

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New Applications Under 35 U.S.C. 111

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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.

Substitute for form 1449B/PTO **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** December 13, 2016 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER Not Yet Assigned	CONFIRMATION NO. 7605	GROUP 3766

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	4,938,228	07-03-1990	Righter *et al.*
	2.	8,388,543 B2	03-05-2013	Chon, *et al.*
	3.	8,417,326	04-09-2013	Chon, *et al.*
	4.	8,998,815 B2	04-07-2015	Venkatraman *et al.*
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Copies of issued U.S. Patents and Published U.S. Applications are not required and are not being provided. We are not listing separately any prior U.S. Patent Office communications regarding the cited documents because the Examiner has access to any such actions through PAIR.

EXAMINER	DATE CONSIDERED

Substitute for form 1449B/PTO	ATTORNEY DOCKET NO.	APPLICATION NO.	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	4147.1020-002 (15-089)	15/178,089	
	FIRST NAMED INVENTOR	FILING DATE	
	Seyed M. A. Salehizadeh	June 9, 2016	
LISTING OF REFERENCES	EXAMINER	CONFIRMATION NO.	GROUP
December 13, 2016	Not Yet Assigned	7605	3766
(Use several sheets if necessary)			

Examiner's Initials	Cite No.	**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*
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	2.	Boreom Lee, *et al.*, "Improved Elimination Of Motion Artifacts From A Photoplethysmographic Signal Using A Kalman Smoother With Simultaneous Accelerometry," *Physiological Measurement*, 31(12):1585 (2010).
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	17.	Maeda, Y., *et al.*, "Relationship Between Measurement Site And Motion Artifacts In Wearable Reflected Photoplethysmography," *J Med Syst*, 35(5):969-76 (2011).
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EXAMINER	DATE CONSIDERED

Petitioner Ex. 1004, 0477

Substitute for form 1449B/PTO **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** December 13, 2016 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER Not Yet Assigned	CONFIRMATION NO. 7605	GROUP 3766

Examiner's Initials	Cite No.	**OTHER DOCUMENTS** *(Including Author, Title, Date, Pertinent Pages, Etc.)*
	19.	Raya, M.A.D. and Sison, L.G., "Adaptive Noise Cancelling Of Motion Artifact In Stress ECG Signals Using Accelerometer," *Engineering in Medicine and Biology, 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, Proceedings of the Second Joint* (2002). 1756-1757
	20.	Reyes, B.A., *et al.*, "Novel Electrodes For Underwater ECG Monitoring," *IEEE Trans Biomed Eng.*, 61(6):1863-76 (2014).
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***Copies of any non-published U.S. Patent Applications are not being provided because the examiner has access to such documents through PAIR. We are not listing separately prior U.S. Patent Office communications regarding the cited documents because the Examiner has access to any such actions through PAIR.**

EXAMINER	DATE CONSIDERED

Petitioner Ex. 1004, 0478

Electronic Acknowledgement Receipt

EFS ID:	27777500
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	13-DEC-2016
Filing Date:	09-JUN-2016
Time Stamp:	16:19:56
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	Transmittal Letter	41471020002SIDSTrans.pdf	91246 7d10c2e94c4e648365532aa59d17257de6213928	no	3

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Information:					
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Information:					
This is not an USPTO supplied IDS fillable form					
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4	Non Patent Literature	Lee_2010_Physiol.pdf	2134008 5f67ffb60a09c85faf9926130ad0ad188409a631	no	20
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6	Non Patent Literature	Dash_Ann-Bio.pdf	403745 0797055b939f804642c63776fcd7282e9a32e9db	no	9
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Information:					
7	Non Patent Literature	Dash_IEEE.pdf	627528 40188b5c687316b1d2ac1540f70659fdfd498f52	no	9
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Information:					
8	Non Patent Literature	Deepak.pdf	3902939 a617ef29f1399b122bd7f206d8d472d7a4faf9c3	no	5
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Information:					

9	Non Patent Literature	Devlin.pdf	2865001 79d41b243e3780203ba9729ba4308a73bb49f037	no	8
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14	Non Patent Literature	Jinseok.pdf	634389 511ae37cd9727cce00ed13a2422cbf84b6f23de0	no	8
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16	Non Patent Literature	Kearney.pdf	223474 8b1e57a3be279286b2af474c12a678be6cd005be	no	4
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17	Non Patent Literature	Kim.pdf	209922 2fc950ce3b8f532a287dfa34f9f54dd742dd71a7	no	3
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Information:					
18	Non Patent Literature	Krishnan.pdf	471066 3ee4935cd003bfadb50decac61144af2dad711a9	no	10
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19	Non Patent Literature	Maeda.pdf	426676 82ed062becdae0a266f57b9f74d79bc72f75f853	no	8
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20	Non Patent Literature	Rahman.pdf	4564524 e8d7cc64d7fa397422277d2e2e1f137e1a84bd7a	no	5
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22	Non Patent Literature	Reyes.pdf	12825855 9ff16594c20dd6a0f7fd70937c22f0785adb9a66	no	14
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23	Non Patent Literature	Salehizadeh_2016.pdf	2664505 ac6b9c1b6583ca70f07310e984bc46fea7ca00e3	no	20
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25	Non Patent Literature	Temko.pdf	827933 0e091b79cf876ac42bce9b72efb9d2e428981754	no	4
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Information:					
26	Non Patent Literature	Seyedtabaii.pdf	3038575 fc59b7543ff0f4ef9f891b5f5a5d33bf457ca179	no	5
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Information:					
27	Non Patent Literature	Wang.pdf	1913554 a808449ef25399a46148e0f083b48bf676181c29	no	13
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31	Non Patent Literature	Zhang_Photo.pdf	965512 187051398fece0539923cc818d1418f3ef87eb50	no	9
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32	Non Patent Literature	Zhang_Troika.pdf	843044 a4d660e5ae8c02d92e6789d13bd90fd492612328	no	10
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33	Non Patent Literature	Yoon.pdf	4546599 d76d34a754e52883bc5424724fa1db5ec6f497e5	no	6
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New Applications Under 35 U.S.C. 111

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	Not Yet Assigned
Confirmation No.:	7605		
For:	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals		

CERTIFICATE OF MAILING OR TRANSMISSION

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TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Alexandria, VA 22313-1450

Commissioner:

This Supplemental Information Disclosure Statement is submitted:

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits; or before the mailing of a first office action after the filing of a Request for Continued Examination)

☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

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☒ Enclosed herewith is a Listing of References. Copies of the cited references are enclosed except as indicated below or in the attached Listing of References.

☐ Copies of the cited references submitted with an Information Disclosure Statement in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed, are not required under 37 CFR 1.98(d)(1) and (2) and are thus not provided.

☐ The listed references were cited in the enclosed Search Report in counterpart foreign application [add application number], which is listed in the attached Listing of References.

☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- ☐ the explanation provided on the attached sheet.
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Respectfully submitted,

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/178,089	06/09/2016	Seyed M. A. Salehizadeh	4147.1020-002 (15-089)

CONFIRMATION NO. 7605

21005
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PUBLICATION NOTICE

OC000000087912202

Title:METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

Publication No.US-2016-0361021-A1
Publication Date:12/15/2016

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Substitute for form 1449B/PTO **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** January 18, 2017 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER	CONFIRMATION NO. 7605	GROUP 3766

U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	2016/0360977 A1	12-15-2016	Salehizadeh et al.

Copies of issued U.S. Patents and Published U.S. Applications are not required and are not being provided. We are not listing separately prior U.S. Patent Office communications regarding the cited documents because the Examiner has access to any such actions through PAIR.

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	WO 2016/201130	12-15-2016	University of Connecticut

EXAMINER	DATE CONSIDERED

Petitioner Ex. 1004, 0489

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 December 2016 (15.12.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/201130 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *A61B 5/0245* (2006.01)
A61B 5/024 (2006.01)

(21) International Application Number:
PCT/US2016/036743

(22) International Filing Date:
9 June 2016 (09.06.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/172,862 9 June 2015 (09.06.2015) US
62/299,944 25 February 2016 (25.02.2016) US

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(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, 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, ST, 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).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

WO 2016/201130 A1

(54) **Title**: METHOD AND APPARATUS FOR HEART RATE MONITORING USING AN ELECTROCARDIOGRAM SENSOR

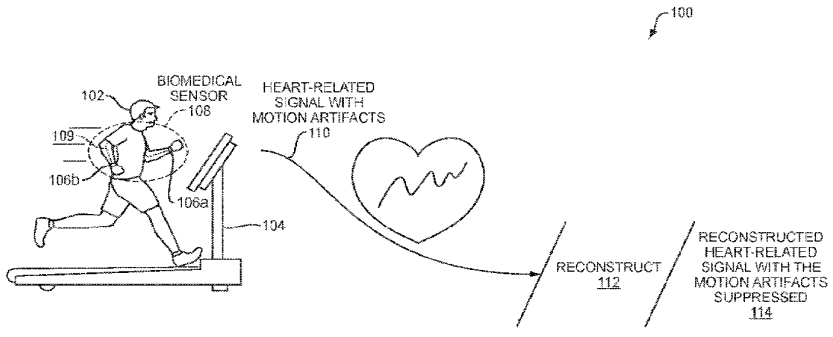


FIG. 1A

(57) **Abstract**: A method and corresponding apparatus employ a time-varying spectral analysis approach for reconstructing an electrocardiogram (ECG) signal that includes motion artifacts. The motion artifacts are produced by motion of an ECG sensor relative to a sensing location. The time-varying spectral analysis based approach enables the ECG signal to be reconstructed with accuracy by suppressing the motion artifacts. Example applications for the method and corresponding apparatus include ECG-based heart rate monitoring in wearable devices for fitness tracking and health monitoring even during intense physical activities.

METHOD AND APPARATUS FOR HEART RATE MONITORING USING AN ELECTROCARDIOGRAM SENSOR

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/172,862 filed June 9, 2015 and U.S. Provisional Application No. 62/299,944 filed February 25, 2016. The entire teachings of the above applications are incorporated herein by reference.

GOVERNMENT SUPPORT

[0002] This invention was made with government support under Grant No. W81XWH-12-1-0541 from the US Army Medical Research and Material Command (USAMRMC). The government has certain rights in the invention.

BACKGROUND

[0003] Cardiovascular disease is the leading cause of death in the world. Considering the fact that a majority of such deaths due to cardiac arrest occur before a patient can get the needed medical care, the patient should be continuously monitored for real time detection of events that can portend cardiac arrest (Deepak Vala, D.T.P., A Survey on Ambulatory ECG and Identification of Motion Artifact. International Journal of Engineering Research and Development, 2012. 1(7): p. 38-41). The electrocardiogram (ECG) is a main measurement device for effectively diagnosing cardiovascular health, and other cardio-respiratory related diseases, and can be used as a guide for cardio-fitness therapy.

SUMMARY OF THE INVENTION

[0004] During exercise and other activities, ECG and other sensors may experience movement, such as shifting position or rotating, relative to a sensing location (*e.g.*, wrist or chest). The movement typically results in an introduction of a motion artifact in an electrical signal produced by the sensor. The motion artifact may be interpreted by a processor as a heart-related signal if not addressed in advance of or as part of the processing in the processor. By properly addressing the motion artifact, an embodiment disclosed herein has improved accuracy in reconstructing the heart-related signal, thereby enabling processes that use the heart-related signal to have better performance.

[0005] Accordingly, a method for reconstructing a heart-related signal output by a biomedical sensor may comprise pre-processing the heart-related signal to produce a pre-processed heart-related signal. The method may further comprise reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal. The reconstructing may be based on a time-varying spectral analysis of the pre-processed heart-related signal, the heart-related signal including motion artifacts. The motion artifacts may be signal artifacts produced by movement of the biomedical sensor relative to a sensing location. The pre-processing may reduce the motion artifacts in the pre-processed heart-related signal for the reconstructing. The method may further comprise outputting the reconstructed representation of the heart-related signal.

[0006] The biomedical sensor may be an electrocardiogram (ECG) sensor.

[0007] The reconstructing may further reduce the motion artifacts reduced by the pre-processing.

[0008] The pre-processing may include down-sampling the heart-related signal to produce a down-sampled heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

[0009] The time-varying spectral analysis may be based on a frequency resolution and the down-sampling may affect the frequency resolution of the time-varying spectral analysis.

[0010] The pre-processing may include computing a derivative of the down-sampled heart-related signal to reduce the motion artifacts.

[0011] The pre-processing may further include computing an absolute value of the derivative to further reduce the motion artifacts.

[0012] The time-varying spectral analysis may include computing a time-frequency spectrum (TFS) of the pre-processed heart-related signal.

[0013] The TFS computed may be a 3-dimensional spectra including a time-varying amplitude or power distribution with respect to time and frequency.

[0014] The TFS computed may be a time-varying power spectral density (PSD).

[0015] The method may further include limiting the TFS computed to a given frequency range. The given frequency range may be 0.5 Hz to 3 Hz.

[0016] The TFS may be computed for each shift of a windowed data segment of the pre-processed heart-related signal and the heart related signal may be reconstructed for each shift of the windowed data segment.

[0017] At each shift of the windowed data segment subsequent to an initial windowed data segment, the method may further include retaining up to a pre-determined number of frequency spectra to produce a subset of frequency spectra. The method may further include selecting a frequency component to produce a selected frequency component for the reconstructing. The selected frequency component may be selected from amongst frequency components of the subset of frequency spectra and a previous frequency component. The previous frequency component may have been selected for a previous shift of the windowed data segment to reconstruct the heart-related signal for the previous shift.

[0018] The time-varying spectral analysis may be a first time-varying spectral analysis. The reconstructing may be further based on a second time-varying spectral analysis of a motion signal, the motion signal output by a motion sensor and representative of the motion artifacts in the heart-related signal.

[0019] The method may further include employing the second time-varying spectral analysis of the motion signal to produce a movement classification of the movement, and wherein the reconstructing is further based on the classification of the movement.

[0020] The heart-related signal and the motion signal may be output, concurrently.

[0021] The biomedical sensor and the motion sensor may be co-located.

[0022] The motion sensor may be an accelerometer.

[0023] The method may further comprise employing the reconstructed representation to determine a heart rate estimate.

[0024] The method may further comprise employing the reconstructed representation to determine a heart rate variability (HRV) estimate.

[0025] The method may further comprise employing the reconstructed representation to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0026] The pre-processing, the reconstructing, and the outputting may be performed in real-time with respect to outputting of the heart-related signal by the biomedical sensor.

[0027] The pre-processing, the reconstructing, and the outputting may be performed in non-real-time with respect to outputting of the heart-related signal by the biomedical sensor.

[0028] According to another embodiment, an apparatus for reconstructing a heart-related signal output by a biomedical sensor may comprise a pre-processing unit configured to pre-

process the heart-related signal to produce a pre-processed heart-related signal. The apparatus may further comprise a reconstruction unit. The reconstruction unit may be configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal. The reconstructing may be based on a time-varying spectral analysis of the pre-processed heart-related signal. The heart-related signal may include motion artifacts, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location. The pre-processing unit may reduce the motion artifacts in the pre-processed heart-related signal for the reconstructing. The method may further comprise an output unit configured to output the reconstructed representation of the heart-related signal.

[0029] Yet another example embodiment may include a non-transitory computer-readable medium having stored thereon a sequence of instructions which, when loaded and executed by a processor, causes the processor to complete methods disclosed herein.

[0030] It should be understood that embodiments disclosed herein can be implemented in the form of a method, apparatus, system, or computer readable medium with program codes embodied thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0032] The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

[0033] FIG. 1A is a block diagram of an example application for which embodiments disclosed herein may be applied.

[0034] FIG. 1B is a block diagram of an example electrocardiogram (ECG) wearable sensor.

[0035] FIG. 2A-B are flow diagrams of an example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0036] FIG. 2B is a flow diagram of another example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0037] FIGS. 3A-C are flow diagrams of example embodiments of yet another method for reconstructing a heart-related signal output by a biomedical sensor.

[0038] FIG. 4 is a block diagram of an example embodiment of a system.

[0039] FIG. 5 is a block diagram of an example embodiment of an apparatus for reconstructing a heart-related signal output by a biomedical sensor.

[0040] FIG. 6A is a plot of ECG recordings and estimated heart rate (HR).

[0041] FIG. 6B is a zoomed in version of FIG. 6A.

[0042] FIG. 7A is a plot of an ECG time-frequency spectrum.

[0043] FIG. 7B is an annotated plot of the ECG time-frequency spectrum of FIG. 7A.

[0044] FIG. 8A is a plot of another ECG time-frequency spectrum.

[0045] FIG. 8B is a plot showing tracking of an HR trace in the ECG spectrum of FIG. 8A.

[0046] FIG. 9 is a plot showing tracking of reconstructed HR compared to a reference HR.

[0047] FIG. 10 shows a comparison between a reconstructed HR and a reference HR.

[0048] FIG. 11A shows a beat-by-beat reconstruction of HR.

[0049] FIG. 11B shows a power spectral density of reconstructed HR.

[0050] FIGS. 12A-B, 13A-B, and 14A-B show reconstructed HR and corresponding power spectral density (PSD) in comparison to a reference HR from an ECG.

[0051] FIG. 15 is a block diagram of an example internal structure of a computer optionally within an embodiment disclosed herein.

DETAILED DESCRIPTION OF THE INVENTION

[0052] A description of example embodiments of the invention follows.

[0053] Accurate estimation of heart rates from electrocardiogram (ECG) signals during intense physical activity is a very challenging problem. This is because strenuous and high intensity movements can result in severe motion artifacts in the ECG signals, making accurate heart rate (HR) estimation difficult.

[0054] For detecting infrequent and episodic cardiac arrhythmias, a Holter monitor is commonly used for continuous monitoring of ECG which can last more than several days. Additionally, to ensure that exercises are effective, during aerobic exercise, a heart-rate

monitor provides a user with information such as the specific heart-rate zone, calories burned, and breathing rate. In addition, as a possible diagnostic outcome underlying many autonomic dysfunction, heart rate variability (HRV) information from wearable sensors including devices that use ECG will become more relevant as these wearable devices are personalized (Achten, J. and A.E. Jeukendrup, Heart rate monitoring: applications and limitations. Sports medicine (Auckland, N.Z.), 2003. 33(7): p. 517-538). Increased HRV has been associated with lower mortality rates and is affected by both age and gender. During graded exercise, the majority of studies show that HRV decreases progressively up to moderate intensities, after which it stabilizes (Laughlin, M.H., Cardiovascular response to exercise. Am J Physiol, 1999. 277(6 Pt 2): p. S244-59).

[0055] Wearable health monitoring systems (WHMS) enable continuous, reliable and long-term monitoring of vital signs and physiological signals during daily normal activities. Recently, a variety of WHMS have also been introduced in an attempt to reduce size, improve comfort and accuracy, and extend the duration of monitoring. Product concepts and prototypes of ECG patches have been introduced by several companies and research groups such as: Curvus, Corventis, iRhythm, Toumaz and Delta. Researchers in (F. Yazicioglu, T.T., J. Penders, I. Romero, H. Kim, P. Merken, B. Gyselinckx, H.J. Yoo, C. Van Hoof. Ultra-low-power wireless sensor nodes. in Proceedings of the 31st Annual International Conference of the IEEE EMBS. 2009. Minneapolis: IEEE; J. Penders, J.v.d.M., M. Altini, F. Yazicioglu and C. Van Hoof. A low-power wireless ECG necklace for reliable cardiac activity monitoring on-the-move. in Proceedings of the International Conference of the IEEE Engineering in Medicine and Biology Society. 2011. IEEE) developed an ultra-low-power ECG platform and a low-power wireless ECG necklace. Samsung created a research WHMS prototype, Simband, for continuous monitoring of ECG and Electrocardiogram (ECG) signals (Aubert, A.E., B. Seps, and F. Beckers, Heart rate variability in athletes. Sports Med, 2003. 33(12): p. 889-919). Wearable and wireless devices allow delocalizing ECG monitoring from hospitals to home environments. Achieving reliable and high integrity recording however remains a challenge in ambulatory conditions due to the high level of noise introduced by motion artifacts. The effectiveness of WHMS can be significantly impaired by motion artifacts which contaminate the signal and that can lead to errors in estimation of cardiac parameters and trigger false alarms. For Holter systems, motion artifacts often lead to

difficult interpretation of whether or not certain arrhythmia has truly occurred even when three or five different channels of ECG data are considered.

[0056] Reducing the motion artifacts would extend the applicability of ambulatory monitors to situations of greater activity as encountered in most daily-life situations. Skin forms a physiological barrier for diffusion of water and ions, and it is charged with a relatively high trans-dermal potential of typically -10 to -30 mV. The potential is generated by a constant ionic gradient and ionic potential of sweat glands (Kearney, K., C. Thomas, and E. McAdams. Quantification of Motion Artifact in ECG Electrode Design. in Engineering in Medicine and Biology Society, 2007. EMBS 2007. 29th Annual International Conference of the IEEE. 2007). The relatively thin (typically between 2 and 20μm) barrier has a very high resistance but allows a capacitive coupling at conventional ECG frequencies. The temporally and spatially varying skin potential accounts for the generation of low frequency noise and artifacts (Kearney, K., C. Thomas, and E. McAdams. Quantification of Motion Artifact in ECG Electrode Design. in Engineering in Medicine and Biology Society, 2007. EMBS 2007. 29th Annual International Conference of the IEEE. 2007).

[0057] Noise and motion artifacts are also caused by several factors, such as baseline wander (BW), power-line interference (PLI), electromyography (EMG) noise and skin-electrode motion artifacts (MA) (Friesen, G.M., et al., A comparison of the noise sensitivity of nine QRS detection algorithms. Biomedical Engineering, IEEE Transactions on, 1990. 37(1): p. 85-98). In practice, motion artifacts (MAs) are difficult to remove because they do not have a predefined narrow frequency band and their spectrum often overlaps that of the ECG signal (Thakor, N.V. and Y.S. Zhu, Applications of adaptive filtering to ECG analysis: noise cancellation and arrhythmia detection. IEEE Trans Biomed Eng, 1991. 38(8): p. 785-94). Several electrical models have been proposed to characterize skin-electrode interface (Webster, N.T.a.J. The origin of skin potential and its variations. in Proc. Ann. Conf. Eng. Biol. Med 1978; Edelberg, R., Local electrical response of the skin to deformation. J Appl Physiol, 1973. 34(3): p. 334-40; Muhlsteff, J. and O. Such. Dry electrodes for monitoring of vital signs in functional textiles. in Engineering in Medicine and Biology Society, 2004. IEMBS '04. 26th Annual International Conference of the IEEE. 2004).

[0058] The corruption introduced by motion artifacts are random variables which depend on the electrode properties, electrolyte properties, skin impedance, and a movement of the patient. Deformation in the skin produces changes in the impedance of the uppermost layers

of the skin that are translated into changes in potential measured at the body surface (Comert, A. and J. Hyttinen, Investigating the possible effect of electrode support structure on motion artifact in wearable bioelectric signal monitoring. Biomed Eng Online, 2015. 14: p. 44). In addition, relative motion of the electrode and skin under motion leads to a charge deformation at the electrode-skin boundary. Consequently, development of methods capable of reconstructing the corrupted signal and removing artifacts is challenging.

[0059] Numerous methods for motion artifact detection and reduction have been proposed in literature. Traditional de-noising techniques are based on time averaging (Afonso, V.X., et al., Comparing stress ECG enhancement algorithms. Engineering in Medicine and Biology Magazine, IEEE, 1996. 15(3): p. 37-44) and frequency analysis such as filter banks (Afonso, V.X., et al., Comparing stress ECG enhancement algorithms. Engineering in Medicine and Biology Magazine, IEEE, 1996. 15(3): p. 37-44) or wavelet transforms (P., A. Separating cardiac and muscular ECG components using adaptive modelling in time-frequency domain. in Proc. of the WACBE World Congress on Bioengineering. 2007). In adaptive filtering, a filter is applied after adjusting its parameters to a time varying noise. This is particularly useful when the noise is non-stationary, like in the case of ambulatory motion artifacts. However, a reference signal has to be additionally recorded together with the ECG. Several adaptive filtering approaches have been proposed to obtain an adequate reference signal such as measurement of skin-electrode impedance (Devlin PH, M.R., Ketchum JW., Detection electrode motion noise in ecg signals by monitoring electrode impedance. Computers in Cardiology, 1984: p. 51-56; Hamilton, P.S., et al. Comparison of methods for adaptive removal of motion artifact. in Computers in Cardiology 2000. 2000), skin stretching measured with optical sensors (Hamilton, P.S., et al. Comparison of methods for adaptive removal of motion artifact. in Computers in Cardiology 2000. 2000; Hamilton, P.S., M. Curley, and R. Aimi, Effect of adaptive motion-artifact reduction on QRS detection. Biomed Instrum Technol, 2000. 34(3): p. 197-202) or accelerometers (Tong, D.A., K.A. Bartels, and K.S. Honeyager. Adaptive reduction of motion artifact in the electrocardiogram. in Engineering in Medicine and Biology, 2002. 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint. 2002; Raya, M.A.D. and L.G. Sison. Adaptive noise cancelling of motion artifact in stress ECG signals using accelerometer. in Engineering in Medicine and Biology, 2002. 24th Annual Conference and

the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint. 2002; Thakor, N.V. and Z. Yi-Sheng, Applications of adaptive filtering to ECG analysis: noise cancellation and arrhythmia detection. Biomedical Engineering, IEEE Transactions on, 1991. 38(8): p. 785-794). Raya and Sison (Raya, M.A.D. and L.G. Sison. Adaptive noise cancelling of motion artifact in stress ECG signals using accelerometer in Engineering in Medicine and Biology, 2002. 24th Annual Conference and the Annual Fall Meeting of the Biomedical Engineering Society EMBS/BMES Conference, 2002. Proceedings of the Second Joint. 2002) used an accelerometer to reduce the motion artifacts (MA) of ECG signals.

[0060] However, the least mean square (LMS) and recursive least square (RLS) were unable to provide acceptable results. MA is difficult to detect because every movement of muscles are different for each person, thus a generalized method that takes into account various MA features may be difficult to develop. As sources of ECG and motion artifacts are uncorrelated, blind source separation (BSS) techniques could be used for separating both signals (Hyvärinen, A. and E. Oja, Independent component analysis: algorithms and applications. Neural Networks, 2000. 13(4–5): p. 411-430; Castells, F., A. Cebrian, and J. Millet, The role of independent component analysis in the signal processing of ECG recordings. Biomed Tech (Berl), 2007. 52(1): p. 18-24; Heenam Yoon, H.K., Sungjun Kwon, Kwangsuk Park, An Automated Motion Artifact Removal Algorithm in Electrocardiogram Based on Independent Component Analysis, in The Fifth International Conference on eHealth, Telemedicine, and Social Medicine. 2013: Nice, France. p. 15-20).

[0061] In order to apply BSS techniques, input signals should be linearly independent. In the case of ECG signals, a multi-lead ECG recording in which the leads are linearly independent is required. Principal Component Analysis (PCA) has been used for reducing noise in single lead ECG segmented in time intervals (Palaniappan R, K.T. Uni-channel PCA for noise reduction from ECG signals. 2004). A combination of PCA and ICA was also proposed by Chawla (Chawla, M.P.S., A comparative analysis of principal component and independent component techniques for electrocardiograms. Neural Computing and Applications, 2009. 18(6): p. 539-556) for ECG de-noising. Lee et al. used empirical mode decomposition (EMD) approach to detection of Motion and noise artifact for the purpose of detection of atrial fibrillation from ECG recordings (Jinseok, L., et al., Automatic Motion and Noise Artifact Detection in Holter ECG Data Using Empirical Mode Decomposition and

Statistical Approaches. Biomedical Engineering, IEEE Transactions on, 2012. 59(6): p. 1499-1506). The main issue with BSS methods is its heavy computational cost and that they are not suitable for real-time processing purposes.

[0062] Embodiments disclosed herein enable accurate reconstruction of motion-corrupted electrocardiogram (ECG) signals and HR based on a time-varying spectral analysis. A spectral filter approach for electrocardiogram motion artifacts and heart rate reconstruction (SegMA) may be referred to interchangeably herein as a SegMA method or SegMA.

[0063] According to some embodiments, the SegMA method may comprise 5 distinct stages: (1) Taking a derivative of a downsampled ECG signal, (2) obtaining a time-varying power spectral density (PSD) of an absolute value of the derivative, (3) spectral filtering, (4) HR reconstruction, and (5) Heart Rate Variability Analysis.

[0064] Embodiments disclosed herein may compute a time-frequency spectrum of an ECG signal for each time shift of a windowed data segment of the ECG signal. By analyzing time-varying spectra of the ECG, those frequency spectra belonging to the HR can be distinguished from the ECG spectrum. Embodiments disclosed herein may preserve (*i.e.*, retain) spectra corresponding to a highest power in the time-frequency spectrum, the most dominant frequency components of the resulting spectrum in each window may represent the HR and may be extracted for each window segment.

[0065] The SegMA approach according to embodiments disclosed herein was applied to datasets recorded in Chon Lab that include 17 min recordings from 10 subjects during a challenging experimental protocol including walking, jogging, running, arm movement, wrist movement, body shaking, and weight lifting activities. ECG and tri-axial accelerometer data were recorded from wrist bands on both right and left wrists of the subjects connected with wire through a tight suit. Reference ECG signals were recorded from the subjects' chests' using a respective Holter monitor.

[0066] The reference ECG signals were recorded to compare a performance of the SegMA method. The method's accuracy was calculated by computing the mean absolute error between SegMA reconstructed HR from the wrist ECG and the reference HR from the Holter ECG. Average estimation errors using the SegMA method on these datasets is less than 2 beats/min. Moreover, it was found that dynamics of heart rate variability (HRV) measures in both time- and frequency-domains can be accurately captured using the SegMA method where the mean Pearson's correlation coefficient was found to be 0.96 between the

power spectral densities of the reference and the reconstructed heart rate time series; there was no significant difference between the reference and reconstructed HRV time-domain parameters.

[0067] These results show that the SegMA method has a potential for ECG-based HR monitoring in wearable devices for fitness tracking and health monitoring during intense physical activities.

[0068] FIG. 1A is a block diagram 100 of an example application for which embodiments disclosed herein may be applied. In FIG. 1A, a subject 102 is running on a treadmill 104. The subject 102 is wearing wrist bands 106a and 106b that include respective electrodes, such as carbon black (CB) electrodes (not shown), that are connected by a wire 109, forming a biomedical sensor 108 that produces a heart-related signal 110. The wrist bands 106a and 106b, respective electrodes, and connecting by the wire 109 disposed therebetween, form one example of an ECG sensor. It should be understood that the ECG sensor may be any suitable ECG sensor, module, or system, that outputs the heart-related signal 110. Further, an electrode may be any suitable electrode, such as the CB electrode, disclosed above.

[0069] The heart-related signal 110 that is produced by the biomedical sensor 108 includes motion artifacts that are signal artifacts produced by movement of the biomedical sensor 108 relative to a sensing location (not shown). The sensing location may be a skin surface of an area on the subject's wrist where the wrist band 106a or 106b is worn, or any other suitable sensing location, such as a chest, at which the biomedical sensor 108 senses the heart-related signal 110.

[0070] It should be understood that a subject referred to herein may be any living being, such as a person or an animal, and may be referred to interchangeably herein as a user or a patient. Further, movement of the biomedical sensor 108 relative to the sensing location may be caused by any suitable source of the movement that causes movement of the biomedical sensor 108 relative to the sensing location, such as vibration experienced during ambulatory transport of the patient to a hospital. Further the heart-related signal 110 may be one or more heart-related signals which in combination, form a heart-related signal.

[0071] Physical activity of the subject 102 may cause movement of the wrist band 106a or 106b, and, thus, movement of the biomedical sensor 108, such as relative movement of one or more of the electrodes at respective sensing locations, such as the skin on the subject 102's left and right wrist, resulting in a charge deformation at the electrode-skin boundary.

As such, strenuous and high intensity exercise of the subject 102, such as running or any other suitable activity, such as riding in an ambulance, may result in movement that rises to a level causing motion artifacts in the heart-related signal 110.

[0072] According to embodiments disclosed herein, the heart-related signal 110 may be reconstructed 112, producing a reconstructed heart-related signal with the motion artifacts suppressed 114. The reconstructed heart-related signal with the motion artifacts suppressed 114 may be used to accurately estimate HR, HRV, or any other suitable heart-related estimate. As such, the reconstructed heart-related signal may be employed to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0073] FIG. 1B is a block diagram 128 of an example electrocardiogram (ECG) wearable sensor 129 that may be employed as the biomedical sensor 108 of FIG. 1A. The ECG wearable sensor 129 comprises a first module 116a and a second module 116b including a first CB electrode 138a and a second CB electrode 138b, respectively. The first CB electrode 138a and the second CB electrode 138b are connected by a wire 119.

[0074] FIG. 2A is a flow diagram 200 of an example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor. The method may start (202) and pre-process (also referred to interchangeably herein as preprocess) the heart-related signal to produce a pre-processed heart-related signal (204). The method may reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal based on a time-varying spectral analysis of the pre-processed heart-related signal, the heart-related signal including motion artifacts (206). The motion artifacts may be signal artifacts produced by movement of the biomedical sensor relative to a sensing location. The pre-processing may reduce the motion artifacts in the pre-processed heart-related signal for the reconstructing. The method may output the reconstructed representation of the heart-related signal (208) and the method thereafter ends (210) in the example embodiment.

[0075] FIG. 2B is a flow diagram of an another example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor. The method corresponds to Stage 1 (ECG pre-processing), Stage 2 (time-varying spectral analysis), Stage 3 (spectral

filtering) and Stage 4 (HR Tracking and Extraction from ECG Spectrum) of Table 1, disclosed below, for reconstructing a heart-related signal output by a biomedical sensor.

Table 1. SegMA method: HR and ECG signal reconstruction

Stage 1. ECG Preprocessing

1.1. Down sample the ECG to ¼ of the original sampling rate
1.2. Compute the derivative of downsampled ECG signal.
1.3. Take an absolute value of the derivative (optional)

Stage 2. Time-Varying Spectral analysis

2.1. Compute the power spectral density of preprocessed ECG data at each time window of 8 sec

Stage 3. Spectral Filtering

3.1. Assume HR to be in the frequency range of [0.5Hz – 3Hz], this accounts for both low and high heart rates.

3.2. The first highest two peaks and their corresponding frequencies in the ECG filtered spectrum are assumed to have HR information.

Stage 4. Heart Rate Tracking and Extraction from ECG Spectrum

Case (1): if the spectrum is corrupted by movement and only the first largest peak is corrupted, then the HR frequency should be the frequency of the second peak in the spectrum.

Case (2): Due to skin-electrode interface changes, the HR frequency cannot be extracted from the spectrum and in this case the previous HR frequency is used or for offline implementation a cubic spline interpolation can be applied to fill in the missing HR information.

Stage 5. Heart Rate Variability Analysis

By using a sample-by-sample windowing strategy, beat-to-beat HR can be extracted, from which dynamics of heart rate variability analysis can be obtained on the SegMA reconstructed HR time series.

[0076] The method may start (222) with a first windowed segment *window[k]* of raw ECG data (224). The raw ECG data (224) may be extracted from a heart-related signal that is output by an ECG sensor in any suitable way. The raw ECG data (224) may be extracted in real-time or non-real-time (*e.g.*, from a database).

[0077] The method may pre-process the ECG signal (226) (see Table 1, Stage 1, ECG Pre-processing) to produce a pre-processed heart-related signal. The pre-processing (226) may include down-sampling the heart-related signal to produce a down-sampled heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate (*e.g.*, ¼ of the original sampling rate). This may improve a frequency resolution in a time-frequency spectrum of the ECG employed by the restructuring, as disclosed below. The pre-processing (226) may include computing a derivative of the down-sampled heart-related signal to reduce the motion artifacts, as the derivative may accentuate peaks of the ECG. The motion artifacts can be reduced to some extent via the derivative as long as the motion is not abrupt and the samples are uniformly corrupted by the movement. The pre-processing may further include computing an absolute value of the derivative to further reduce the motion artifacts by further accentuating the peaks of the ECG. As such, the pre-processing may reduce the motion artifacts in the pre-processed heart-related signal for the restructuring.

[0078] The method may include computing a time-frequency spectrum (TFS) (see Table 1, Stage 2, Time Varying Spectral Analysis) of the pre-processed heart-related signal (228). The TFS computed may be a 3-dimensional spectra including a time-varying amplitude or power distribution with respect to time and frequency, such as a time-varying power spectral density (PSD). Any suitable time-frequency technique may be employed, such as a variable frequency complex demodulation (VFCDM), disclosed in U.S. Patent No. 8,388,543 B2, incorporated herein in its entirety by reference, smoothed pseudo wigner-ville method, or a wavelet based method.

[0079] The method may further include limiting the TFS computed to a given frequency range (see Table 1, Spectral Filtering). The given frequency range may be 0.5 Hz to 3 Hz to account for both low and high heart rates. The HR estimation may be based on a strategy that eliminates (*i.e.*, discards) frequencies that are outside of this HR range as they are most likely due to motion artifacts or harmonics of the HR frequency. As such, this is one aspect in which the reconstructing may further reduce the motion artifacts reduced by the pre-processing.

[0080] Based on an assumption that the HR frequency component is a dominant peak (*i.e.*, peak having highest power or amplitude relative to other peaks at a time point) in the PSD window k of a clean ECG signal, the filtered time-frequency spectrum using the first N (*e.g.*, two) largest peaks of PSD at each window k can be extracted (230), as shown in FIG.

8A, disclosed below. The method may check (232) if there are any peaks in the spectrum. If not (see Table 1, Heart Rate Tracking and Extraction from ECG, Case (2)), the reconstructed representation *HR(k)* (234) may be set to a previous reconstructed representation *HR(k-1)* (or a moving average of several past HR beats or some other variant) a for real-time implementation; alternatively, an offline implementation may be used, such as a cubic spline interpolation that can be applied to fill in the missing HR information, and the method thereafter ends (242) in the example embodiment.

[0081] If there is a peak present (232), up to a pre-determined number *N* of frequency spectra (also referred to interchangeably herein as frequency components) may be retained to produce a subset of frequency spectra, such as Peak 1 and Peak 2 shown in FIG. 8A, disclosed below. The method may select a spectral peak for the reconstructing. The selected spectral peak may be selected from amongst spectral peaks of the subset (*e.g.*, the peaks $i = 1...N$) of the frequency spectra and a previous frequency component, such as *HR(k-1)* (or a moving average of several past HR beats or some other variant). The previous frequency component may have been selected for a previous shift, such as *k-1*. It should be understood that the spectral peak is being selected for a point in time in the time-frequency spectrum. For example, it should be understood that the two peaks, Peak 1 and Peak 2, are being tracked at each point in time in the time-frequency spectrum shown in FIG. 8A, disclosed below.

[0082] For a case in which the windowed ECG signal is clean, the first highest peak in the spectrum may represent the HR fundamental frequency. For a case in which the windowed ECG signal is corrupted by movement and the second peak corresponds to HR, while the HR spectral peak may be detectable, the difference between its value and that of the previous HR, for example, *HR(k-1)*, may be more than a given difference value (also referred to interchangeably herein as distance value), such as 10 beats-per-minute (bpm) or 15 bpm, or any other suitable difference value. As such, it may be replaced by the most recent HR value from a previous window segment (or a moving average of several past HR beats or some other variant).

[0083] According to some embodiments, a criterion may be set that the HR value cannot change more than the given difference value, such as 15 bpm, or any other suitable value, from a previous time window. A respective difference value may be computed (236) for each spectral peak in the subset and each respective difference may be checked (238) to select from amongst the subset (*e.g.*, the peaks $i = 1...N$) or the previous *HR(k-1)*. For example, if

none of the spectral peaks meet the criterion checked (238), the previous *HR(k-1)* may be selected (234) and the method thereafter ends (242) in the example embodiment. If, however, one or more spectral peaks in the subset do meet the criterion, a spectral peak having a smallest difference value may be selected (240) and the method thereafter ends (242) in the example embodiment. It should be understood that the TFS may be computed for each shift *k* of a windowed data segment *window(k)* of the heart-related signal that is pre-processed (226) and that the heart related signal may be reconstructed for each shift *k* of the windowed data segment *window(k)*.

[0084] It can be observed from FIG. 8B, disclosed below, that in most cases, the blue circle which represents the largest spectral peak is chosen (*i.e.*, selected, extracted); however, in other cases, green circles are chosen for certain time points. For the HR peaks associated with the green circles, they are chosen because either the first highest peak is related to a motion artifact or the highest magnitude peak deviates more than the given difference value, such as 15 bpm, from the previous HR value. As such, another aspect in which the reconstructing may further reduce the motion artifacts reduced by the pre-processing may result based on the particular spectral peak that is chosen for a time point.

[0085] The method may employ the reconstructed representation to determine a heart rate variability (HRV) estimate, as disclosed Stage 5, Heart Rate Variability Analysis, of Table 1, disclosed above. The method may employ the reconstructed representation to determine a heart rate estimate. The method may employ the reconstructed representation to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0086] According to some embodiments, the SegMA method may reduce motion artifacts by employing a motion signal from a motion sensor. The heart-related signal and the motion signal may be produced, concurrently. The method may further comprise segmenting the heart-related signal into a plurality of windowed heart-related signal data segments and the motion signal into a corresponding plurality of windowed motion signal data segments and repeating the pre-processing, the reconstructing, and the outputting for each windowed heart-related signal data segment and each corresponding motion signal data segment. The time window may be a value in a range from 2 to 32 seconds. For example, the *window[k]* of raw ECG data of FIG. 3A, element 304, disclosed below, and the *window[k]* of raw accelerometer

data shown in FIG. 3A, element 310, disclosed below, may each include data from the respective ECG and accelerometer signals that may be collected over a time window from 2 to 32 seconds. According to one embodiment, the time window may be 8 seconds.

[0087] According to some embodiments, the biomedical sensor may be an ECG sensor. The motion sensor may be an accelerometer, or any other suitable device that produces a motion signal. If an accelerometer, the accelerometer may be a 3-axial type accelerometer, or any other suitable type of accelerometer. The biomedical sensor and the motion sensor may be co-located. For example, the wrist bands 106a and 106b of FIG. 1A, disclosed above, may be smartwatches and the biomedical sensor and motion sensor may be an ECG sensor and an accelerometer, respectively, that are both disposed in each smartwatch or other suitable wearable device.

[0088] For a SegMA method employing the motion signal, the time-varying spectral analysis may be a first time-varying spectral analysis. The reconstructing may be further based on a second time-varying spectral analysis of a motion signal, the motion signal output by a motion sensor and representative of the motion artifacts in the heart-related signal. The method may further include employing the second time-varying spectral analysis of the motion signal to produce a movement classification of the movement, and wherein the reconstructing is further based on the classification of the movement.

[0089] FIGS. 3A-C are flow diagrams of example embodiments of a SegMA method employing the motion signal for reconstructing a heart-related signal output by a biomedical sensor based on embodiments disclosed in Tables 2-4, disclosed below.

Table 2. Stages 1 and 2

Stage 1. Time-Varying Spectral analysis (see FIG. 3A) 1.1. Filter the ECG and Accelerometer signal with cutoff frequency [1, 50]/Fs/2 Hz. 1.2. Down sample the ECG and Accelerometer signal to ¼ of original sampling rate (Fs). 1.3 Compute the derivative of the ECG and an absolute value (optional) of the derivative 1.3. Compute the time frequency spectrum of both ECG and Accelerometers [0-10 Hz]. Stage 2. Movement Classification (see FIG. 3A) 2.1. Check each accelerometer (X, Y or Z) amplitude modulation at each window and compare to a pre-defined motion amplitude threshold. (The threshold varies depending on the type of accelerometer sensor). Signal is clean if AM[$Acc_{x\ or\ y\ or\ z}(k)$] < Motion_Threshold and the signal is corrupted by motion otherwise. If the signal is clean calculate the Heart Rate from peak-to-peak intervals,

otherwise go to step 2.2.

2.2. If the signal is corrupted check if the movement is pseudo-periodic (e.g. during walk, jog, run) or non-periodic (e.g. any random movements)

The assumption is when movement is pseudo-periodic the accelerometer data should comprised of a fundamental frequency component and harmonics of the fundamental frequency at its double and third frequency band. This means the ratio of the first harmonic to the fundamental frequency should be almost 2 and the second harmonic to the fundamental should be around 3.

2.2.1. Extract the fundamental frequency component, the 1st and 2nd harmonics from (e.g., VFCDM) time-frequency spectrum of accelerometers. The first three highest peaks in spectral array should represent the fundamental, 1st and 2nd harmonics as long as the movement is pseudo-periodic.

2.2.2. Calculate the ratio of the extracted 1st and 2nd fundamental frequency to the extracted fundamental frequency. If the ratios are close to 2 and 3, this indicates that the movement is most likely pseudo-periodic otherwise it is non-periodic.

2.2.3. If the movement is pseudo-periodic do the Stages 3-5 (See Table 2 and FIG. 3B), otherwise go to Stage 6 (See Table 3 and FIG. 3C).

Table 3. Stages 3-5

Stage 3. Spectral Filtering (see FIG. 3B)

3.1. Assume HR to be in the frequency range of [0.5Hz – 3Hz], this accounts for both low and high heart rates.
3.2. The first highest (e.g., three peaks) and their corresponding frequencies in the ECG filtered spectrum are assumed to have HR information.
3.3. Only the largest frequency peak (that represents the fundamental frequency of movement) of the accelerometers' spectra is used for motion artifact detection in Stage 4.

Stage 4. Motion Artifact Detection (see FIG. 3B)

4.1. Compare the frequencies of the three peaks in the ECG spectrum with the frequency of the largest peak in the accelerometers' spectra. If the first or second largest peaks in the ECG spectrum are similar to that of the accelerometers' peaks, then motion artifact is present in the ECG.
4.2. If motion artifact is detected from 3.1, then the corresponding frequency peak (usually the first or second largest peak) in the ECG spectrum should be discarded.

Stage 5. Heart Rate Tracking and Extraction from ECG Spectrum (see FIG. 3B)

Case (1): From 3.1- if the spectrum is corrupted by movement and only the first largest peak is corrupted, then the HR frequency should be the frequency of the second peak in the spectrum.
Case (2): From 3.1- if the spectrum is corrupted by movement and both the first and second

largest peaks have similar frequencies to those of the accelerometers' peaks, then the HR frequency should be the frequency of the third peak in the spectrum.
Case (3): Due to a gap between the pulse oximeter and a subject's skin, the HR frequency cannot be extracted from the spectrum and in this case the previous HR frequency is used or for offline implementation a cubic spline interpolation can be applied to fill in the missing HR information.

Table 4. Stage 6

Stage 6. Adaptive Bandpass Filtering (non-periodic movements) (see FIG. 3C)

When the movement is random and non-periodic it is difficult or not possible to identify HR trace from time-frequency spectrum (for example if stage 5 is not applicable). In this case which may happen more often, a new procedure is adopted that is called adaptive bandpass filtering. The assumption here is that HR does not deviate more than 10 bpm from the average of previous m HR values within 2 seconds.

6.1. Set averaging window length to m (e.g. m=5) and calculate the average of recent m estimated HR values.

$$HR_{mavg} = \frac{1}{m}\sum_{j=1}^{m} HR(k-j)$$

Where k is the current window. The window length m=5 should only be used for up to 10 seconds of consecutive motion artifact corrupted datapoints. If motion corrupted data last more than 10 seconds, m should be increased to more than 5.

6.2. Take the most recent estimated HR value and calculate bandpass filter cutoff frequency.

$$F_{CutOff} = [HR_{mavg} - 10, HR_{mavg} + 10\ ]/60/Fs/2$$

Design a bandpass filter of order 4 with cutoff frequency (F_{CutOff}). Apply the filter on the ECG segment.
6.3. Calculate HR from peak-to-peak intervals of the filtered data segment obtained from 6.2. Take the average of the instantaneous HR as estimated HR value at window k.

[0090] FIG. 3A is a flow diagram (300) of an example embodiment of a method for a time-varying spectral analysis and movement classification, as disclosed in Stage 1 (time-varying spectral analysis) and Stage 2 (movement classification), respectively, in Table 2, for reconstructing the representation. The method may start (302) and the time-varying spectral analysis may be employed on a first windowed segment *window[k]* of raw ECG data (304) and a second windowed segment *window [k]* of raw accelerometer (ACC) data (310). The raw ECG data (304) and the raw ACC data (310) may be extracted from a heart-related signal that is an ECG signal and a motion signal that is an accelerometer signal, respectively.

[0091] As disclosed in Stage 1 of Table 2, the time-varying spectral analysis of FIG. 3A may include pre-processing the heart-related signal (306) to produce a pre-processed heart-related signal. The pre-processing (306) may include filtering the heart-related signal to produce a filtered heart-related signal. The pre-processing (306) may further include down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate, to produce a down-sampled, filtered heart-rate signal. The pre-processing may include computing a derivative of the down-sampled heart-related signal to reduce the motion artifacts. The pre-processing may further include computing an absolute value of the derivative to further reduce the motion artifacts.

[0092] The time-varying spectral analysis may further include pre-processing the motion signal (312) to produce a pre-processed motion signal. The pre-processing (312) may include filtering the motion signal to produce a filtered motion signal. The pre-processing (312) may further include down-sampling the filtered motion signal, the down-sampling being at a sampling rate less than an original sampling rate, to produce a down-sampled, filtered motion signal.

[0093] As further disclosed in Stage 1 of Table 2, the time-varying spectral analysis of FIG. 3A may include computing a first time-frequency spectrum (TFS) to produce a first TFS (308) of the down-sampled, filtered heart-related signal and computing a second TFS to produce a second TFS (314) of the down-sampled, filtered motion signal. According to some embodiments, filtering and down-sampling of the heart-related signal and motion signal for computing the first TFS (308) and the second TFS (314), respectively, may be optional. The first TFS (308) (also referred to interchangeably herein as the first TFS computed) and the second TFS (314) (also referred to interchangeably herein as the second TFS computed) may be 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

[0094] For example, the first TFS computed may be a first time-varying power spectral density (PSD) and the second TFS computed may be a second time-varying PSD. A time-frequency technique, such as a variable frequency complex demodulation (VFCDM), disclosed in U.S. Patent No. 8,388,543 B2, incorporated herein in its entirety by reference, may be used for computing the first TFS (308), that is, a TFS of the ECG signal, and the second TFS (314), that is, a TFS of the accelerometer signal. However, it should be

understood that any suitable time-frequency technique may be used, such as a smoothed pseudo wigner-ville method, or a wavelet based method.

[0095] As disclosed in Stage 2 of Table 2, classifying the classification of the movement (316) in FIG. 3A may include comparing an amount of amplitude modulation in the second TFS (314) computed to an amplitude modulation threshold. The amplitude modulation threshold may be dependent on a type of the motion detector sensor, such as a type of the accelerometer. The classification of the movement may indicate whether the movement rises to a level causing motion artifacts in the heart-related signal, that is, the ECG signal, based on a result of the comparing, as disclosed in Stage 2 of Table 2.

[0096] In an event the movement classification (316) of FIG. 3A indicates that the movement does not rise to a level causing the motion artifacts (322), a peak-peak interval (PP) of the filtered heart-related signal, or alternatively, the filtered, down-sampled heart-rate signal, may be computed (318) and the reconstructed representation HR(k) may be based on an average value of peak-to-peak intervals (320) in the pre-processed heart-related signal, and the method thereafter ends (325) in the example embodiment.

[0097] In an event the movement classification (316) indicates that the movement does rise to the level causing the motion artifacts (323), classifying the classification of the movement may further include determining (324) whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement, as disclosed in Stage 2 of Table 2.

[0098] With reference to Stage 2 of Table 2, in determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS. The first, second, and third peaks may have largest power or amplitude values relative to other peaks in the second TFS at the point in time. The first spectral peak may be a largest spectral peak amongst the first, second, and third spectral peaks.

[0099] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may compute a first ratio of the second frequency identified to the first frequency identified. The method may determine a first comparison result by comparing the first ratio computed to a first ratio

value. The method may compute a second ratio of the third frequency identified to the first frequency identified and determine a second comparison result by comparing the second ratio computed to a second ratio value. The classification may further indicate the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result. The first ratio value may be 2 and the second ratio value may be 3. The classification of the movement may be periodic if the first ratio and the second ratio are exactly 2 and 3, respectively, while the classification of the movement may be pseudo-periodic if the first ratio and the second ratio are approximately 2 and 3, respectively, within a pre-determined level of accuracy.

[00100] In an event the classification of the movement is periodic or pseudo-periodic, the method of FIG. 3A may continue with the method of FIG. 3B, disclosed below. In an event the classification of the movement is random, the method of FIG. 3A continues to the method of FIG. 3C, disclosed below.

[00101] FIG. 3B is a flow diagram (330) of an example embodiment of a method for spectral filtering, motion artifact detection, and heart rate tracking and extraction, as disclosed in Stages 3, 4, and 5, respectively, of Table 3, for reconstructing the representation. The reconstructed representation may be referred to herein as a current reconstructed representation or HR(k). As disclosed above with regard to FIG. 3A, in an event the classification of the movement (316) is periodic or pseudo-periodic, the method of FIG. 3A may continue with the method of FIG. 3B.

[00102] The method of FIG. 3B may start (331) and retain (332) up to a pre-determined number N of candidate spectral peaks located at a first point in time in the first TFS, that is, the first TFS from FIG. 3A. It should be understood that the method of FIG. 3B may be performed for each point in time of the first TFS and the second TFS. According to one embodiment, the pre-determined number N may be 2 or 3. The candidate spectral peaks retained may be based on having corresponding frequencies within a given frequency range. The candidate spectral peaks may be N peaks in the given frequency range that have highest amplitude or power values relative to other spectral peaks, that is, the first N highest peaks. It should be understood that the other spectral peaks have respective frequencies also within the given frequency range and are peaks located at the first point in time in the first TFS. The given frequency range may be 0.5 Hz to 3 Hz. As such, the N first highest peak in the range

0.5 Hz to 3 Hz in the first TFS may be retained at the first time point. Since no peaks in the given frequency range may be present at the first time point, the method may determine (336) whether at least one spectral peak is present.

[00103] Based on the determination (336) that no peak is present, the current reconstructed representation HR(k) may be based on a prior reconstructed representation HR(k-1) (340), the prior reconstructed representation *HR(k-1)* associated with a previous point in time, such as the previous window *k-1*, in the first TFS computed, and the method thereafter ends (354) in the example embodiment.

[00104] Based on a determination (336) that the at least one spectral peak is present, the method may discard (338) each of the candidate spectral peaks retained, that is, each peak of the N first highest peaks determined at (332), if the peak is associated with a same frequency as a dominant spectral peak located at a second point in time in the second TFS (314) computed as disclosed above with regard to FIG. 3A. The first point in time and the second point time may have same time values. The dominant spectral peak may have a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS. The method may determine (342) whether any peaks are retained after the discarding (338). The discarding (338) may be referred to herein as a first discarding.

[00105] In an event the discarding (338) discards each of the candidate spectral peaks retained, reconstructing the current representation HR(k) may be based on the prior reconstructed representation, HR(k-1) (340), and the method thereafter ends (354) in the example embodiment.

[00106] In an event the first discarding (338) results in at least one remaining candidate spectral peak retained, reconstructing the current representation may further include second discarding (348). The second discarding (348) may discard remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced (346) by at least a frequency difference threshold, such as 10bpm, from a prior reconstructed representation's frequency, that is, a frequency associated with, for example, *HR(k-1)*.

[00107] Based on each at least one remaining candidate spectral peak retained having been discarded by the second discarding (348), reconstructing the current representation may be

based on the prior reconstructed representation *HR(k-1)* (350), and the method thereafter ends (354) in the example embodiment.

[00108] Based on at least one last candidate spectral peak remaining from the second discarding (348), reconstructing the current representation may be based on a selected candidate spectral peak (352). The selected candidate spectral peak may be selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining, and the method thereafter ends (354) in the example embodiment.

[00109] As disclosed above with regard to FIG. 3A, in an event the classification of the movement (316) is random, the method of FIG. 3A may continue with the method of FIG. 3C.

[00110] FIG. 3C is a flow diagram (330) of an example embodiment of a method for adaptive bandpass filtering of non-periodic movements, that is, random movements, for reconstructing the representation, as disclosed in Stage 6 of Table 4. The method of FIG. 3C may start (362) and compute an average value of a number m of prior reconstructed representations outputted prior to the reconstructing (362). The number m may be based on a duration of consecutive motion artifacts, detected prior to the reconstructing of the representation HR(k). For example, if motion artifacts were detected for windows *k-1, k-2, and k-3*, *m* may be understood to be 3.

[00111] The method may compute a bandpass filter cutoff frequency (366). The cutoff frequency F_c may be based on the average value computed HR_{mavg}. The method may filter the pre-processed heart-rate signal (306), disclosed in FIG. 3A, above, by applying the band pass filter computed (368) to produce a filtered, pre-processed heart-related signal. The reconstructed representation *HR(k)* may be based on an average peak-to-peak interval value (372) of the filtered, pre-processed heart-rate signal, and the method thereafter ends (374) in the example embodiment.

[00112] FIG. 4 is a block diagram of an example embodiment of a system (400). The system includes an apparatus 420 for reconstructing a heart-related signal 410c output by a biomedical sensor (not shown). The apparatus 420 includes a pre-processing unit 415, a reconstruction unit 416, and an output unit 418. The pre-processing unit 415 may be configured to pre-process the heart-related signal 410c to produce a pre-processed heart-

related signal 419. The reconstruction unit 416 may be configured to reconstruct a representation of the heart-related signal 410c to produce a reconstructed representation of the heart-related signal 414c. The reconstructing may be based on a time-varying spectral analysis of the pre-processed heart-related signal 419.

[00113] The heart-related signal 410c may include motion artifacts, the motion artifacts being signal artifacts produced by movement of a biomedical sensor (not shown) relative to a sensing location (not shown). The pre-processing unit 415 may reduce the motion artifacts in the pre-processed heart-related signal 419 for the reconstructing by the reconstruction unit 416. The reconstruction unit 416 may further reduce the motion artifacts reduced by the pre-processing unit 415. The output unit 418 may be configured to output the reconstructed representation of heart-related signal 414c.

[00114] The apparatus 420 may be communicatively coupled to a network 401 to receive the heart related signal 410c and, optionally, a motion signal 411c. The motion signal 411c (optional) may be output by a motion sensor (not shown) and representative of motion artifacts in the heart-related signal 410c.

[00115] The network may be a wireless network or any other suitable network. The pre-processing, the reconstructing, and the outputting may be performed in near real-time with respect to production of the heart-related signal 410c and, optionally, the motion signal 411c. Alternatively, the apparatus may be coupled to a database (not shown) storing representations of the heart related signal 410c and, optionally, the motion signal 411c, and the pre-processing, the reconstructing, and the outputting may be performed in non-real-time with respect to production of the heart-related signal 410c and the motion signal 414c.

[00116] The heart-related signal 410c may include raw heart-related signal data that includes the raw heart-related signal data 410a and the raw heart-related signal data 410b output by biometric sensors (not shown) that sense the heart-related signal data 410a and the raw heart-related signal data 410b from sensing locations (not shown) on a first user 406a and a second user 406b, respectively. The motion signal 411c (optional) may include raw motion signal data that includes the raw motion signal data 411a (optional) and the raw motion signal data 411b (optional) from the motion sensors (not shown). The raw motion signal data 411a (optional) and the raw motion signal data 411b (optional) may represent motion artifacts in the heart-related signal data 410a and the raw heart-related signal data 410b, respectively.

[00117] It should be understood that the raw heart-related signal data 410a-b and, optionally, the raw motion signal data 411a-b, may be sent to the apparatus 420 in any suitable way. For example, the raw heart-related signal data 410a and the raw motion signal data 411a (optional) may be sent in a payload of a packet; alternatively the raw heart-related signal data 410a and the raw motion signal data 411a (optional) may be sent in payloads of different packets. Similarly, the raw heart-related signal data 410b and the raw motion signal data 411b (optional) may be sent in a payload of a packet; alternatively, the raw heart-related signal data 410b and the raw motion signal data 411b (optional) may be sent in payloads of different packets.

[00118] The user 406a may be at a gym where the user 406a is exercising, and such physical activity by the user 406a may cause motion artifacts in the raw heart-related signal data 410a. The user 406b may be in a different location, such as a hospital. The user 406b may perform movements out of boredom, such as wrist shaking, causing motion artifacts in the raw heart-related signal data 410b. As such, the corresponding motion artifacts may be suppressed (i.e., reduced, mitigated) in the reconstructed representations 414a and 414b of the heart-related signals 414a and 414b, respectively, according to embodiments disclosed herein. The reconstructed representations 414a and 414b, or information derived therefrom, may be sent to biometric devices or other devices communicatively coupled to the network 401 and the user, such as the user 406a or 406b may have access to such devices. Alternatively, the reconstructed representations 414a and 414b, or information derived therefrom, may be sent in any suitable manner to another device communicatively coupled to the network 401 such that the reconstructed representations 414a and 414b, or information derived therefrom, may be accessible to a third party, such as doctor, or any other suitable party.

[00119] FIG. 5 is a block diagram 500 of an example embodiment of an apparatus (520) for reconstructing a heart-related signal 510 output by a biomedical sensor 508. The apparatus 520 includes a pre-processing unit 515 configured to pre-process the heart-related signal 510 to produce a pre-processed heart-related signal 519. The apparatus may comprise a reconstruction unit 516 configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal 514, the reconstructing based on a time-varying spectral analysis of the pre-processed heart-related signal 519. The heart-related signal may include motion artifacts, the motion artifacts being signal artifacts

produced by movement of the biomedical sensor relative to a sensing location. The pre-processing unit 515 may reduce (*i.e.*, mitigate) the motion artifacts in the pre-processed heart-related signal 519 for the reconstructing. The reconstruction unit 516 may further reduce the motion artifacts reduced by the pre-processing unit 515. The apparatus 520 may further comprise an output unit 518 configured to output the reconstructed representation of the heart-related signal 514.

[00120] Pre-processing by the pre-processing unit 515 may include down-sampling the heart-related signal 510 to produce a down-sampled heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate. The time-varying spectral analysis may be based on a frequency resolution and the down-sampling affects the frequency resolution of the time-varying spectral analysis.

[00121] The pre-processing unit 515 may be further configured to compute a derivative of the down-sampled heart-related signal to reduce the motion artifacts. The pre-processing unit 515 may be further configured to compute an absolute value of the derivative to further reduce the motion artifacts.

[00122] The time-varying spectral analysis may include computing a time-frequency spectrum (TFS) of the pre-processed heart-related signal. The TFS computed may be a 3-dimensional spectra including a time-varying amplitude or power distribution with respect to time and frequency. The TFS computed may be a time-varying power spectral density (PSD).

[00123] The reconstruction unit 516 may be further configured to limit the TFS computed to a given frequency range. The given frequency range may be 0.5 Hz to 3 Hz.

[00124] The TFS may be computed for each shift of a windowed data segment of the pre-processed heart-related signal 519 and the reconstruction unit 516 may be further configured to reconstruct the heart related signal 510 for each shift of the windowed data segment.

[00125] At each shift of the windowed data segment subsequent to an initial windowed data segment, reconstructing the representation may include retaining up to a pre-determined number of frequency spectra to produce a subset of frequency spectra and selecting a frequency component to produce a selected frequency component for the reconstructing. The selected frequency component may be selected from amongst frequency components of the subset of frequency spectra and a previous frequency component, the previous frequency

component having been selected for a previous shift of the windowed data segment to reconstruct the heart-related signal for the previous shift.

[00126] The time-varying spectral analysis may be a first time-varying spectral analysis and the reconstructing may be further based on a second time-varying spectral analysis of a motion signal 511 (optional), the motion signal 511 (optional) may be output by a motion sensor 509 and representative of the motion artifacts in the heart-related signal 510.

[00127] The apparatus 520 may employ the second time-varying spectral analysis of the motion signal to produce a movement classification of the movement. The reconstructing by the reconstruction unit 516 may be further based on the classification of the movement.

[00128] The heart-related signal 510 and the motion signal 511 (optional) may be output by the biometric sensor 508 and the motion sensor 509 (optional), concurrently. The apparatus 520 may include the biomedical sensor 508 and the motion sensor 509 (optional). The motion sensor may be an accelerometer. The biomedical sensor 508 may be an electrocardiogram (ECG) sensor.

[00129] The apparatus 520 may comprise a heart rate unit (not shown) configured to employ the reconstructed representation 514 to determine a heart rate estimate. The apparatus 520 may comprise a heart rate variability (HRV) unit (not shown) configured to employ the reconstructed representation 514 to determine a heart rate variability (HRV) estimate. The apparatus 520 may comprise an ailment unit (not shown) configured to employ the reconstructed representation 514 to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[00130] The reconstruction unit 516, the output unit 518, and the pre-processing unit 515 may be configured to reconstruct, pre-process, and output, respectively, in real-time with respect to outputting of the heart-related signal 510 by the biomedical sensor 508. Alternatively, the reconstruction unit 516, the output unit 518, and the pre-processing unit 515 may be configured to reconstruct, pre-process, and output, respectively, in non-real-time with respect to outputting of the heart-related signal by the biomedical sensor.

[00131] The apparatus 520 may be a wearable device, such as a smartwatch, or any other suitable device, such as a wearable personal biometric monitoring device. The apparatus 520 may have a user interface (not shown) to present the reconstructed representation of the heart-related signal 514 or information derived therefrom, such as a characteristic, notification,

alarm, or any other suitable information. The reconstructed representation of heart-related signal 514 or the information derived therefrom may be presented to a user via a user interface that may be a visual or audio based user interface.

[00132] As disclosed above, according to embodiments disclosed herein, HR and ECG signal reconstruction, may be based on a time-varying spectral analysis. As disclosed above, according to some embodiments, the SegMA method may be comprised of five distinct stages: (1) Taking a derivative of a downsampled ECG (2) obtaining a time-varying power spectral density (PSD) of an absolute value of the derivative, (3) spectral filtering, (4) HR reconstruction, and (5) HRV analysis. If employing a motion signal for the reconstructing, embodiments disclosed herein may employ a window-segmented power spectral density of both ECG and accelerometer signals in real-time to scale each estimate of the PSD by the equivalent noise bandwidth of the window (Stoica, P. and R.L. Moses, Introduction to Spectral Analysis. 1997: Prentice Hall). The simplest way to approach the the time-varying PSD calculation may be to employ the Welch periodogram. However, it has the drawbacks that it is an inconsistent spectrum estimator, has high variance, and has leakage effects (Stoica, P. and R.L. Moses, Introduction to Spectral Analysis. 1997: Prentice Hall). Thus, a dominant spectral peak can lead to an estimated spectrum that contains power in frequency bands where there should be no power. According to embodiments disclosed herein, both problems may be solved by down-sampling the raw signal and taking a derivative of the data and, optionally, an absolute value of the derivative, and then using a sufficiently small frequency step by setting a large number of frequency points. According to some embodiments disclosed herein, a heart-related signal, such as an ECG signal, may be resampled from the original sampling frequency, such as to 1/4 of it, and then after taking a derivative of the downsampled signal, and, optionally, an absolute value of the derivative, a periodogram method with frequency resolution of 0.001 may be employed. The PSD spectrum may be limited to a given range, such as a heart rate frequency range of [0.5Hz – 3 Hz], and then the frequency and power information of a pre-determined number N of first highest peaks in the PSD, such as a first three highest peaks in the PSD, may be retained at each window and signal segment. Some embodiments disclosed herein may be based on an observation that a heart rate component in a typical clean (motion free) ECG signal is always the dominant frequency component in the time-varying power spectrum, that is, a spectral

peak with highest power or amplitude at a time point, and thus, the highest peak of the spectrum corresponds to the HR frequency.

[00133] Thus, when movement happens the dominant component can be replaced by movement components which shift the HR to the second peak in the spectrum. A such, embodiments disclosed herein may find two highest peaks and then choose the corresponding frequencies of the ECG to those highest powers in the spectrum. Embodiments disclosed herein may employ a tracking strategy that the highest peak that is closest to the estimated HR of the previous window may be chosen at each window. According to a Results section, disclosed below, the SegMA method not only improves ECG signal and HR reconstruction but also the potential to do heart rate variability analysis on the results. As disclosed below, the SegMA method can improve HR estimations by almost 10 times better accuracy than without SegMA reconstruction.

[00134] Experimental Section

[00135] An experiment with a physically challenging protocol that includes 17-min ECG recordings from 10 healthy subjects was designed, in which each subject was asked to wear a wrist-worn ECG device as shown in FIG. 1B, disclosed above. Table 5, disclosed below, summarizes various ECG wearable devices including the wrist-worn ECG device. The wearable system is called NohChon and was custom designed in a laboratory. The wearable system comprises two wrist modules which are designed to fabricate a 1-channel ECG signal (Lead I configuration) on the top of right and left wrists. This device was designed and developed for ECG measurement based on two leads with virtual right-leg driven circuit and provides a frequency band at -3 dB from 0.05 to 150 Hz with second-order high-pass and low-pass filters to cover the full ECG range. In both modules, 3-axis accelerometric data were collected to reject MNAs using accelerometer (MMA8652FC, Freescale, TX, USA) which has a sensitivity of ±2 g. A wire was connected between both left and right wrist-based electrodes to produce an ECG signal and is threaded to a compression shirt for minimizing motion artifacts that may be caused by wire movements. The ECG signal was sampled at 360 Hz with 12-bit resolution over a range between 0 and 3.3 volts. Electrodes for ECG measurement are carbon black (CB) based film electrode (Posada-Quintero, H.F., et al., Low Impedance Carbon Adhesive Electrodes with Long Shelf Life. Ann Biomed Eng, 2015. 43(10): p. 2374-82; Reyes, B.A., et al., Novel electrodes for underwater ECG monitoring. IEEE Trans Biomed Eng, 2014. 61(6): p. 1863-76).

Table 5. ECG Wearable Devices

Device	Piix (Corventis) [1]	iRhythm (Zio)	Imec ECG necklace [2]	NohChon ECG wrist
Sensor modalities	ECG (1-lead), Respiration , Skin Temperature, Body fluids, Accelerometer	ECG (1-lead)	ECG (1-lead), Respiration, Accelerometer	ECG (1-lead), Electrodermal acitivity, Accelerometer
Sampling Frequency (ECG)	200 Hz	120 Hz	256 Hz	360 Hz
Analog front-end	Not disclosed	Not disclosed	imec ULP 1-ch ECG ASIC	Instrumentation amplifier
ADC resolution	10-bits	10-bits	12-bits	12-bits
Functionality	Event detection (Arrhythmia)	None	Beat-to-beat HR and HRV, seizure detection	Motion Artifact Reduction, Beat-to-beat HR and HRV
Wireless Connectivity	Event sent to z-link; and downloaded for off-line analysis	None	Real-time interface to mobile phone (using dongle)	Real-time interface to smart devices (using Bluetooth)
Power consumption	40 mW	Not disclosed	3 mW (data streaming); 7 mW (embedded data processing)	100 mW (data processing and transmitting via Bluetooth)
Form factor	Patch (160 mm x 60 mm)	Patch (123 mm x 53 mm)	Necklace (60 mm x 40 mm) + lead wires to disposable electrodes	Wrist bands + CB film electrodes (2.5mm x 2.5mm)
Usability	Disposable	Recycle	Disposable	Disposable

[00136] The electrode is comprised of adhesive so it enables collection of stable ECG signal even without hydrogel, and there was no complaint about skin irritation from the subjects. Each subject was asked to perform different types of physical activities (see Table 6) during the experiment to investigate the performance of the SegMA method in variety types of daily activities and movements. The reference ECG signals for evaluation of SegMA were recorded from a chest using Holter monitor. Table 5, disclosed above, presents various ECG wearable patches and devices in comparison to the NohChon wearable module.

Table 6. ECG Datasets and Experiments Settings

[3]Subject	Dataset	Activity Type	Setup	Subject's Age/Sex
1	3 (Chon Lab)	Depicted in Table (2)	See FIG. 1B	26-55 y (10 Males)
2				
3				
4				
5				
6				
7				
8				
9				
10				

[00137] Table 7, disclosed below, represents the experimental protocol of ECG data collection. A video of the activities each subject performed during the experiment is available from (Laughlin, M.H., Cardiovascular response to exercise. Am J Physiol, 1999. 277(6 Pt 2): p. S244-59).

Table 7. Experiment Protocol

Activity Type	Rest (Supine Position)	Walking (2 mph) Jogging (4 mph) Running (6 mph)	Rest (Standing)	Standing/Sitting on a arm chair	Arm Movements (Up/Down) and (Left/Right)	Wrist Rotation/Shaking	Weight Lifting and Box Moving	Deep Breathing
Duration (min)	**5**	**1.5**	**0.5**	**0.5**	**3**	**3**	**3**	**0.5**

[00138] Methodology

[00139] Embodiments of the SegMA method employed for the HR monitoring during intensive movements are summarized in Table 1, disclosed above. Details of each stage are disclosed in subsections *i* to *v*, below.

[00140] i. ECG Pre-processing

[00141] The first phase of the SegMA method may be to resample the ECG signal to ¼ (that is, downsample) of its original sampling rate. This improves the frequency resolution in the time-frequency spectrum. Next a derivative of the resampled ECG signal may be computed so that the R-peaks are accentuated. The idea is that motion and noise artifacts can be reduced to some extent via the derivative as long as the motion is not abrupt and the samples are uniformly corrupted by motion. Further, optionally, an absolute value of the derivative may be taken to further accentuate the R-peaks.

[00142] FIGS. 6A-B show representative ECG recordings from both the NohChon wrist device (Wrist ECG) and the Holter (Ref ECG). Specifically, FIG. 6A is a plot of ECG recordings and estimated HR from subject #3; [top]: reference ECG, [middle]: Wrist ECG, and [bottom] reference HR vs actual HR.

[00143] FIG. 6B is a zoomed in version of FIG. 6A. FIGS. 6A-B show the HR estimations from R-R intervals of the reference HR and the wrist ECG. The reference HR provides a clean and accurate HR and the estimated HR from the wrist ECG signifies inaccurate HR estimation especially during running, wrist movements, and weight lifting periods of experiment. FIGS. 6A-B indicate a reason for using a HR reconstruction approach according to embodiments disclosed herein.

[00144] ii. Time-Varying Spectral Analysis of ECG data

[00145] Embodiments disclosed herein may obtain a time-varying spectrum by taking a T-sec window of the ECG signal and computing a power spectral density (PSD) of the segment and then sliding the window through the whole dataset which yields a time-frequency matrix in which each array represents the power of the signal corresponding to a specific frequency and sliding time-step (shift) of S-sec. The sliding process and frequency step specify the resolution and dimension of the time-frequency matrix.

[00146] Embodiments disclosed herein may employ two different sliding window approaches depending on the application. For estimating either heart rates or heart rate variability, data may be shifted sample-by-sample with no overlap for the entire dataset. Such a sliding window approach enables capturing beat-to-beat dynamics of HRV which requires sample-to-sample estimation of PSD. Given a down-sampled data of Fs = 20 Hz, each data point may be shifted by 0.05 seconds. For estimating only the heart rates, the data may be shifted segment-by-segment rather than sample-by-sample. Such a coarse-grain windowing approach has less computational cost and it can provide good tracking of heart rates, but may not be useful for HRV. For the experimental results, a window segment length T was set to 8 seconds and was shifted (S) by 2 seconds. The 8 second data segment and the shift of 2 seconds were chosen because one of the goals was to compare the SegMA method results to other methods which have used this chosen data segment length and time shift. Moreover, the assumption of an 8 second data length largely stems from the fact that heart rates do not change instantaneously, hence, an 8 second duration may be a reasonable choice.

Hence, according to embodiments disclosed herein, a time-frequency spectrum of the derivative of the resampled ECG may be computed.

[00147] FIG. 7A is a plot of an ECG time-frequency spectrum. As a representative example, the resultant frequency components in the time-frequency matrix of recordings from subject #3 of the dataset, for a window length of 8 seconds that is shifted by every 2 seconds, is shown in FIG. 7A.

[00148] FIG. 7B is a plot of the example ECG time-frequency spectrum from FIG. 7A. In FIG. 7B, two major frequency components (A) and (B) are observed in the time-frequency spectrum plot: one of them appears to represent HR and the other may represent the first harmonic of HR. In order to verify this conjecture these components may be extracted from the time-frequency spectrum. To this end, in another phase of the SegMA method, Spectral Filtering, disclosed below, a filtering strategy may be applied to keep (*i.e.*, preserve, retain) the major components of the spectrum and remove the unnecessary information.

[00149] iii. Spectral Filtering

[00150] Based on an assumption that the HR frequency component is the dominant peak in the power spectral density (PSD) of each 8 sec window of a clean ECG signal, the filtered time-frequency spectrum using the first two largest peaks of PSD at each window can be extracted, as shown in FIG. 8A, disclosed below.

[00151] FIG. 8A is a plot of a time-frequency spectrum: Blue, Green circles correspond to the first two highest peaks in the defined HR frequency range of (30-180 bpm), respectively, at each sliding window. FIG. 8B is a plot showing tracking of the HR trace in the filtered ECG spectrum of FIG. 8A.

[00152] From the time-frequency spectrum of FIG. 8A, the first two largest peaks of PSD at each window can be extracted, according to embodiments disclosed herein. After obtaining the power spectral density at each window, the HR frequency is assumed to be confined in the range [0.5 Hz – 3 Hz], which takes into account both at rest and high HR due to either tachycardia or exercise scenarios. Hence, for HR estimation, the strategy is to eliminate frequencies that are outside of this HR frequency range as they are most likely due to motion artifacts or harmonics of the HR frequency.

[00153] In general, HR frequency in the power spectral density of ECG at each window can have three different scenarios: (1) ECG is devoid of MA and there is no spatial gap between the electrode and the subject's skin during recording, (2) ECG is corrupted by MA

and there is no spatial gap between the electrode and the subject's skin during recording, and (3) There is a spatial gap between the electrode and the subject's skin during recording. For the ideal case (1), HR can be extracted and it is most likely represented as the highest peak in the ECG spectrum. For case (2), MA dynamics can result in the dominant peak and HR frequency peak's magnitude become smaller than the MA frequency peak in the power spectrum. The only scenario that makes it difficult to extract HR from the spectrum is scenario (3) when there is a spatial gap between the ECG electrodes and the subject's skin during recording. In this scenario, assuming that the motion artifacts are short lasting, the missing HR values can be interpolated using the cubic spline approach. Turning back to FIG. 8A, FIG. 8A shows retaining only the two largest frequency peaks at each time point within the defined HR range (30-180 bpm) and they are represented as blue and green colors, respectively. Retaining only the two largest frequency peaks at each time point may be reasonable for the first two cases, outlined above. The component (A) is distinguishable from the filtered spectrum, as shown in FIG. 8A.

[00154] iv. Heart Rate Tracking & Extraction

[00155] According to embodiments disclosed herein, a next phase may be to extract HR frequencies with time, such as the frequency components of FIG. 8A, disclosed above. Note that in FIG. 8A, there are two peaks at each time instance, thus, the question is how to identify which of the two peaks represents the HR at each time point. For the initial time window of 8 seconds, a clean data segment may be employed, so that true HR can be determined. This scenario is case 1 described above in the spectral filtering section, and the detection of HR may simply be the highest peak in the spectrum. Next, HR may be estimated for each sliding window of data and a HR peak may be chosen (*i.e.*, selected, extracted) from the ECG spectrum with the knowledge of estimated HR values in previous time windows.

[00156] Two main scenarios may be considered: (1) no peak exists in the spectrum that can represent HR, and (2) there is a spectral peak among the first two highest peaks of spectrum that belongs to the HR component. In case (1), where HR is not detectable in the window (*e.g.*, due to spatial gap between the ECG electrode and skin), a real-time implementation of the SegMA method may take the previous window's HR value as the current HR (or simply use the moving average of several past HR beats or some other variant). In offline processing (*i.e.*, non-real time), a cubic spline interpolation can be used to fill in the missing HR information. In the more general case (2), where the HR peak is

among the first two highest peaks in the spectrum, two possible scenarios can occur: (2-A) the windowed ECG signal is clean and the first highest peak in the spectrum represents the HR fundamental frequency, (2-B) the windowed ECG signal is corrupted by movement and the second peak corresponds to HR, (2-C) while the HR spectral peak is detectable, the difference between its value and that of the previous HR may be more than a given difference value (also referred to interchangeably herein as a given distance value), such as 10 bpm (beats-per-minute) or 15 bpm, or any other suitable difference value, so it may be replaced by the most recent HR value from a previous window segment (or a moving average of several past HR beats or some other variant). According to some embodiments, a criterion may be set that the HR value cannot change more than the given difference value, such as 15 bpm, from a previous time window. It can be observed from FIG. 8B, disclosed above, that in most cases, the blue circle which represents the largest spectral peak is chosen but in other cases, green circles are chosen for certain time points. For the HR peaks associated with the green circles, they are chosen because either the first highest peak is related to a motion artifact or the highest magnitude peak deviates more than the given difference value, such as 15 bpm, from the previous HR value.

[00157] FIG. 9 is a plot showing the tracking of reconstructed HR compared to the reference during different activities involved in the experiment. FIG. 9. shows a comparison of reference HR to the HR tracking from filtered time-frequency spectrum of ECG recordings from subject #3, labeled with respective type of activities.

[00158] FIG. 10 shows a comparison of reconstructed HR obtained from SegMA, estimated from simultaneous ECG recordings#3, to a reference HR. FIG. 10 shows the SegMA reconstructed HR (red color) from ECG spectra of recording#3 using SegMA along with the 8-sec moving average of reference ECG-derived HR (black color). In order to calculate the performance of the SegMA method, the error value in each time window was calculated from the estimated HR to the reference ECG-derived HR.

[00159] Two measurement indices of absolute error similar to the indices in (Rahman, M.Z.U., R.A. Shaik, and D.V.R.K. Reddy. An Efficient Noise Cancellation Technique to Remove Noise from the ECG Signal Using Normalized Signed Regressor LMS Algorithm. in Bioinformatics and Biomedicine, 2009. BIBM '09. IEEE International Conference on. 2009) were used.

$$Error(1) = \frac{1}{W}\sum_{k=1}^{w}\left|HR_{SegMA}(k) - HR_{ref}(k)\right| \quad (1)$$

$$Error(2) = \frac{1}{W}\sum_{k=1}^{w}\frac{\left|HR_{SegMA}(k) - HR_{ref}(k)\right|}{HR_{ref}(k)} \times 100\% \quad (2)$$

[00160] v. Heart Rate Variability analysis

[00161] For an HRV analysis application, the above-disclosed procedures are identical but the only difference is a beat-by-beat shift of data rather than the 8 second data segment shift or it's variant.

[00162] FIG. 11A shows a beat-by-beat reconstruction of HR using SegMA. FIG. 11A shows a time-domain comparison of reconstructed and reference HR.

[00163] FIG. 11B shows the power spectral density of reconstructed HR. It can be observed that the correlation between PSD of estimated SegMA and reference HRV in the frequency range of [0-0.4] Hz is almost 100%. The spectral comparison of heart rate variability between the reconstructed HR and reference HR was calculated from the reference ECG using Pan & Tompkin peak detection approach (F. Yazicioglu, T.T., J. Penders, I. Romero, H. Kim, P. Merken, B. Gyselinckx, H.J. Yoo, C. Van Hoof. Ultra-low-power wireless sensor nodes. in Proceedings of the 31st Annual International Conference of the IEEE EMBS. 2009. Minneapolis: IEEE).

[00164] Results

[00165] Table 8, disclosed below, represents the average absolute error (E1) and the average absolute error percentage (E2) of HR estimations of the SegMA method on the dataset. The SegMA method is compared to the HR estimations before applying the reconstruction method, where both before and after reconstruction estimations are compared to the reference HR from ECG, and reference SpO2 from a Masimo commercial device. The forth column in Table 8 shows that SegMA on average improves the HR estimations with almost 1000% comparing to those estimations before reconstruction. The improvement rate was calculated as follows:

$$ImRate1(\%) = \frac{1}{W}\sum_{k=1}^{w}\frac{\left|Error1_{SegMA}(k) - Error1_{Act}(k)\right|}{Error1_{SegMA}(k)} \times 100\% \quad (3)$$

$$ImRate2(\%) = \frac{1}{W}\sum_{k=1}^{W}\frac{|Error2_{SegMA}(k) - Error2_{Act}(k)|}{Error2_{SegMA}(k)} \times 100\% \quad (4)$$

Table 8. SegMA Method Performance Comparison

Subject	Actual HR estimation error		SegMA HR estimation error		SegMA Improvement Rate	
	E1	E2%	E1	E2%	ImRate1%	ImRate1%
1	13.66	13.98	**1.31**	**1.46**	943.1	857.5
2	22.69	24.37	**2.05**	**2.16**	1006.9	1028.2
3	8.66	8.71	**0.60**	**0.62**	1343.3	1304.8
4	15.32	15.06	**1.64**	**1.78**	834.4	746.1
5	33.32	31.87	**4.87**	**5.50**	584.20	479.4
6	20.84	21.56	**2.43**	**2.61**	757.66	726.05
7	26.85	23.93	**2.61**	**2.31**	928.7	935.9
8	16.15	16.66	**0.97**	**1.00**	1582.3	1582.8
9	10.19	10.83	**0.72**	**0.75**	1315.7	1344.2
10	9.43	9.37	**0.84**	**0.93**	1022.6	907.5
mean±std	17.71±8.1	17.63±7.6	1.80±1.3	1.91±1.4	1031.9±300.8	991.2±332.4

[00166] FIGS. 12A-B, 13A-B, and 14A-B show the reconstructed HR and corresponding PSD of a sample-sample windowed HR in comparison to the reference HR from an ECG.

[00167] FIG. 12A shows the Reconstructed HR vs. reference HR for subject #8.

[00168] FIG. 12B shows a spectral comparison of reconstructed HR and reference HR (estimated from reference ECG). As can be observed, the E1 for this particular subject is as low as 0.97 bpm and the correlation between the PSD of reconstructed HR and reference HR is as high as 97%.

[00169] FIG. 13A shows the Reconstructed HR vs. reference HR for subject #5. FIG. 13A shows the comparison between the reconstructed HR and the reference HR for subject #5 and recording #7 that have the highest errors. Higher error from recording #7 can be due to rapid changes of physiological HR and the motion artifacts during the activities. In the case of subject #5, it can be observed that the error is due to losing track of HR during weight lifting activity. This could be due to skin-electrode interface gap.

[00170] FIG. 13B shows the Reconstructed HR vs. reference HR for subject #7.

[00171] FIG. 14A shows the Reconstructed HR vs. reference HR for subject #4.

[00172] FIG. 14B shows a spectral comparison of reconstructed HR and reference HR (estimated from reference ECG). It can be seen that the E1 for this subject is around 1.7 bpm and the correlation between the PSD of reconstructed HR and reference HR is as high as 99%.

[00173] All subjects' results are provided in Table 10. Table 10 represents the correlation and statistical difference using the student's t-test between PSD of estimated and reference HRV in both LF (0.04-0.15 Hz) and HF (0.15-0.4 Hz) frequency ranges. The correlation values in the table are calculated based on Pearson's linear correlation coefficient. As shown in Table 9, there was no difference between the reference and SegMA-derived HRV for LF in all but one subject and the difference was seen in only 4 out of 10 subjects for HF. Table 10 shows some of the widely-reported time-domain HRV parameters such as the mean HR, standard-deviation (SDNN) of the normal-to-normal (NN) interval, root-mean-square of successive difference (RMSSD) of the NN interval, and the number of interval differences of successive NN intervals greater than 50 ms divided by the total number of NN intervals (pNN50) estimated from SpaMA in comparison to the reference ECG NN interval. None of these parameters were found to be significantly different between the SegMA-derived and the reference HRV.

Table 9. Frequency Domain HRV analysis Comparison: PSD of SpaMA vs. reference

Subjects	Correlation	
	LF (LF is [0.04-0.15] Hz and HF is [0.15-0.4] Hz)	**HF**
1	0.99	0.98
2	0.98	0.95*
3	1.00	0.98
4	1.00	0.99
5	0.94* (Statistical difference)	0.85*
6	0.97	0.91*
7	0.96	0.90*
8	0.97	0.98
9	1.00	0.99
10	1.00	0.99
mean	0.99	0.96

Table 10. Time Domain HRV analysis Comparison: SpaMA vs. reference HRV

Subjects	SDNN		meanNN		RMSSD		pNN50	
	SpaMA	Reference	SpaMA	Reference	SpaMA	Reference	SpaMA	Reference
1	1874.70	1729.15	28097.82	28087.09	18.15	14.10	0.044	0.007
2	1996.62	1998.02	28157.83	28231.82	31.09	15.43	0.019	0.011
3	2987.54	3005.81	24278.31	24517.17	44.90	36.69	0.112	0.125
4	2129.40	1993.10	10313.61	11764.64	22.64	18.12	0.016	0.016
5	1493.53	1529.24	14591.50	13100.12	43.50	74.97	0.039	0.046
6	2153.20	2246.96	14357.50	14398.22	45.81	69.78	0.022	0.022
7	1980.40	1993.71	12181.57	11762.11	28.28	18.11	0.015	0.016
8	6757.14	6405.54	15858.31	16916.03	60.75	98.69	0.031	0.292
9	2544.54	2693.81	14778.82	13940.62	39.58	44.95	0.013	0.012
10	3481.65	3502.19	11525.21	12091.71	36.77	53.45	0.041	0.017
p-value	> 0.05		> 0.05		> 0.05		> 0.05	

A video of the real-time implementation of SegMA is available from (Laughlin, M.H., Cardiovascular response to exercise. Am J Physiol, 1999. 277(6 Pt 2): p. S244-59).

[00174] Discussion and Conclusions

[00175] Wearable sensors have recently enjoyed much public attention and interests. This is well deserved as many wrist-worn devices promise to provide reasonable estimates of heart rates and other health related information including the calories burned based on the number of steps or activities taken throughout the course of a day. More importantly, these devices provide an attractive feature where for the first time individuals can track and manage their own health-related data. In spirit of these recent development in wrist-worn sensors, the objective of embodiments disclosed herein was to develop a robust and accurate method that can mitigate motion artifacts so that more accurate heart rates and other relevant diagnostic information can be estimated. Certainly, this is challenging since wrist-worn devices are especially prone to more challenging and varied motion artifacts when compared to sensors placed on other parts of the body.

[00176] While wearable ECG devices are normally worn as either a Holter monitor or a patch on the chest, recent advances in non-contact capacitive and dry electrodes has resulted in textile worn ECG measurements. The form factor and locations of these textile-based ECG sensors can be found from the traditional ECG electrode placements around the chest area to electrodes incorporated directly into a belt (Posada-Quintero, H.F., et al., Low Impedance Carbon Adhesive Electrodes with Long Shelf Life. Ann Biomed Eng, 2015. 43(10): p. 2374-82, and Reyes, B.A., et al., Novel electrodes for underwater ECG monitoring. IEEE Trans Biomed Eng, 2014. 61(6): p. 1863-76.

[00177] A custom wrist-worn ECG device using custom dry flexible electrodes (Posada-Quintero, H.F., et al., Low Impedance Carbon Adhesive Electrodes with Long Shelf Life. Ann Biomed Eng, 2015. 43(10): p. 2374-82; Reyes, B.A., et al., Novel electrodes for underwater ECG monitoring. IEEE Trans Biomed Eng, 2014. 61(6): p. 1863-76) was developed and this is the device that was used to collect experimental data as disclosed above.

[00178] As disclosed above, SegMA, based on time-varying spectral analysis of the ECG signal is introduced to combat (*i.e.*, suppress, reduce, mitigate) motion artifacts. To fully test the robustness of the SegMA method, a design for the types of motion artifacts introduced for the experiments was cognizant of the wide variety movements subjects might encounter

during their daily activities. In all of the recordings, the reference HR was calculated from an ECG signal that was collected simultaneously with the ECG signal. The estimated HR was calculated from the spectrum of ECG in 8 second time windows. It was shown that the SegMA method can be used for tracking fast HR changes as they varied more than 70 beats/min in less than 2 minutes and despite severe motion artifacts since the subjects were running at a full speed on a treadmill, the average error of just 1.80 bpm was found when compared to that of the reference ECG. This average error also includes when subjects were introducing challenging motion artifacts by performing wrist shaking and bending exercises.

[00179] The results from Table 8, disclosed above, show that the SegMA method can be effectively applied to monitor HR from ECG wrist wearable devices. Several observations were made while analyzing the data. The tracking ability of the SegMA method decreased as the dynamics of the motion artifact increased. This phenomenon mostly was observed while dealing with the subject #7 and is due to fast changing HR and abrupt movements which consequently made it more difficult to track the HR-related frequencies in the spectrum.

[00180] The main sources of noise and corruption during recording ECG signal using NohChon wrist band was (1) movement of wire inside of tight suit, (2) electromyogram (EMG) interference when subjects were either shaking or bending the wrist, and (3) contact issues with the skin-electrode interface during movements. SegMA has been shown to address the first two type of noise and motion artifacts. However the third noise type which can be due to gaps or poor contact between skin-electrode interfaces is the most challenging scenario for any motion artifact reconstruction method. This is because a gap between electrode and skin, ECG signal strength would decrease due to impedance mismatch (Taji, B., et al., Impact of Skin– Electrode Interface on Electrocardiogram Measurements Using Conductive Textile Electrodes. Instrumentation and Measurement, IEEE Transactions on, 2014. 63(6): p. 1412-1422), and if severe, it can lead to loss of signal. The electrodes used in for the experiments were a thin flexible film type made out of carbon black powder adhered to a skin with adhesive (Posada-Quintero, H.F., et al., Low Impedance Carbon Adhesive Electrodes with Long Shelf Life. Ann Biomed Eng, 2015. 43(10): p. 2374-82; Reyes, B.A., et al., Novel electrodes for underwater ECG monitoring. IEEE Trans Biomed Eng, 2014. 61(6): p. 1863-76), but it can wrinkle or loose contact with the skin when subjected to severe bending or flexing motions. Certainly, this type of noise could be minimized by choosing electrodes that have thicker foam electrodes that cannot be deformed

easily. However, the tradeoff is that certain flexible exercises are possible with these thicker electrodes as they may all together pop off the skin depending on the severity of the flexing exercises. Among the 10 recordings datasets, the lowest performance seen for recordings #5 is most likely due to a gap between the ECG electrode and skin caused by the bending and reflexing motion artifacts.

[00181] By using the sample-by-sample windowing process, the SegMA method can be utilized for both Heart Rate monitoring and HRV analysis in both frequency- and time-domains. From the Results section, it can be observed that the method is able to replicate both the low frequency (0.04-0.15Hz) and the high frequency (0.15-0.4) dynamics well, albeit better the former than the latter, when compared to the reference HRV. For time-domain HRV measures, the mean HR, SDNN, RMSSD, and pNN50 from the SegMA method were all found to be not significantly different than the reference HRV. It has long been shown that during dynamic exercise, heart rate increases due to both parasympathetic withdrawal and an augmented sympathetic activity (Iellamo, F., Neural mechanisms of cardiovascular regulation during exercise. Auton Neurosci, 2001. 90(1-2): p. 66-75; Bernardi, L. and M.F. Piepoli, [Autonomic nervous system adaptation during physical exercise]. Ital Heart J Suppl, 2001. 2(8): p. 831-9). The relative role of the two drives depends on the movement intensity (Sarmiento, S., et al., Heart rate variability during high-intensity exercise. Journal of Systems Science and Complexity, 2013. 26(1): p. 104-116; Roure, R., et al., Autonomic nervous system responses correlate with mental rehearsal in volleyball training. Eur J Appl Physiol Occup Physiol, 1998. 78(2): p. 99-108; Perini, R., et al., The influence of exercise intensity on the power spectrum of heart rate variability. Eur J Appl Physiol Occup Physiol, 1990. 61(1-2): p. 143-8). Analysis of HRV permits insight into these control mechanisms (Aubert, A.E., B. Seps, and F. Beckers, Heart rate variability in athletes. Sports Med, 2003. 33(12): p. 889-919). HRV analysis from ECG during severe movements and physical activities has been problematic in the past. With SegMA, missing portions of corrupted data during severe motion artifacts can reconstructed with a good confidence.

[00182] The SegMA method can be implemented in real time. The method written in Matlab® takes around 75 msec on data segmented into 8 seconds. Therefore, given the high accuracy of SegMA in estimating HR despite severe motion artifacts, SegMA has the potential to be applicable for real-time implementation on wearable devices such as smart watches and ECG-based fitness sensors.

[00183] FIG. 15 is a block diagram of an example of the internal structure of a computer 1500 in which various embodiments of the present disclosure may be implemented. The computer 1500 contains a system bus 1502, where a bus is a set of hardware lines used for data transfer among the components of a computer or processing system. The system bus 1502 is essentially a shared conduit that connects different elements of a computer system (e.g., processor, disk storage, memory, input/output ports, network ports, etc.) that enables the transfer of information between the elements. Coupled to the system bus 1502 is an I/O device interface 1504 for connecting various input and output devices (e.g., keyboard, mouse, displays, printers, speakers, etc.) to the computer 1500. A network interface 1506 allows the computer 1500 to connect to various other devices attached to a network. Memory 1508 provides volatile storage for computer software instructions 1510 and data 1512 that may be used to implement embodiments of the present disclosure. Disk storage 1514 provides non-volatile storage for computer software instructions 1510 and data 1512 that may be used to implement embodiments of the present disclosure. A central processor unit 1518 is also coupled to the system bus 1502 and provides for the execution of computer instructions.

[00184] Further example embodiments disclosed herein may be configured using a computer program product; for example, controls may be programmed in software for implementing example embodiments. Further example embodiments may include a non-transitory computer-readable medium containing instructions that may be executed by a processor, and, when loaded and executed, cause the processor to complete methods described herein. It should be understood that elements of the block and flow diagrams, such as the reconstruction unit 416, output unit 418, pre-processing unit 515, reconstruction unit 516, output unit 518, heart rate unit, arterial oxygen saturation (SpO2) unit, and ailment unit, disclosed above, may be implemented in software, hardware, such as via one or more arrangements of circuitry of FIG. 15, disclosed above, or equivalents thereof, firmware, a combination thereof, or other similar implementation determined in the future. In addition, the elements of the block and flow diagrams described herein may be combined or divided in any manner in software, hardware, or firmware. If implemented in software, the software may be written in any language that can support the example embodiments disclosed herein. The software may be stored in any form of computer readable medium, such as random access memory (RAM), read only memory (ROM), compact disk read-only memory (CD-ROM), and so forth. In operation, a general purpose or application-specific processor or

processing core loads and executes software in a manner well understood in the art. It should be understood further that the block and flow diagrams may include more or fewer elements, be arranged or oriented differently, or be represented differently. It should be understood that implementation may dictate the block, flow, and/or network diagrams and the number of block and flow diagrams illustrating the execution of embodiments disclosed herein.

[00185] The teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety.

[00186] While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A method for reconstructing a heart-related signal output by a biomedical sensor, the method comprising:

pre-processing the heart-related signal to produce a pre-processed heart-related signal;

reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on a time-varying spectral analysis of the pre-processed heart-related signal, the heart-related signal including motion artifacts, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, the pre-processing reducing the motion artifacts in the pre-processed heart-related signal for the reconstructing; and

outputting the reconstructed representation of the heart-related signal.

2. The method of Claim 1, wherein the biomedical sensor is an electrocardiogram (ECG) sensor.

3. The method of Claim 1, wherein the reconstructing further reduces the motion artifacts reduced by the pre-processing.

4. The method of Claim 1, wherein the pre-processing includes down-sampling the heart-related signal to produce a down-sampled heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

5. The method of Claim 4, wherein:

the time-varying spectral analysis is based on a frequency resolution; and

the down-sampling affects the frequency resolution of the time-varying spectral analysis.

6. The method of Claim 4, wherein the pre-processing includes computing a derivative of the down-sampled heart-related signal to reduce the motion artifacts.

7. The method of Claim 6, wherein the pre-processing further includes computing an absolute value of the derivative to further reduce the motion artifacts.

8. The method of Claim 1, wherein the time-varying spectral analysis includes computing a time-frequency spectrum (TFS) of the pre-processed heart-related signal.

9. The method of Claim 8, wherein the TFS computed is a 3-dimensional spectra including a time-varying amplitude or power distribution with respect to time and frequency.

10. The method of Claim 8, wherein the TFS computed is a time-varying power spectral density (PSD).

11. The method of Claim 8, further including limiting the TFS computed to a given frequency range.

12. The method of Claim 11, wherein the given frequency range is 0.5 Hz to 3 Hz.

13. The method of Claim 8, wherein:

the TFS is computed for each shift of a windowed data segment of the pre-processed heart-related signal; and

the heart related signal is reconstructed for each shift of the windowed data segment.

14. The method of Claim 13, wherein, at each shift of the windowed data segment subsequent to an initial windowed data segment, the method further includes:

retaining up to a pre-determined number of frequency spectra to produce a subset of frequency spectra; and

selecting a frequency component to produce a selected frequency component for the reconstructing, the selected frequency component selected from amongst frequency components of the subset of frequency spectra and a previous frequency component, the previous frequency component having been selected for a previous shift of the windowed data segment to reconstruct the heart-related signal for the previous shift.

15. The method of Claim 1, wherein the time-varying spectral analysis is a first time-varying spectral analysis and wherein the reconstructing is further based on a second time-varying spectral analysis of a motion signal, the motion signal output by a motion sensor and representative of the motion artifacts in the heart-related signal.

16. The method of Claim 15, further including employing the second time-varying spectral analysis of the motion signal to produce a movement classification of the movement, and wherein the reconstructing is further based on the classification of the movement.

17. The method of Claim 15, wherein the heart-related signal and the motion signal are output, concurrently.

18. The method of Claim 15, wherein the biomedical sensor and the motion sensor are co-located.

19. The method of Claim 15, wherein the motion sensor is an accelerometer.

20. The method of Claim 1, further comprising employing the reconstructed representation to determine a heart rate estimate.

21. The method of Claim 1, further comprising employing the reconstructed representation to determine a heart rate variability (HRV) estimate.

22. The method of Claim 1, further comprising employing the reconstructed representation to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

23. The method of Claim 1, wherein the pre-processing, the reconstructing, and the outputting are performed in real-time with respect to outputting of the heart-related signal by the biomedical sensor.

24. The method of Claim 1, wherein the pre-processing, the reconstructing, and the outputting are performed in non-real-time with respect to outputting of the heart-related signal by the biomedical sensor.

25. An apparatus for reconstructing a heart-related signal output by a biomedical sensor, the apparatus comprising:

a pre-processing unit configured to pre-process the heart-related signal to produce a pre-processed heart-related signal;

a reconstruction unit configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on a time-varying spectral analysis of the pre-processed heart-related signal, the heart-related signal including motion artifacts, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, the pre-processing unit reducing the motion artifacts in the pre-processed heart-related signal for the reconstructing; and

an output unit configured to output the reconstructed representation of the heart-related signal.

26. The apparatus of Claim 25, wherein the biomedical sensor is an electrocardiogram (ECG) sensor.

27. The apparatus of Claim 25, wherein the reconstruction unit further reduces the motion artifacts reduced by the pre-processing unit.

28. The apparatus of Claim 25, wherein pre-processing by the pre-processing unit includes down-sampling the heart-related signal to produce a down-sampled heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

29. The apparatus of Claim 28 wherein:

the time-varying spectral analysis is based on a frequency resolution; and

the down-sampling affects the frequency resolution of the time-varying spectral analysis.

30. The apparatus of Claim 28, wherein the pre-processing unit is further configured to compute a derivative of the down-sampled heart-related signal to reduce the motion artifacts.

31. The apparatus of Claim 30, wherein the pre-processing unit is further configured to compute an absolute value of the derivative to further reduce the motion artifacts.

32. The apparatus of Claim 25, wherein the reconstruction unit is further configured to perform the time-varying spectral analysis by computing a time-frequency spectrum (TFS) of the pre-processed heart-related signal.

33. The apparatus of Claim 32, wherein the TFS computed is a 3-dimensional spectra including a time-varying amplitude or power distribution with respect to time and frequency.

34. The apparatus of Claim 32, wherein the TFS computed is a time-varying power spectral density (PSD).

35. The apparatus of Claim 32, wherein the reconstruction unit is further configured to limit the TFS computed to a given frequency range.

36. The apparatus of Claim 35, wherein the given frequency range is 0.5 Hz to 3 Hz.

37. The apparatus of Claim 32, wherein:

the TFS is computed for each shift of a windowed data segment of the pre-processed heart-related signal; and

the reconstruction unit is further configured to reconstruct the heart related signal for each shift of the windowed data segment.

38. The apparatus of Claim 37, wherein, at each shift of the windowed data segment subsequent to an initial windowed data segment, the reconstruction unit reconstructs the representation by:

retaining up to a pre-determined number of frequency spectra to produce a subset of frequency spectra; and

selecting a frequency component to produce a selected frequency component for the reconstructing, the selected frequency component selected from amongst frequency components of the subset of frequency spectra and a previous frequency component, the previous frequency component having been selected for a previous

shift of the windowed data segment to reconstruct the heart-related signal for the previous shift.

39. The apparatus of Claim 25, wherein the time-varying spectral analysis is a first time-varying spectral analysis and wherein the reconstruction unit is further configured to perform the reconstructing based on a second time-varying spectral analysis of a motion signal, the motion signal output by a motion sensor and representative of the motion artifacts in the heart-related signal.

40. The apparatus of Claim 39, wherein the reconstruction unit is further configured to employ the second time-varying spectral analysis of the motion signal to produce a movement classification of the movement, and wherein the reconstructing is further based on the classification of the movement.

41. The apparatus of Claim 39, wherein the heart-related signal and the motion signal are output by the biomedical sensor and the motion sensor, respectively, concurrently.

42. The apparatus of Claim 39, wherein the apparatus includes the biomedical sensor and the motion sensor.

43. The apparatus of Claim 39, wherein the motion sensor is an accelerometer.

44. The apparatus of Claim 25, further comprising a heart rate unit configured to employ the reconstructed representation to determine a heart rate estimate.

45. The apparatus of Claim 25, further comprising a heart rate variability (HRV) unit configured to employ the reconstructed representation to determine a heart rate variability (HRV) estimate.

46. The apparatus of Claim 25, further comprising an ailment unit configured to employ the reconstructed representation to detect or predict a heart-related ailment, the heart-related ailment including at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

47. The apparatus of Claim 25, wherein the reconstruction unit, the output unit, and the pre-processing unit are configured to reconstruct, pre-process, and output,

respectively, in real-time with respect to outputting of the heart-related signal by the biomedical sensor.

48. The apparatus of Claim 25, wherein the reconstruction unit, the output unit, and the pre-processing unit are configured to reconstruct, pre-process, and output, respectively, in non-real-time with respect to outputting of the heart-related signal by the biomedical sensor.

49. A non-transitory computer-readable medium having encoded thereon a sequence of instructions which, when loaded and executed by a processor, causes the processor to reconstruct a heart-related signal output by a biomedical sensor, the processor reconstructing the heart-related signal by:

pre-processing the heart-related signal to produce a pre-processed heart-related signal;

reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on a time-varying spectral analysis of the pre-processed heart-related signal, the heart-related signal including motion artifacts, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, the pre-processing reducing the motion artifacts in the pre-processed heart-related signal for the reconstructing; and

outputting the reconstructed representation of the heart-related signal.

Petitioner Ex-1004, 0542

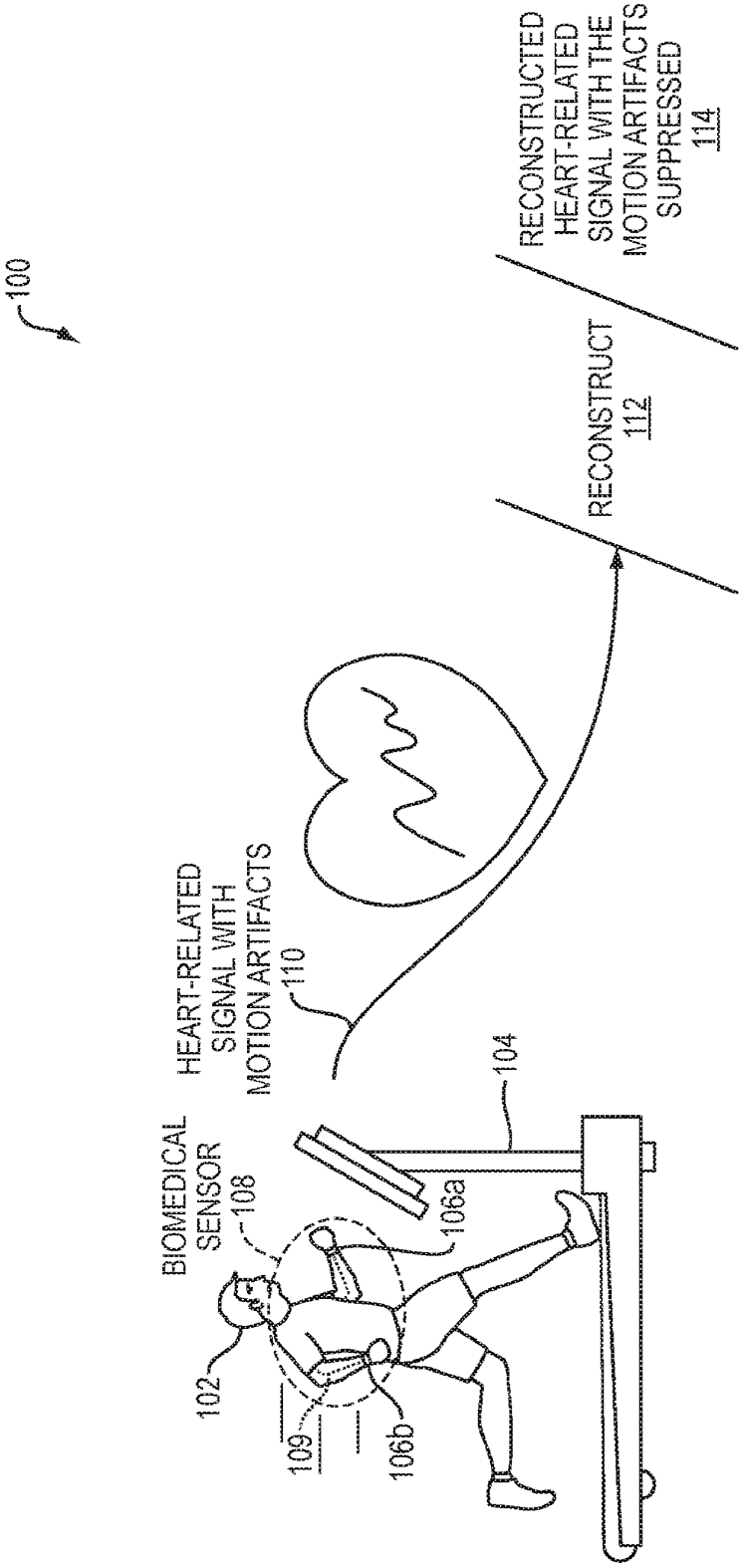


FIG. 1A

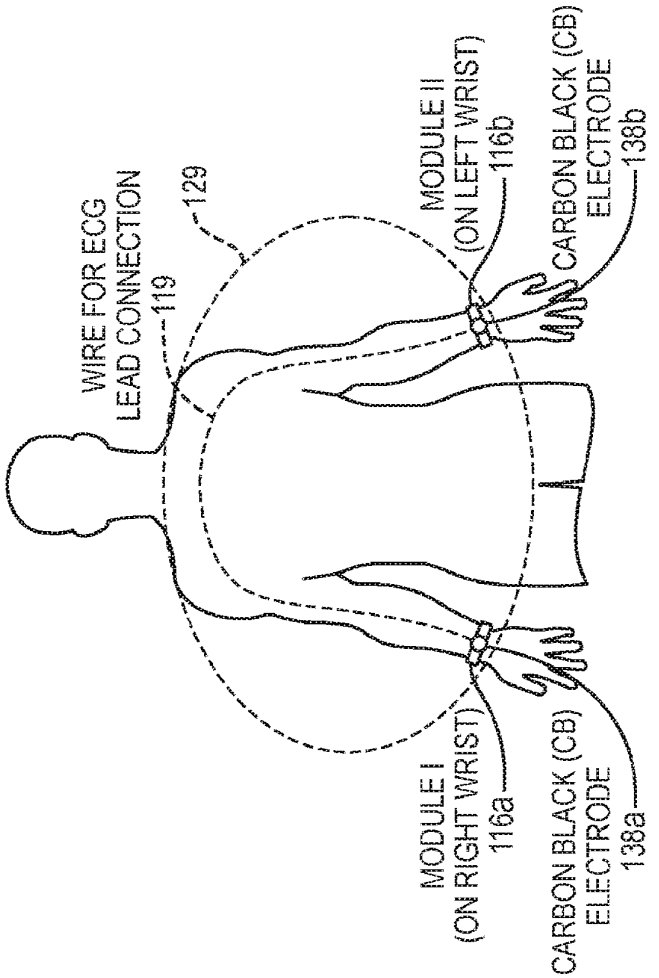

128
WIRE FOR ECG LEAD CONNECTION
119
129
MODULE II (ON LEFT WRIST)
116b
CARBON BLACK (CB) ELECTRODE
138b
MODULE I (ON RIGHT WRIST)
116a
CARBON BLACK (CB) ELECTRODE
138a

FIG. 1B

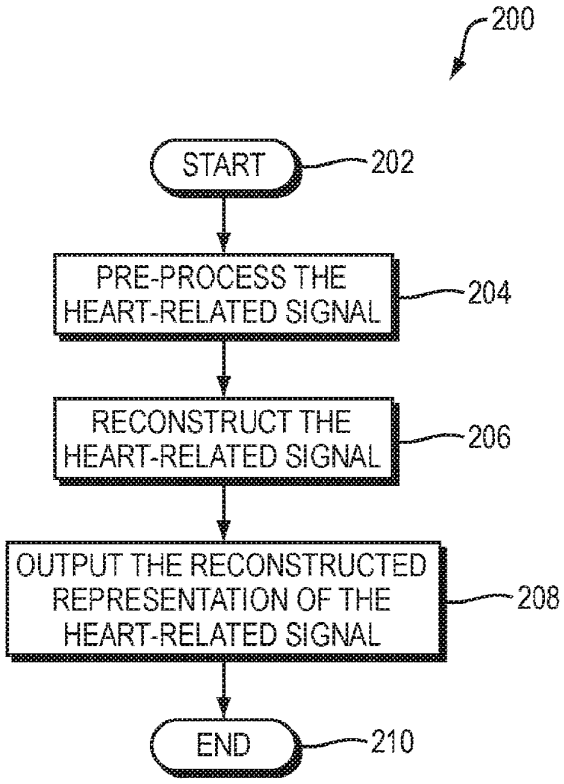

200
START
202
PRE-PROCESS THE HEART-RELATED SIGNAL
204
RECONSTRUCT THE HEART-RELATED SIGNAL
206
OUTPUT THE RECONSTRUCTED REPRESENTATION OF THE HEART-RELATED SIGNAL
208
END
210

FIG. 2A

Petitioner Ex-1004, 0545

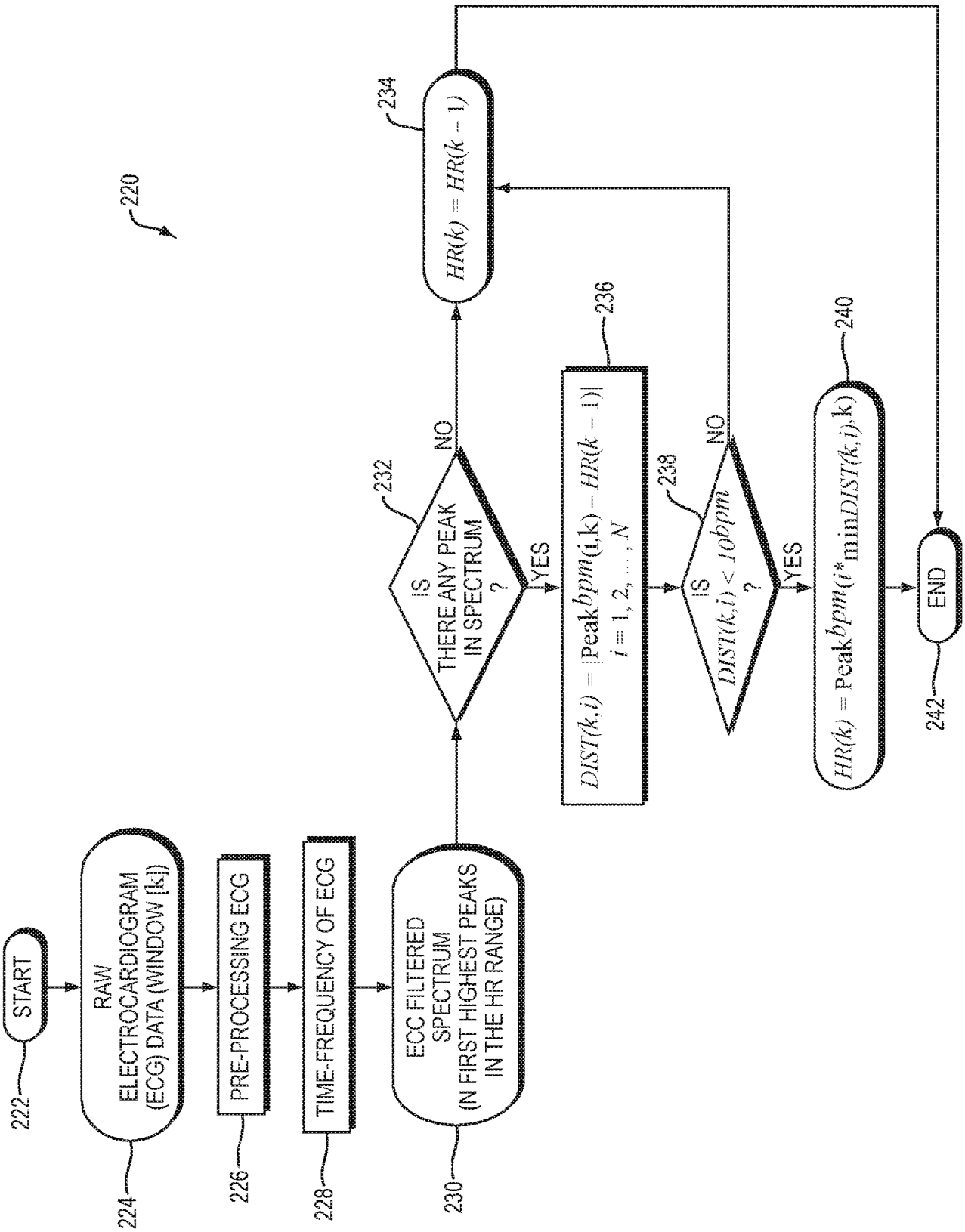


FIG. 2B

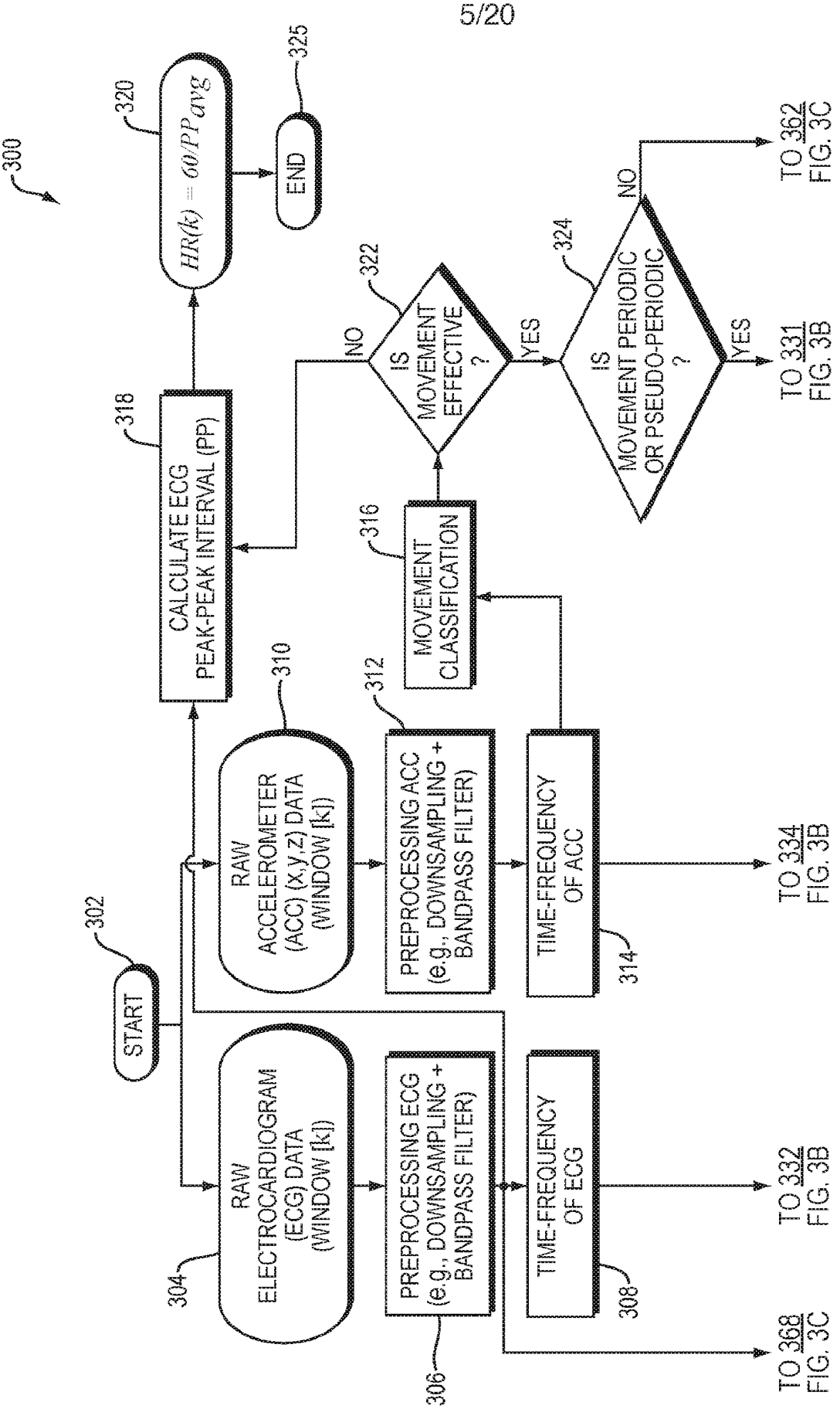


FIG. 3A

Petitioner Ex-1004, 0546

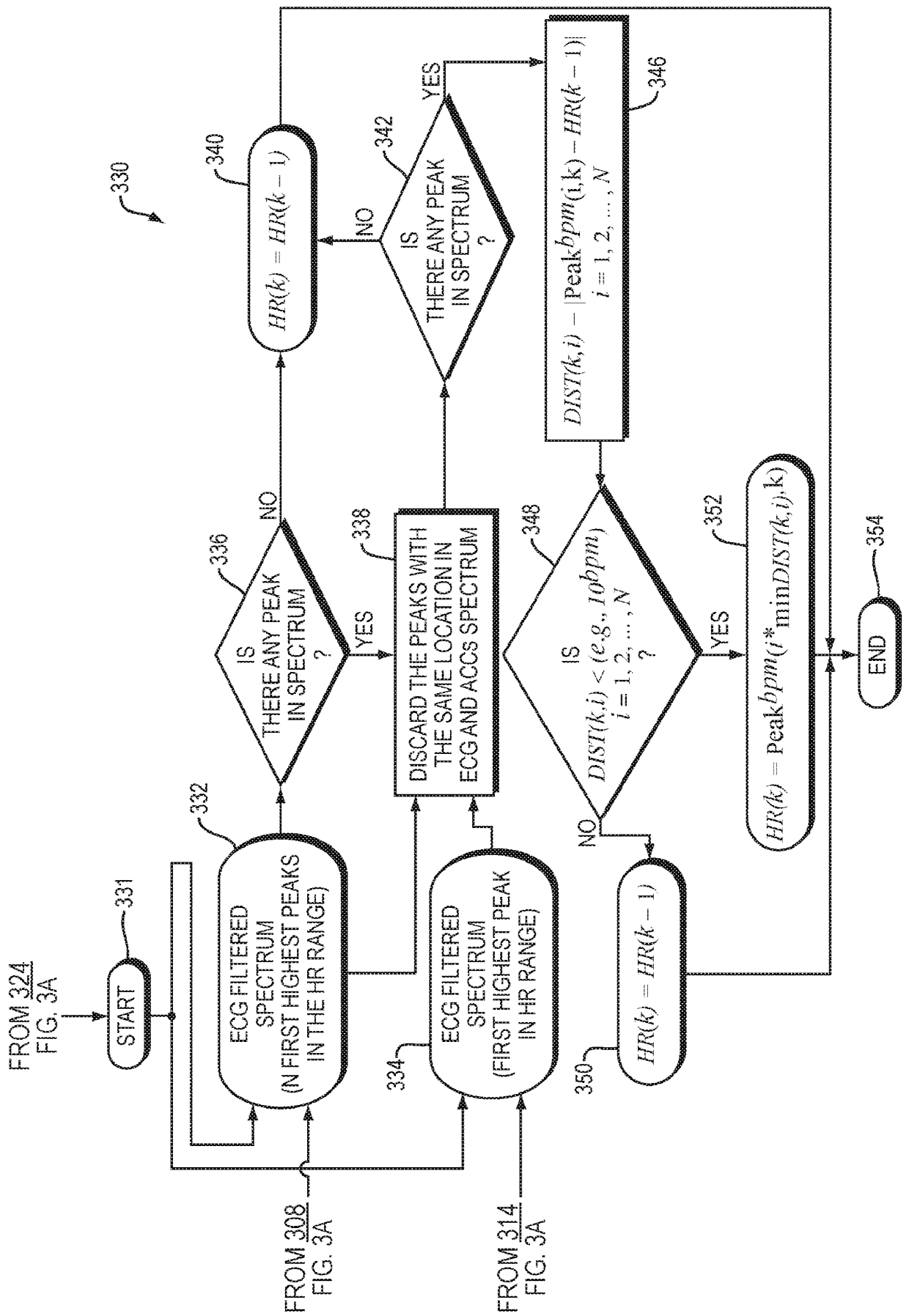


FIG. 3B

Petitioner Ex-1004, 0547

Petitioner Ex-1004, 0548

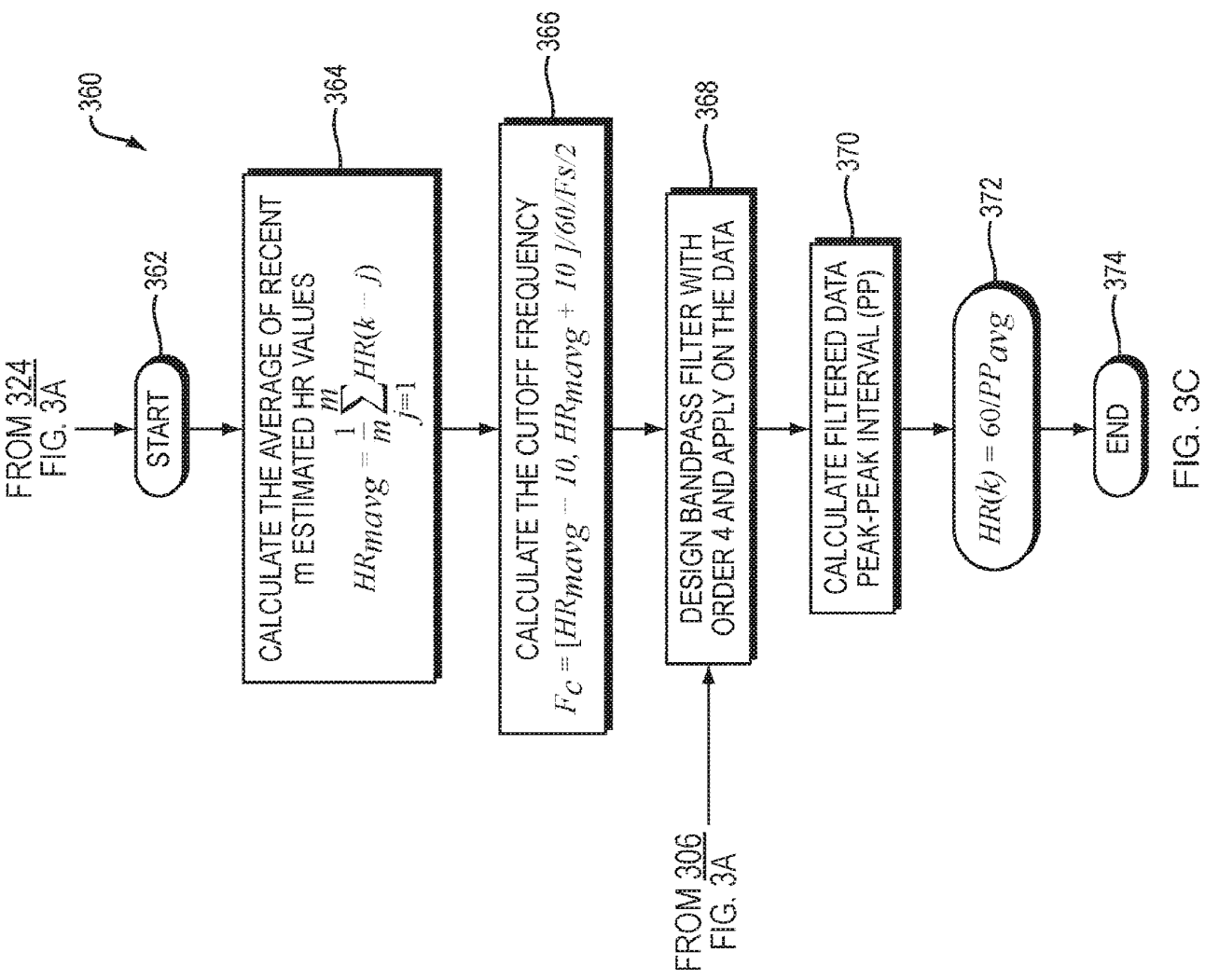


FIG. 3C

FIG. 4

SUBSTITUTE SHEET (RULE 26)

Petitioner Ex-1004, 0549

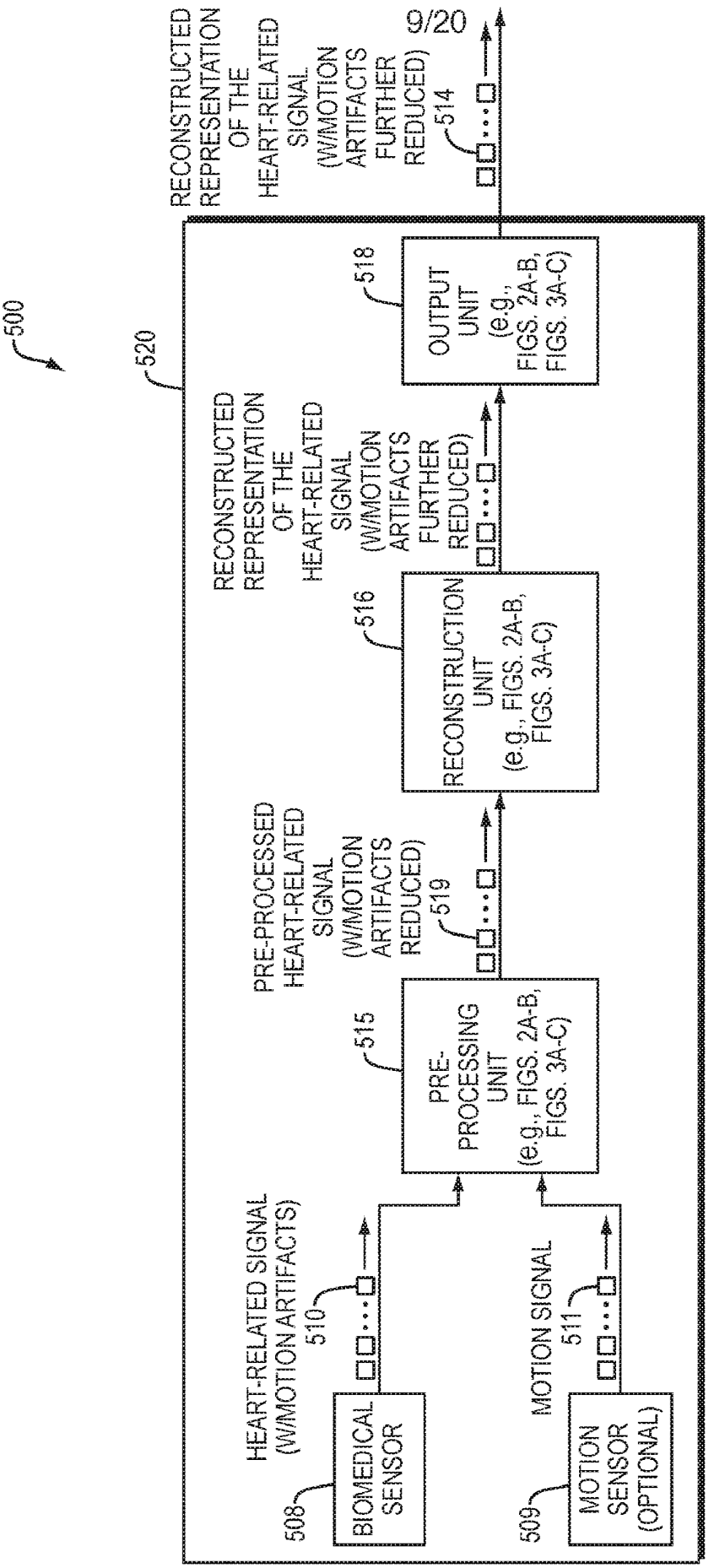


FIG. 5

Petitioner Ex-1004, 0550

Petitioner Ex-1004, 0551

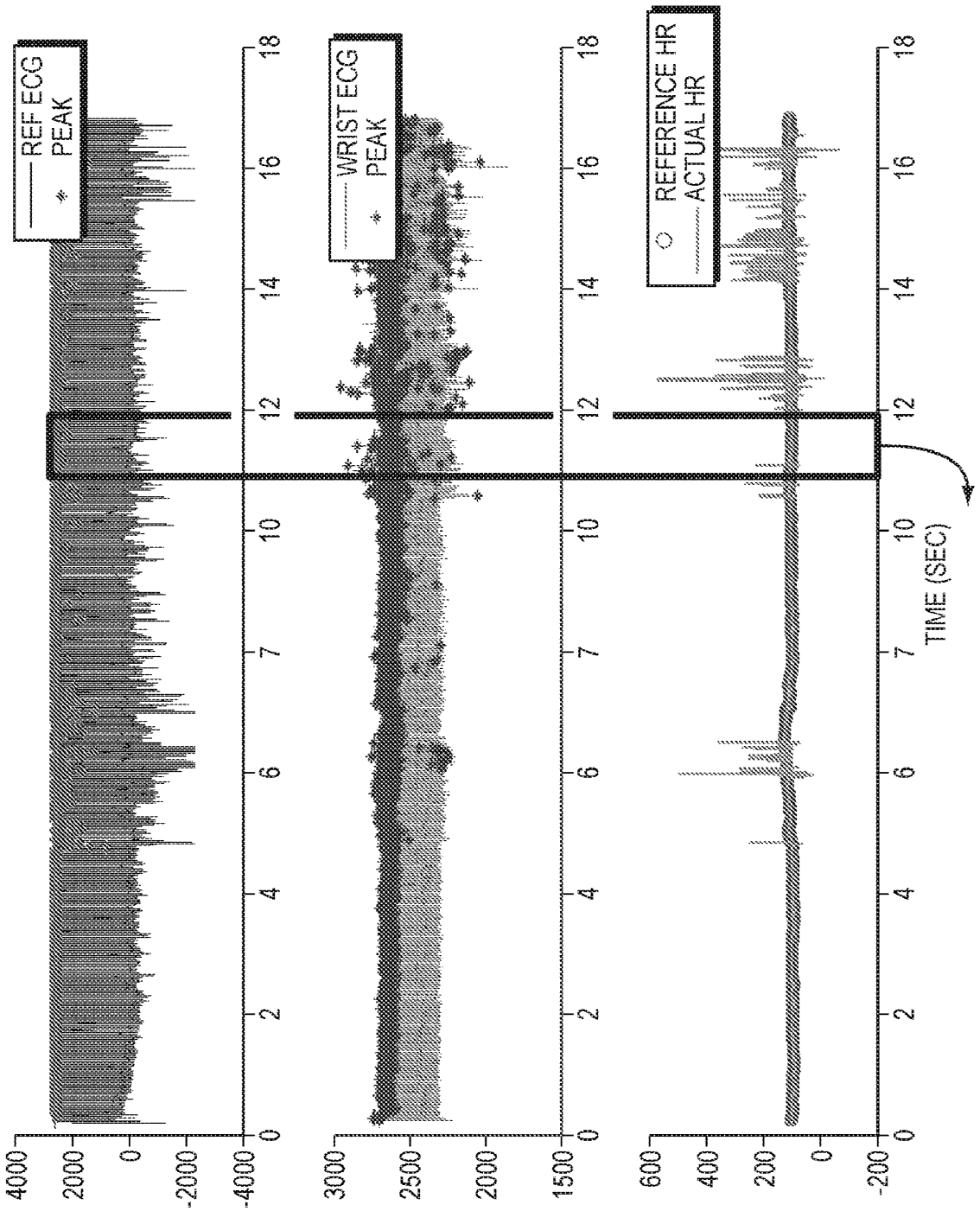


FIG. 6A

Petitioner Ex-1004, 0552

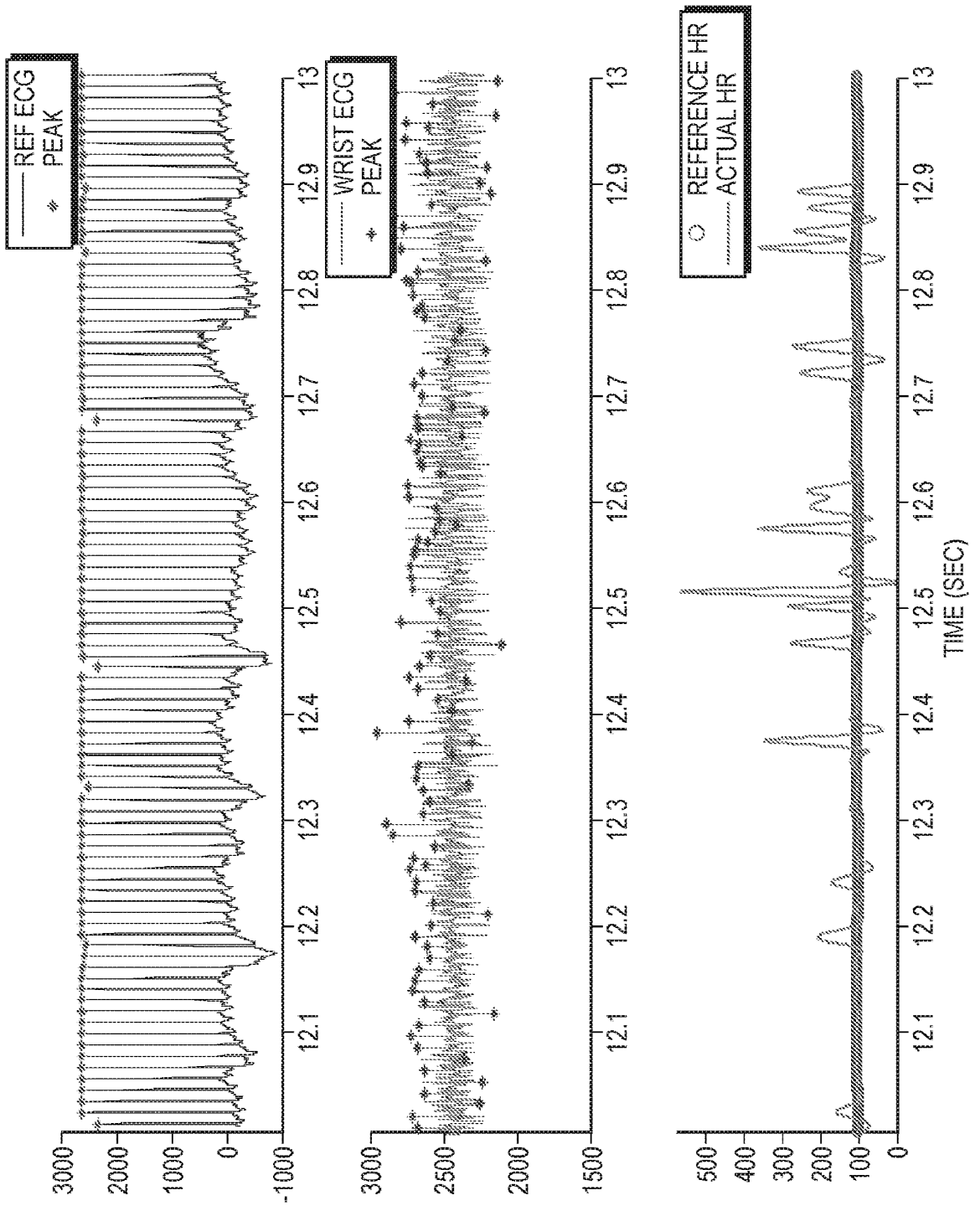


FIG. 6B

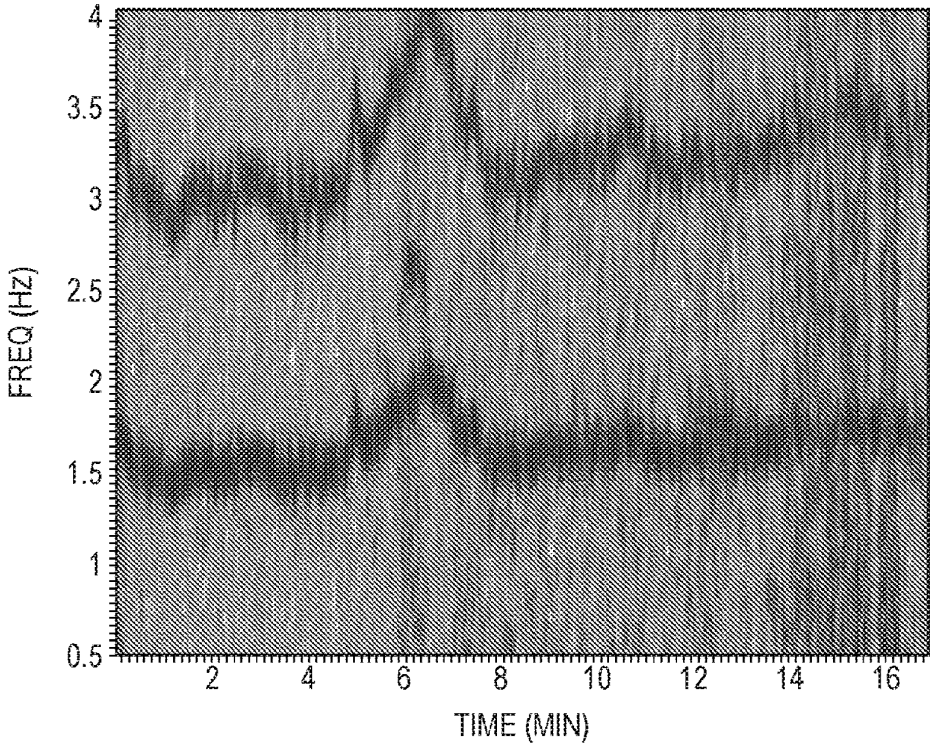

FREQ (Hz)
4
3.5
3
2.5
2
1.5
1
0.5
2
4
6
8
10
12
14
16
TIME (MIN)

FIG. 7A

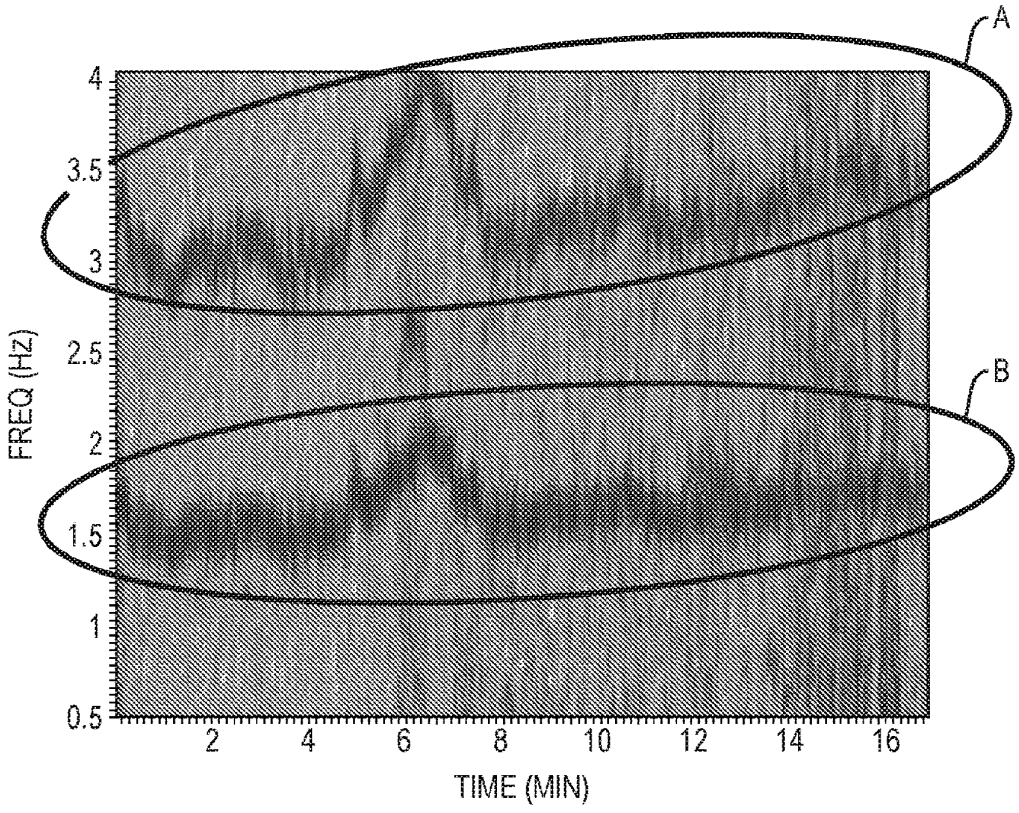

A
B
FREQ (Hz)
4
3.5
3
2.5
2
1.5
1
0.5
2
4
6
8
10
12
14
16
TIME (MIN)

FIG. 7B

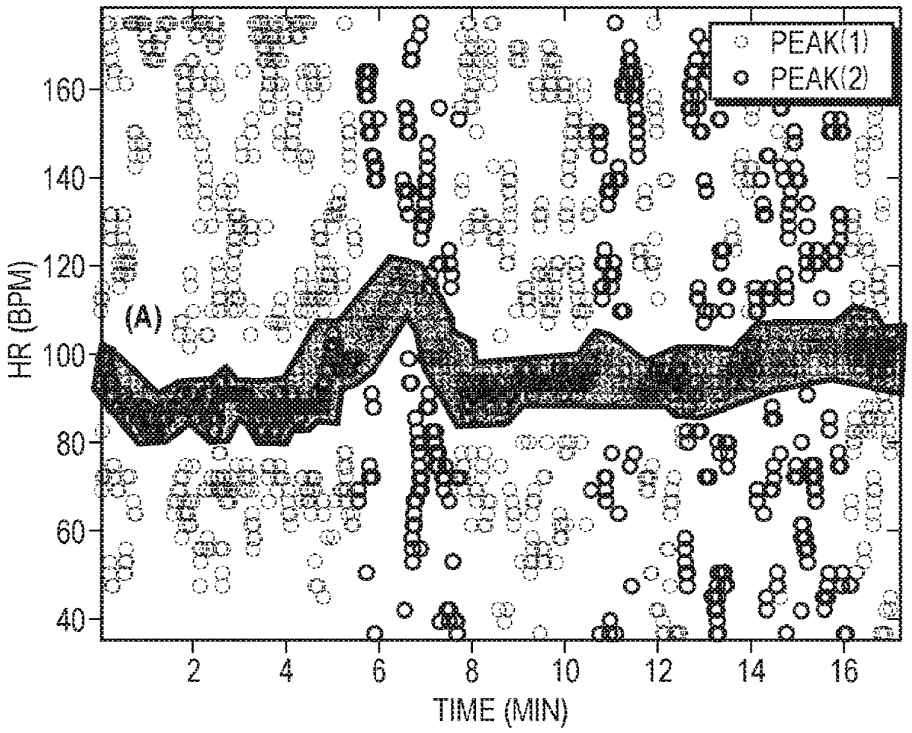

PEAK(1)
PEAK(2)
(A)
HR (BPM)
160
140
120
100
80
60
40
2
4
6
8
10
12
14
16
TIME (MIN)

FIG. 8A

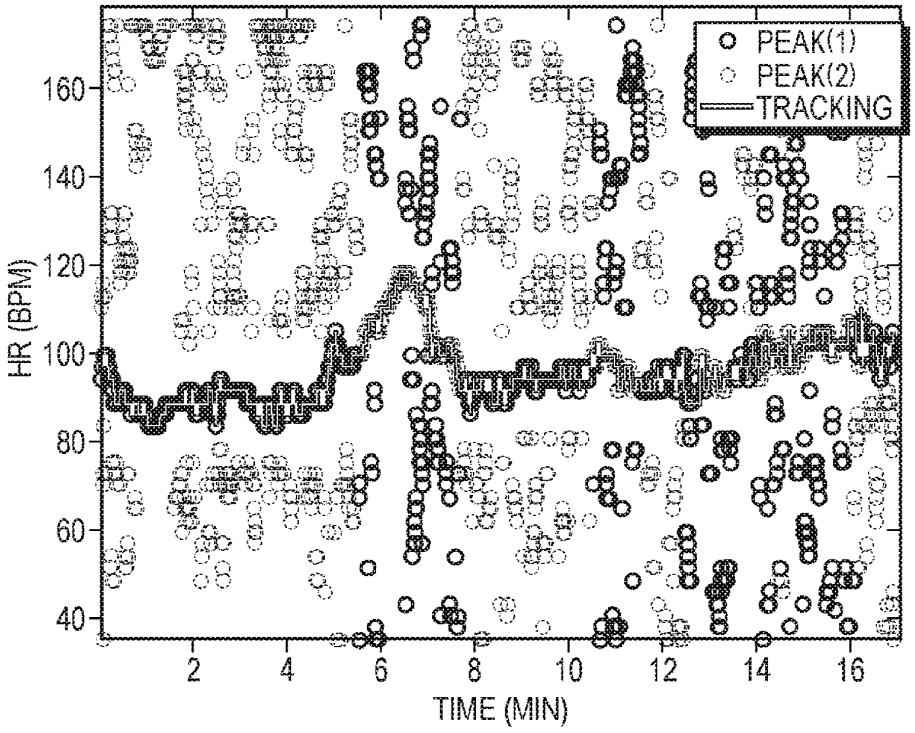

PEAK(1)
PEAK(2)
TRACKING
HR (BPM)
160
140
120
100
80
60
40
2
4
6
8
10
12
14
16
TIME (MIN)

FIG. 8B

Petitioner Ex-1004, 0555

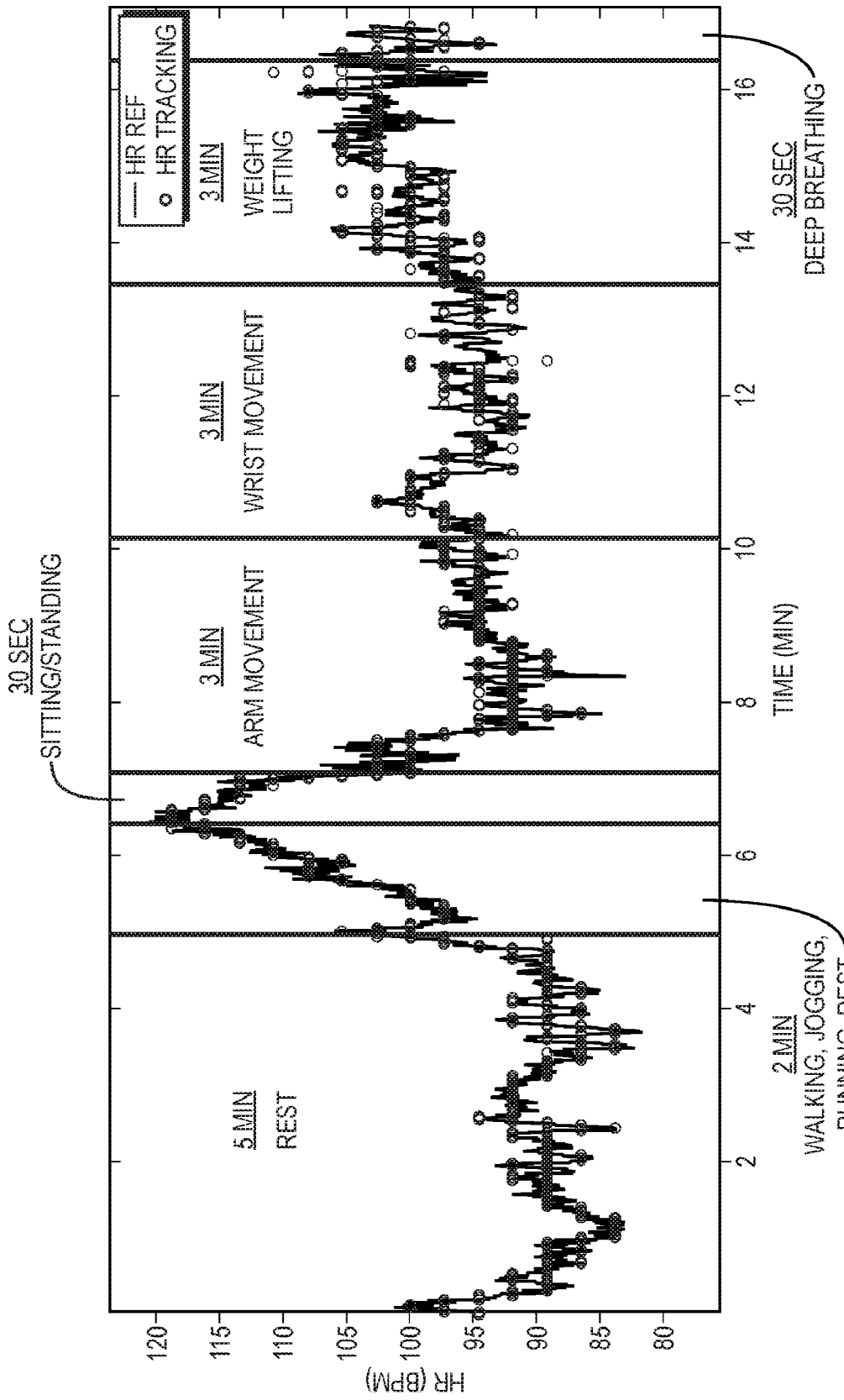


FIG. 9

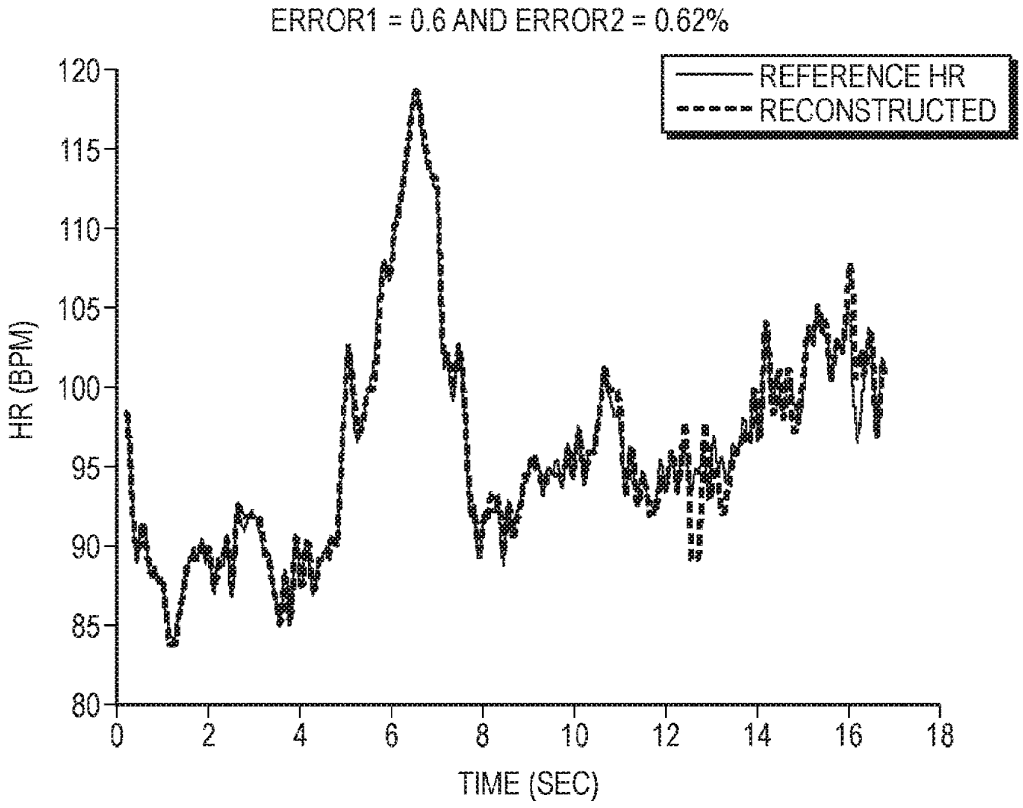

ERROR1 = 0.6 AND ERROR2 = 0.62%
REFERENCE HR
RECONSTRUCTED
HR (BPM)
120
115
110
105
100
95
90
85
80
0
2
4
6
8
10
12
14
16
18
TIME (SEC)

FIG. 10

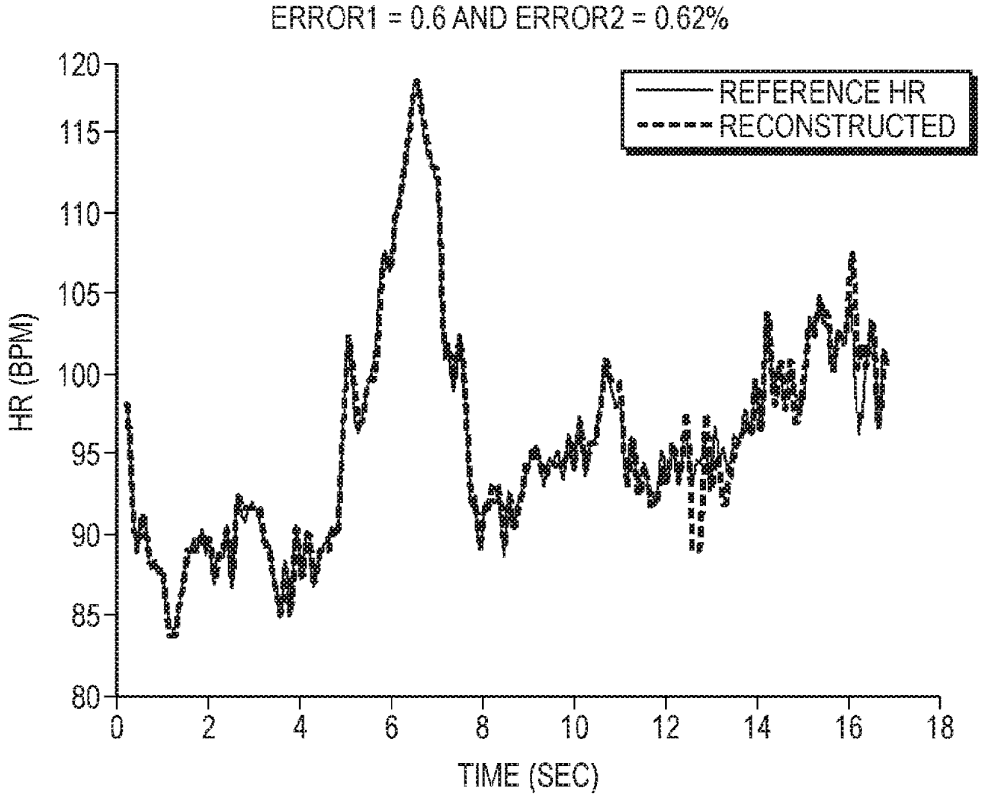


FIG. 11A

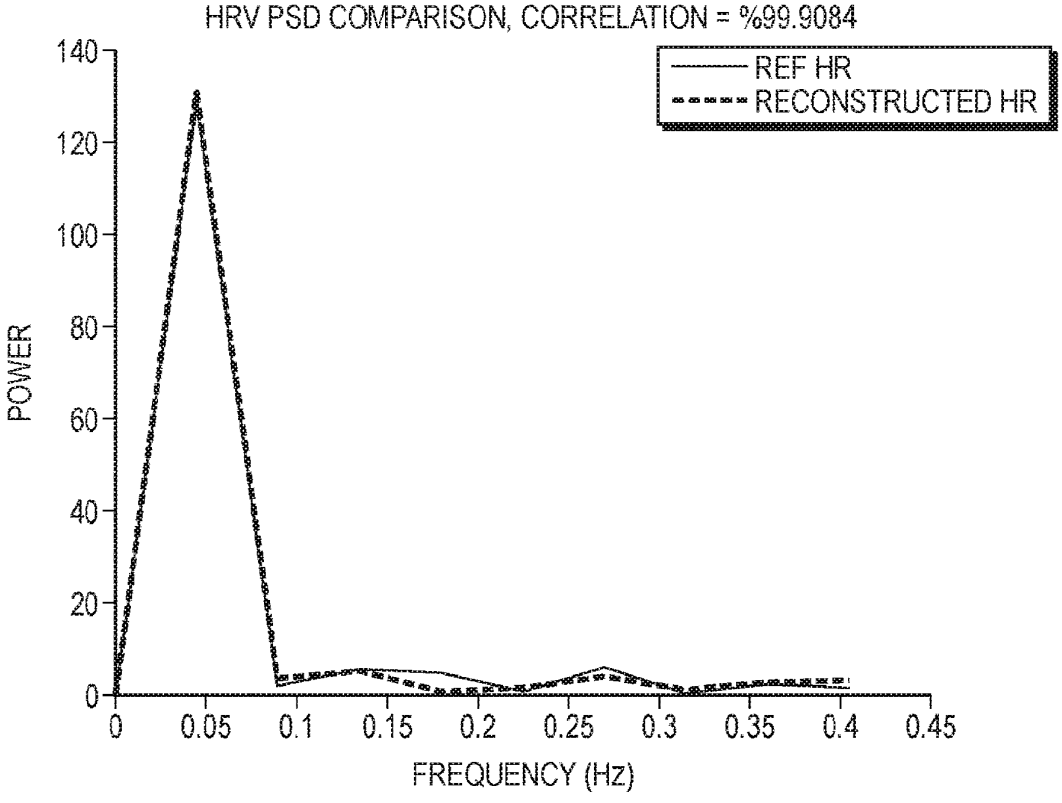


FIG. 11B

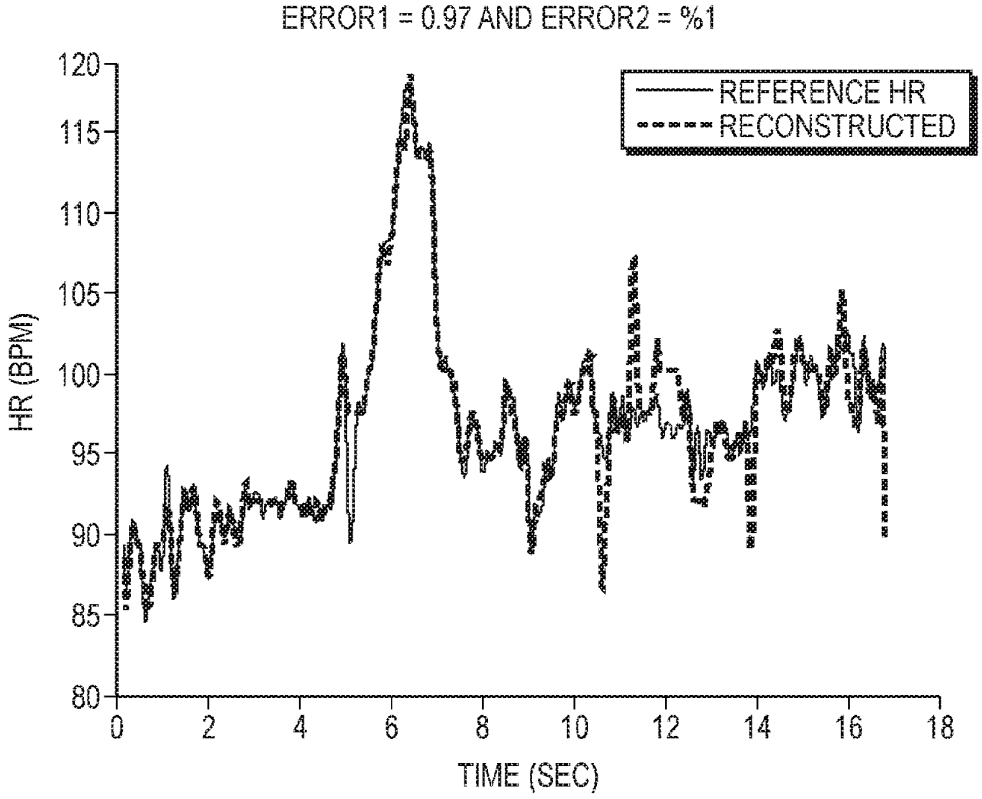


FIG. 12A

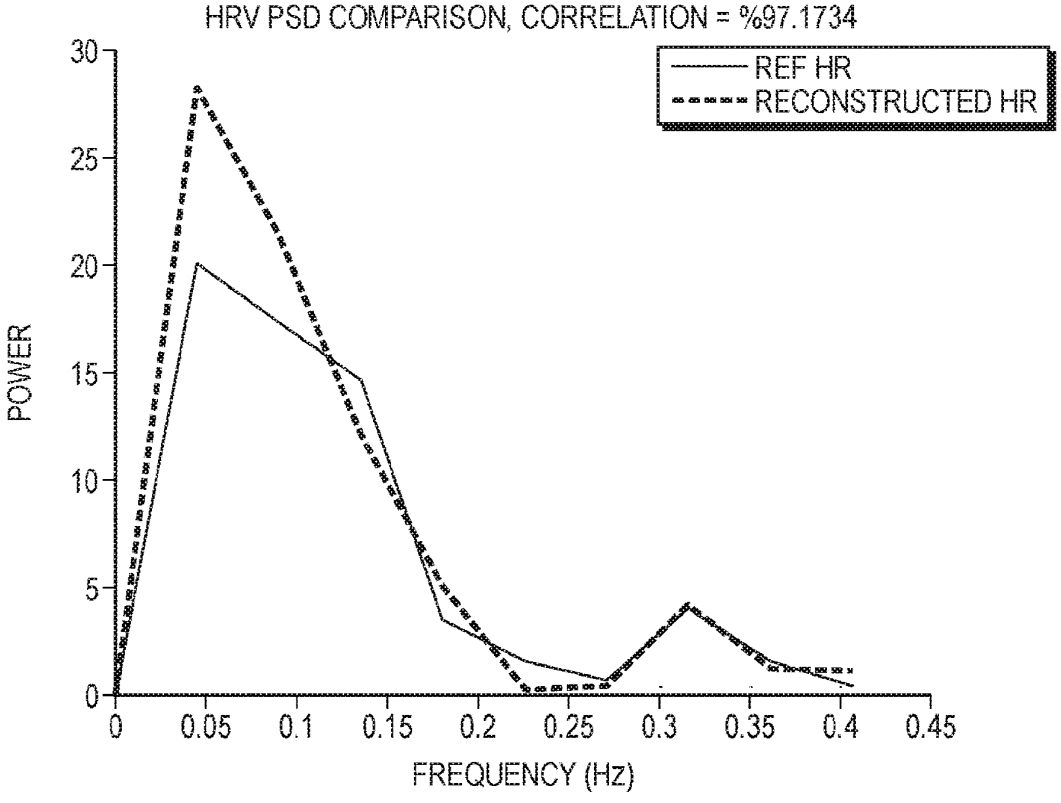


FIG. 12B

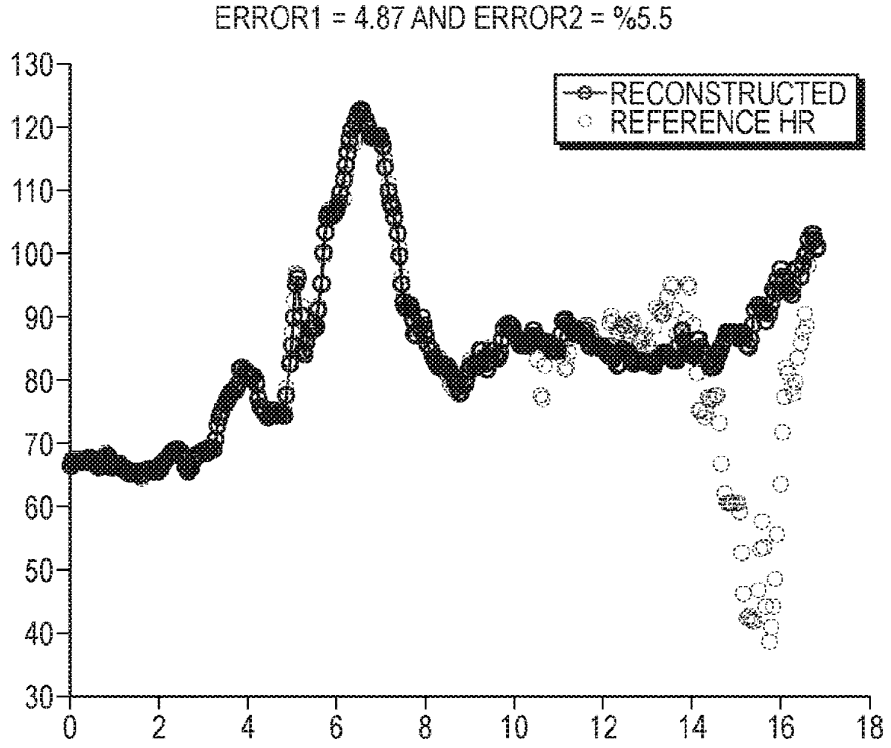


FIG. 13A

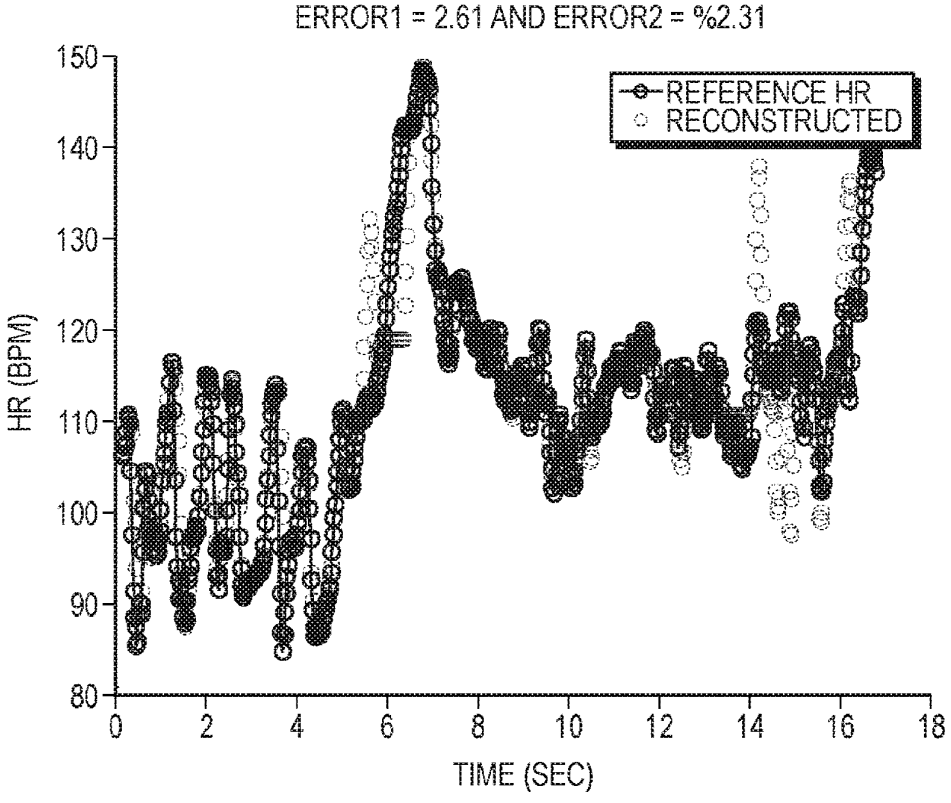


FIG. 13B

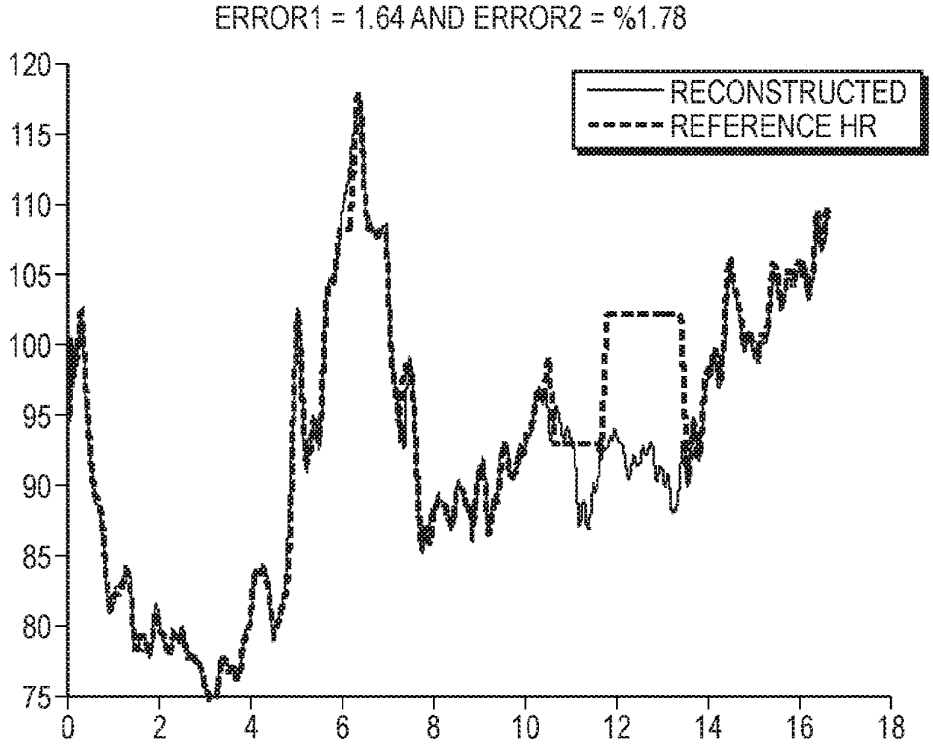


FIG. 14A

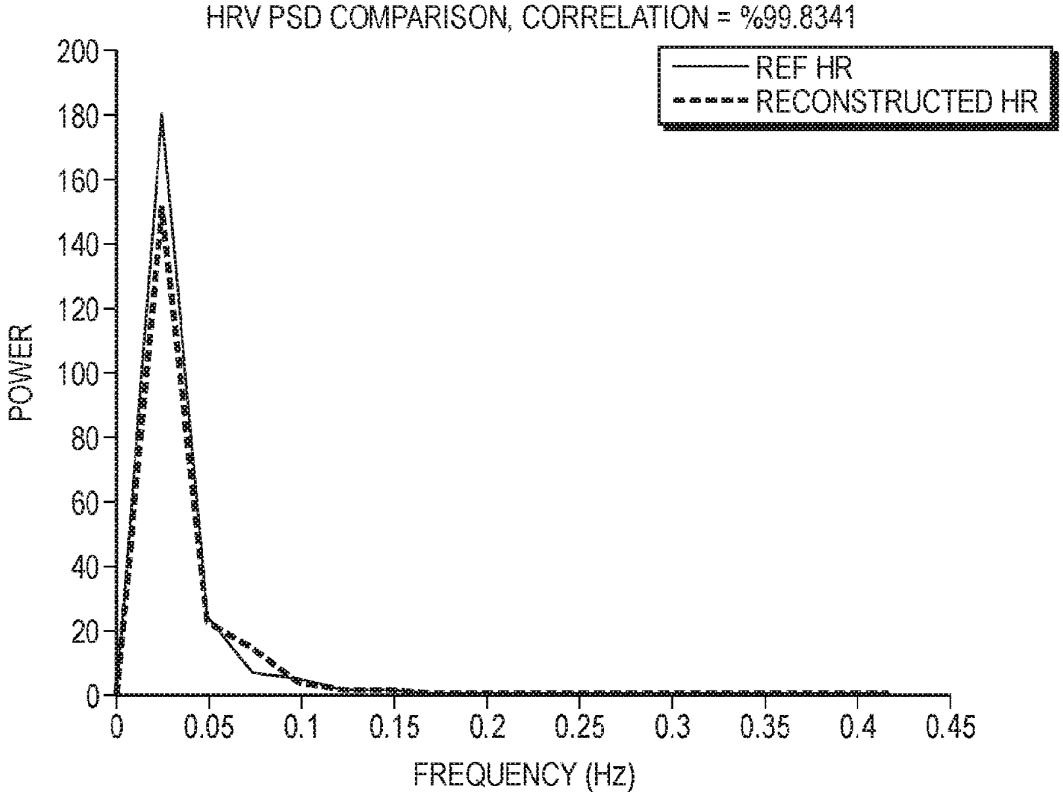


FIG. 14B

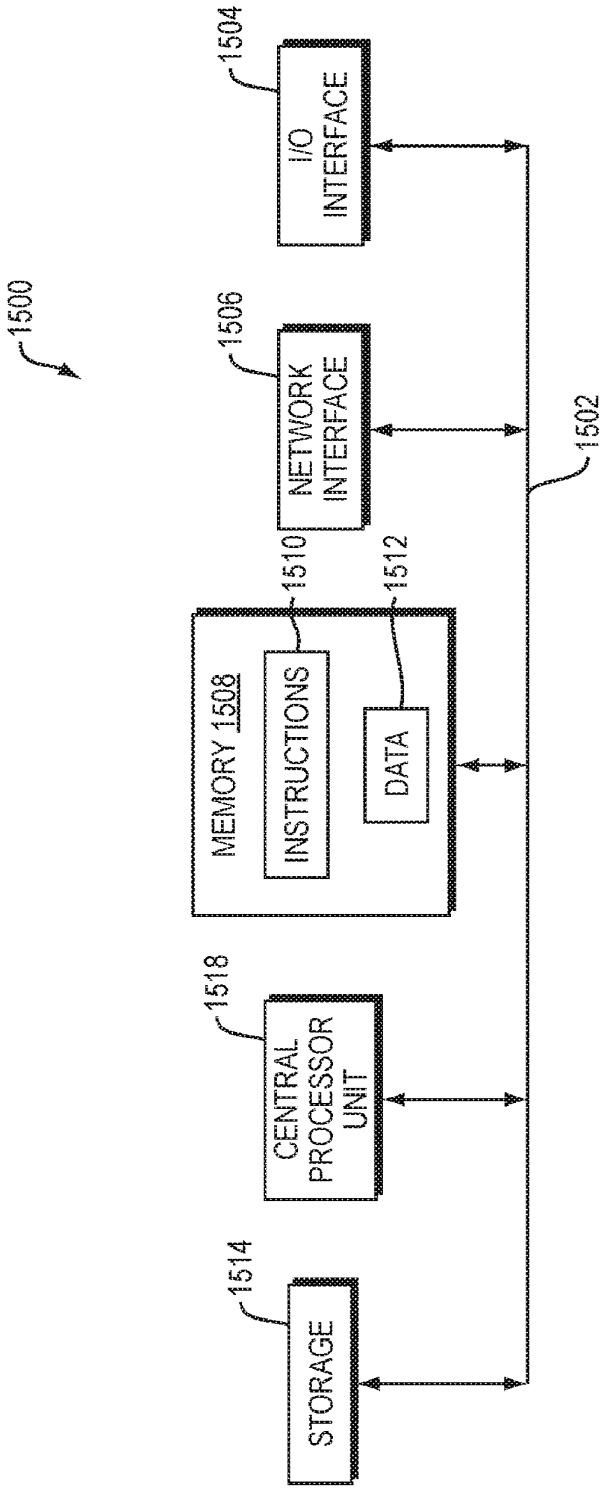

1500
1502
1504
I/O INTERFACE
1506
NETWORK INTERFACE
MEMORY 1508
1510
INSTRUCTIONS
1512
DATA
1514
STORAGE
1518
CENTRAL PROCESSOR UNIT

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/036743

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/024 A61B5/0245
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 724 684 A1 (BUSI INCUBATEUR D ENTPR S D AU [FR]) 22 November 2006 (2006-11-22) paragraphs [0017], [0162], [0172], [0173], [0176], [0187], [0192] - [0195] paragraphs [0198], [0206], [0258] figures 29, 30, 40 -----	1-3, 6-27, 30-49
X	US 2009/069703 A1 (TAKLA GEORGE [US] ET AL) 12 March 2009 (2009-03-12) paragraphs [0008], [0013], [0046] - [0051], [0065] - [0070], [0088], [0089] figures 4-9 -----	1-20, 23-44, 47-49

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 August 2016	30/08/2016

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	Meyer, Wolfgang

1

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/036743

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FEI ZHANG ET AL: "Novel QRS Detection by CWT for ECG Sensor", BIOMEDICAL CIRCUITS AND SYSTEMS CONFERENCE, 2007. BIOCAS 2007. IEEE, IEEE, PISCATAWAY, NJ, USA, 27 November 2007 (2007-11-27), pages 211-214, XP031237069, ISBN: 978-1-4244-1524-3 abstract chapter "I. introduction" chapter "IV. Results and Discussion" paragraph "C. Continuous Wavelet Transform"; page 212 figures 1-3 equation (3)	1-3, 6-19, 25-43,49
A	WO 03/000125 A1 (CARDIODIGITAL LTD [GB]; ADDISON PAUL STANLEY [GB]; WATSON JAMES NICHOL) 3 January 2003 (2003-01-03) page 5, lines 12-20 page 18, lines 6-10 page 19, line 22 - page 20, line 12 figures 3-5, 8-11	8-14, 32-38
A	US 2011/066041 A1 (PANDIA KEYA R [US] ET AL) 17 March 2011 (2011-03-17) paragraph [0155] - paragraph [0160] figure 2	15-19, 39-43
A	EP 2 792 297 A1 (STICHTING IMEC NEDERLAND [NL]) 22 October 2014 (2014-10-22) the whole document	1-49
A	WO 2012/100175 A1 (WORCESTER POLYTECH INST [US]; CHON KI H [US]; LEE JINSEOK [US]; SELVAR) 26 July 2012 (2012-07-26) the whole document	1-49
A	US 2012/123232 A1 (NAJARIAN KAYVAN [US] ET AL) 17 May 2012 (2012-05-17) the whole document	1-49
A	US 2008/109041 A1 (DE VOIR CHRISTOPHER S [US]) 8 May 2008 (2008-05-08) the whole document	1-49

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/036743

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1724684 A1	22-11-2006	NONE	
US 2009069703 A1	12-03-2009	NONE	
WO 03000125 A1	03-01-2003	AT 424139 T	15-03-2009
		AT 520341 T	15-09-2011
		EP 1399056 A1	24-03-2004
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		ES 2321282 T3	04-06-2009
		JP 4278048 B2	10-06-2009
		JP 2005500876 A	13-01-2005
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		US 2005070774 A1	31-03-2005
		WO 03000125 A1	03-01-2003
US 2011066041 A1	17-03-2011	EP 2501277 A1	26-09-2012
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		JP 5791624 B2	07-10-2015
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		JP 2013511349 A	04-04-2013
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		US 2011066041 A1	17-03-2011
		WO 2011063092 A1	26-05-2011
		WO 2011068687 A1	09-06-2011
EP 2792297 A1	22-10-2014	EP 2792297 A1	22-10-2014
		US 2014309943 A1	16-10-2014
WO 2012100175 A1	26-07-2012	CA 2825331 A1	26-07-2012
		CN 103596491 A	19-02-2014
		EP 2665410 A1	27-11-2013
		US 2012190947 A1	26-07-2012
		WO 2012100175 A1	26-07-2012
US 2012123232 A1	17-05-2012	NONE	
US 2008109041 A1	08-05-2008	NONE	

Electronic Acknowledgement Receipt

EFS ID:	28092001
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	18-JAN-2017
Filing Date:	09-JUN-2016
Time Stamp:	15:49:01
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	Transmittal Letter	41471020002SIDSTrans.pdf	90261 279177e5e3420f351e51426ef83d044beee7bf4a	no	3

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	41471020002LOR.pdf	84314 bc32070d16e7daa75baf26e4b4ead25db45feb23	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2016201130.pdf	8029427 4c8d4a5c43281d27458a82fad917adee3dbd61d0	no	75
Warnings:					
Information:					
			Total Files Size (in bytes):	8204002	

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

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	
Confirmation No.:	7605		
For:	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals		

TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

This Supplemental Information Disclosure Statement is submitted:

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits; or before the mailing of a first office action after the filing of a Request for Continued Examination)

☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before any of a final action, notice of allowance, or an action that closes prosecution, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(Filed after final action, notice of allowance, or an action that otherwise closes prosecution, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee) [Consider QPIDS Pilot]

No aspect of this submission constitutes a disclaimer of claim scope.

Statement Under 37 CFR 1.97(e)

☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)
Applies to original applications (other than design) filed on or after May 29, 2000

☐ (1) A paper containing only an information disclosure statement in compliance with §§ 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution (processing or examination) of the application under paragraphs (c)(6), (c)(8), (c)(9), or (c)(10) of this section if it is accompanied by a statement that each item of information contained in the information disclosure statement:

☐ (i) Was first cited in any communication from a patent office in a counterpart foreign or international application or from the Office, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement; or

☐ (ii) Is a communication that was issued by a patent office in a counterpart foreign or international application or by the Office, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.

☒ Enclosed herewith is a Listing of References. Copies of the cited references are enclosed except as indicated below or in the attached Listing of References.

☐ Copies of the cited references submitted with an Information Disclosure Statement in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed, are not required under 37 CFR 1.98(d)(1) and (2) and are thus not provided.

☐ The listed references were cited in the enclosed Search Report in counterpart foreign application [add application number], which is listed in the attached Listing of References.

☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

Method of payment:

☐ Authorization is NOT granted to charge any fees which may be due in this matter to our Deposit Account.

☐ Please charge Deposit Account 08-0380 in the amount of $[ ].

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Concord, MA 01742-9133
Dated: 1/18/2017

Substitute for form 1449B/PTO **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION** **LISTING OF REFERENCES** February 14, 2017 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 4147.1020-002 (15-089)	APPLICATION NO. 15/178,089	
	FIRST NAMED INVENTOR Seyed M. A. Salehizadeh	FILING DATE June 9, 2016	
	EXAMINER	CONFIRMATION NO. 7605	GROUP 3766

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	1.	WO 2017019184 A2	02-02-2017	University of Connecticut
	2.			
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EXAMINER	DATE CONSIDERED

Petitioner Ex. 1004, 0570

Electronic Acknowledgement Receipt

EFS ID:	28352875
Application Number:	15178089
International Application Number:	
Confirmation Number:	7605
Title of Invention:	METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS
First Named Inventor/Applicant Name:	Seyed M. A. Salehizadeh
Customer Number:	21005
Filer:	Mark B Solomon/Katie Norris
Filer Authorized By:	Mark B Solomon
Attorney Docket Number:	4147.1020-002 (15-089)
Receipt Date:	14-FEB-2017
Filing Date:	09-JUN-2016
Time Stamp:	16:22:37
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	Transmittal Letter	41471020002SIDSTrans.pdf	90286 61c24e1a867c3d2586db877a8fe1dfb07dea5304	no	3

Warnings:

Information:					
2	Foreign Reference	WO2017019184.pdf	10433565 dd255240fadec00cc2ebebe60128b533993dd1b5	no	102
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	41471020002LOR.pdf	75235 35f9ab704a168e5e0ab1696bad909eebc6829d25	no	1
Warnings:					
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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

Inventors:	Seyed M. A. Salehizadeh, Ki H. Chon and Yeonsik Noh		
Application No.:	15/178,089	Group:	3766
Filed:	June 9, 2016	Examiner:	
Confirmation No.:	7605		
For:	Method And Apparatus For Removing Motion Artifacts From Biomedical Signals		

TRANSMITTAL LETTER FOR SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

This Supplemental Information Disclosure Statement is submitted:

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits; or before the mailing of a first office action after the filing of a Request for Continued Examination)

☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before any of a final action, notice of allowance, or an action that closes prosecution, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a $[180/90/45] fee under 37 CFR 1.17(p), or

(Filed after final action, notice of allowance, or an action that otherwise closes prosecution, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application file.
(Filed after payment of issue fee) [Consider QPIDS Pilot]

No aspect of this submission constitutes a disclaimer of claim scope.

Statement Under 37 CFR 1.97(e)

☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

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Concord, MA 01742-9133
Dated: 2/14/2017

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 February 2017 (02.02.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/019184 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2016/036734

(22) International Filing Date:
9 June 2016 (09.06.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/172,862 9 June 2015 (09.06.2015) US
62/299,944 25 February 2016 (25.02.2016) US

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(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, 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, ST, 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).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

(54) **Title**: METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

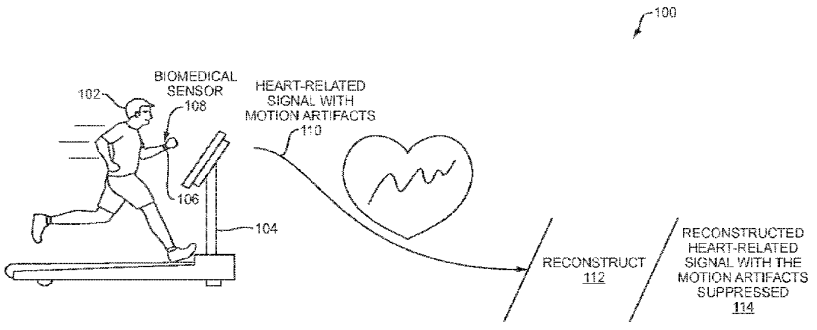


FIG. 1

(57) **Abstract**: A method and corresponding apparatus employ a time-varying spectral analysis approach for reconstructing a heart-related signal that includes motion artifacts. The motion artifacts are produced by motion of a biomedical sensor relative to a sensing location. By comparing time-varying spectra of the heart-related signal and a motion signal, those frequency peaks resulting from the motion artifacts may be suppressed in a time-varying spectrum of the heart-related signal. The time-varying spectral analysis based approach enables the heart-related signal to be reconstructed with accuracy by suppressing the motion artifacts. Example applications for the method and corresponding apparatus include training aids (e.g., runners' heart-rate monitors) and hospital patient heart-rate monitors.

WO 2017/019184 A2

METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACTS FROM BIOMEDICAL SIGNALS

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/172,862 filed June 9, 2015 and U.S. Provisional Application No. 62/299,944 filed February 25, 2016.

The entire teachings of the above applications are incorporated herein by reference.

GOVERNMENT SUPPORT

[0002] This invention was made with government support under Grant No. W81XWH-12-1-0541 from the US Army Medical Research and Material Command (USAMRMC). The government has certain rights in the invention.

BACKGROUND

[0003] Heart rate monitors have become widely-used training aids for a variety of sports. Some heart rate monitors use sensors based on photoplethysmography (PPG) technology. The PPG sensors include infrared light-emitting diodes (LEDs) and photodetectors, and offer a simple, reliable, low-cost means of monitoring pulse rate noninvasively, both at rest and during exercise.

SUMMARY

[0004] During exercise and other activities, PPG and other sensors may experience movement, such as shifting position or rotating, relative to a sensing location (*e.g.*, wrist or finger). The movement typically results in an introduction of a motion artifact in an electrical signal produced by the sensor. The motion artifact may be interpreted by a processor as a heart-related signal if not addressed in advance of or as part of the processing in the processor. By properly addressing the motion artifact, an embodiment disclosed herein has improved accuracy in reconstructing the heart-related signal, thereby enabling processes that use the heart-related signal to have better performance.

[0005] Accordingly, a method for reconstructing a heart-related signal output by a biomedical sensor may comprise reconstructing a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal. The reconstructing may be based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and the classification of the movement may be based on (ii) a classification of the movement. The method may further comprise outputting the reconstructed representation of the heart-related signal.

[0006] The motion artifacts may be suppressed in the reconstructed representation of the heart-related signal.

[0007] The time-varying spectral analysis may include pre-processing the heart-related signal to produce a pre-processed heart-related signal. In an event the classification indicates that the movement does not rise to a level causing the motion artifacts, the reconstructed representation may be based on an average value of peak-to-peak intervals in the pre-processed heart-related signal.

[0008] The pre-processing may include filtering the heart-related signal to produce a filtered heart-related signal.

[0009] The pre-processing may further include down-sampling the filtered heart-related signal, the down-sampling being at a sampling rate less than an original sampling rate.

[0010] The time-varying spectral analysis may include computing a first time-frequency spectrum (TFS) of the heart-related signal and computing a second TFS of the motion signal.

[0011] The first TFS computed and the second TFS computed may be 3-dimensional spectra, the first TFS computed and the second TFS computed each including a respective time-varying amplitude or power distribution with respect to time and frequency.

[0012] The first TFS computed may be a first time-varying power spectral density (PSD) and the second TFS computed may be a second time-varying PSD.

[0013] The reconstructed representation may be a current reconstructed representation. Based on the classification indicating that the movement does rise to a level causing the motion artifacts and is a pseudo-periodic movement or a periodic movement, the reconstructing may include determining whether at least one spectral peak is present having a corresponding frequency within a given frequency range at a point in time in the first TFS

computed, the current reconstructed representation being reconstructed for the point in time. Based on a determination that the at least one spectral peak is not present, the current reconstructed representation may be based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed. The given frequency range may be 0.5 Hz to 3 Hz.

[0014] The reconstructing may include retaining up to a pre-determined number of candidate spectral peaks located at a first point in time in the first TFS computed. The candidate spectral peaks retained may be based on having corresponding frequencies within a given frequency range and highest amplitude or power values relative to other spectral peaks located at the first point in time, the other spectral peaks having respective frequencies within the given frequency range. The reconstructing may further include discarding each of the candidate spectral peaks retained that is associated with a same frequency as a dominant spectral peak located at a second point in time in the second TFS computed. The first point in time and the second point time may have same time values. The given frequency range may be 0.5 Hz to 3 Hz.

[0015] The representation may be a current representation and the reconstructed representation may be a current reconstructed representation. In an event the discarding discards each of the candidate spectral peaks retained, reconstructing the current representation may be based on a prior reconstructed representation, the prior reconstructed representation associated with a previous point in time in the first TFS computed, the previous point in time being an earlier point in time with respect to the first point in time.

[0016] The discarding may be a first discarding, the representation may be a current representation and, in an event the first discarding results in at least one remaining candidate spectral peak retained, reconstructing the current representation may further include second discarding. The second discarding may discard remaining candidate spectral peaks, of the at least one remaining candidate spectral peak retained, based on whether a corresponding frequency of the at least one remaining candidate spectral peak retained is distanced by at least a frequency difference threshold from a prior reconstructed representation's frequency. The prior reconstructed representation associated with a previous point in time in the first TFS computed. The previous point in time may be an earlier point in time with respect to the first point in time.

[0017] Based on each of the at least one remaining candidate spectral peak retained having been discarded by the second discarding, reconstructing the current representation may be based on the prior reconstructed representation. Based on at least one last candidate spectral peak remaining, the at least one last candidate spectral peak remaining not discarded by the second discarding, reconstructing the current representation may be based on a selected candidate spectral peak. The selected candidate spectral peak may be selected from amongst the at least one last candidate spectral peak remaining having a closest corresponding frequency to the prior reconstructed representation's frequency relative to respective frequencies of each of the at least one last candidate spectral peak remaining.

[0018] The dominant spectral peak may have a largest power or amplitude value relative to other peaks located at the second point in time in the second TFS.

[0019] The retaining and the discarding may be based on the classification indicating that the movement is a pseudo-periodic movement or a periodic movement, and determining that at least one spectral peak with a corresponding frequency in the given frequency range is present at the first point in time.

[0020] The time-varying spectral analysis may further include pre-processing the heart-related signal and the motion signal for the computing of the first TFS and the second TFS.

[0021] The pre-processing may include filtering the heart-related signal and the motion signal to produce a filtered heart-related signal and a filtered motion signal, respectively. The pre-processing may further include down-sampling both the filtered heart-related signal and the filtered motion signal, the down-sampling being at a sampling rate less than an original sampling rate.

[0022] The method may further include classifying the classification of the movement by comparing an amount of amplitude modulation in the second TFS computed to an amplitude modulation threshold. The amplitude modulation threshold may be dependent on a type of the motion detector sensor. The classification may indicate whether the movement rises to a level causing the motion artifacts based on a result of the comparing. In an event the result indicates that the movement does rise to the level causing the motion artifacts, classifying the classification of the movement may further include determining whether the movement is either a pseudo-periodic movement or a periodic movement, versus a random movement.

[0023] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include

identifying a first, second, and third frequency associated, respectively, with a first, second, and third spectral peak in the second TFS at a point in time in the second TFS. The first, second, and third peaks may have largest power or amplitude values relative to other peaks in the second TFS at the point in time. The first spectral peak may be a largest spectral peak amongst the first, second, and third spectral peaks.

[0024] In determining whether the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, the method may further include computing a first ratio of the second frequency identified to the first frequency identified. The method may determine a first comparison result by comparing the first ratio computed to a first ratio value. The method may compute a second ratio of the third frequency identified to the first frequency identified. The method may determine a second comparison result by comparing the second ratio computed to a second ratio value. The classification may further indicate the movement is either the pseudo-periodic movement or the periodic movement, versus the random movement, based on the first comparison result and the second comparison result. The first ratio value may be 2 and the second ratio value may be 3.

[0025] The time-varying signal analysis may include pre-processing the heart-related signal to produce a pre-processed heart-related signal and, in an event the classification of the movement indicates the random movement, the reconstructing may include computing an average value of a number of prior reconstructed representations outputted prior to the reconstructing. The number may be based on a duration of consecutive motion artifacts, detected prior to the reconstructing. The time-varying signal analysis may further include computing a bandpass filter cutoff frequency based on the average value computed, and filtering the pre-processed heart-rate signal by applying the band pass filter computed to produce a filtered, pre-processed heart-related signal. The reconstructed representation may be based on an average peak-to-peak interval value of the filtered, pre-processed heart-rate signal.

[0026] The heart-related signal and the motion signal may be produced, concurrently.

[0027] The method may comprise segmenting the heart-related signal into a plurality of windowed heart-related signal data segments and segmenting the motion signal into a corresponding plurality of windowed motion signal data segments. The method may comprise repeating the reconstructing and the outputting for each windowed heart-related

signal data segment and each corresponding motion signal data segment. The time window may be a value in a range from 2 to 32 seconds.

[0028] The biomedical sensor may be at least one of: a photoplethysmogram (PPG) sensor, piezoelectric sensor, Light Emitting Diode (LED) based sensor, camera sensor, and pulse oximeter sensor, and the motion sensor may be an accelerometer.

[0029] The biomedical sensor and the motion sensor may be co-located.

[0030] The method may further comprise employing the reconstructed representation to determine a heart rate estimate.

[0031] The method may further comprise employing the reconstructed representation to determine an arterial oxygen saturation (SpO2) estimate.

[0032] The method may further comprise employing the reconstructed representation to detect or predict a heart-related ailment. The heart-related ailment may include at least one of a heart rate variability (HRV) condition, atrial fibrillation condition, congestive heart failure condition, and tachycardia condition.

[0033] The reconstructing and the outputting may be performed in real-time with respect to production of the heart-related signal and the motion signal.

[0034] The reconstructing and the outputting may be performed in non-real-time with respect to production of the heart-related signal and the motion signal.

[0035] According to another embodiment, an apparatus for reconstructing a heart-related signal output by a biomedical sensor may comprise a reconstruction unit. The reconstruction unit may be configured to reconstruct a representation of the heart-related signal to produce a reconstructed representation of the heart-related signal, the reconstructing based on (i) a time-varying spectral analysis of the heart-related signal and a motion signal, the motion signal output by a motion sensor and representative of motion artifacts in the heart-related signal, the motion artifacts being signal artifacts produced by movement of the biomedical sensor relative to a sensing location, and (ii) a classification of the movement. The apparatus may further comprise an output unit configured to output the reconstructed representation of the heart-related signal.

[0036] Yet another example embodiment may include a non-transitory computer-readable medium having stored thereon a sequence of instructions which, when loaded and executed by a processor, causes the processor to complete methods disclosed herein.

[0037] It should be understood that embodiments disclosed herein can be implemented in the form of a method, apparatus, system, or computer readable medium with program codes embodied thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

[0039] The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

[0040] FIG. 1 is a block diagram of an example application for which embodiments disclosed herein may be applied.

[0041] FIG. 2 is a flow diagram of an example embodiment of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0042] FIGS. 3A-C are flow diagrams of example embodiments of a method for reconstructing a heart-related signal output by a biomedical sensor.

[0043] FIG. 4 is a block diagram of an example embodiment of a system.

[0044] FIG. 5 is a block diagram of an example embodiment of an apparatus for reconstructing a heart-related signal output by a biomedical sensor.

[0045] FIGS. 6A-6C show Time-Frequency spectra of a recording from a dataset.

[0046] FIG. 7 is a filtered time-frequency spectral plot of a photoplethysmogram (PPG) signal.

[0047] FIGS. 8A-8B show motion artifact detection in a PPG spectrum according to embodiments disclosed herein.

[0048] FIG. 9 shows a comparison of reconstructed heart rate (HR) obtained, according to embodiments disclosed herein, to reference HR obtained from simultaneous electrocardiogram (ECG) recordings.

[0049] FIG. 10A is an example embodiment of PPG signal reconstruction according to embodiments disclosed herein.

[0050] FIG. 10B is a zoomed-in version of FIG. 10A.

[0051] FIGS. 11A-B show comparisons of heart rate variability (HRV) spectra between a reference and a reconstructed HRV time series (*e.g.*, as shown in FIGS. 10A-B) from a motion artifact-contaminated PPG signal for a given dataset.

[0052] FIGS. 12A, 12B, 13A, 13B, 14A, and 14B show the reconstructed HR and corresponding power spectral density (PSD) of a sample-sample windowed HR, according to embodiments disclosed herein, in comparison to a reference HR from an ECG.

[0053] FIGS. 15A-B show an example resultant variable frequency complex demodulation (VFCDM) time-frequency spectrum of recordings from a given subject.

[0054] FIG. 16 shows twelve components corresponding to the Infrared (IR) and Red signal for the given subject.

[0055] FIGS. 17A-C are example spectra plots corresponding to three scenarios.

[0056] FIG. 18A shows a representative filtered time-frequency spectral plot of PPG recording from subject #5.

[0057] FIG. 18B shows tracking of HR based on embodiments disclosed herein.

[0058] FIGS. 19A-B represent comparisons of an estimated 8 second moving average HR from a spectral approach for filtering motion artifacts for oxygen saturation estimation (OxiMA) method to a reference HR, and an HR calculated from a motion-corrupted PPG signal compared to a reference HR from an ECG, respectively.

[0059] FIGS. 20A-C are example plots of data showing less motion-corrupted data that can be used for oxygen saturation estimation.

[0060] FIGS. 21A-C and FIGS. 22A-B show reconstructed arterial oxygen saturation (SpO2) and HR in comparison to the reference HR from ECG recordings for the given subject.

[0061] FIG. 23 is a block diagram of an example internal structure of a computer optionally within an embodiment disclosed herein.

DETAILED DESCRIPTION

[0062] A description of example embodiments of the invention follows.

[0063] Accurate estimation of a heart rate (HR) and changing arterial oxygen saturation (SpO2) from a heart-related signal, such as a photoplethysmogram (PPG) signal, during intense physical activity is a very challenging problem. This is because strenuous and high

intensity exercise can result in severe motion artifacts (MAs) in the heart-related signal, making accurate HR and SpO2 estimation difficult.

[0064] HR monitoring using PPG signals has many advantages compared to using traditional ECG sensors, such as simpler hardware implementation, lower cost, and no need for daily application of electrodes (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Fluctuations of the PPG signal are caused by changes in arterial blood volume associated with each heartbeat, where the magnitude of the fluctuations depends on the amount of blood rushing into the peripheral vascular bed, the optical absorption of the blood, skin, and tissue, and the wavelength used to illuminate the blood. The pulse oximeter signal contains not only the blood oxygen saturation and heart rate (HR) data, but also other vital physiological information (Chon, K.H., S. Dash, and J. Kihwan, Estimation of Respiratory Rate From Photoplethysmogram Data Using Time–Frequency Spectral Estimation. Biomedical Engineering, IEEE Transactions on, 2009. 56(8): p. 2054-2063; Lee, J. and K.H. Chon, Respiratory Rate Extraction Via an Autoregressive Model Using the Optimal Parameter Search Criterion. Annals of Biomedical Engineering, 2010. 38(10): p. 3218-3225; Dash, S., et al., Estimation of Respiratory Rate From ECG, Photoplethysmogram, and Piezoelectric Pulse Transducer Signals: A Comparative Study of Time–Frequency Methods. Biomedical Engineering, IEEE Transactions on, 2010. 57(5): p. 1099-1107; Jinseok, L. and K.H. Chon, Time-Varying Autoregressive Model-Based Multiple Modes Particle Filtering Algorithm for Respiratory Rate Extraction From Pulse Oximeter. Biomedical Engineering, IEEE Transactions on, 2011. 58(3): p. 790-794. The fluctuations of PPG signals contain the influences of arterial, venous, autonomic and respiratory systems on the peripheral circulation. Utilizing a pulse oximeter as a multi-purpose vital sign monitor has clinical appeal, since it is familiar to the clinician and comfortable for the patient (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Even simple knowledge of HR patterns would provide more useful clinical information than just HR and blood oxygenation, especially in situations in which a pulse oximeter is the sole monitor available. One major example of such benefits can be seen in a study by Chong et al. which shows that

accurate detection of atrial fibrillation can be obtained from PPG data (Jo Woon, C., et al., Arrhythmia Discrimination Using a Smart Phone. Biomedical and Health Informatics, IEEE Journal of, 2015. 19(3): p. 815-824). In addition to the acquisition of HR in response to exercise, research has recently focused on obtaining HRV information from wearable sensors including devices that use PPGs (Achten, J. and A.E. Jeukendrup, Heart rate monitoring: applications and limitations. Sports medicine (Auckland, N.Z.), 2003. 33(7): p. 517-538). Increased HRV has been associated with lower mortality rates and is affected by both age and sex (Achten, J. and A.E. Jeukendrup, Heart rate monitoring: applications and limitations. Sports medicine (Auckland, N.Z.), 2003. 33(7): p. 517-538). During graded exercise, the majority of studies show that HRV decreases progressively up to moderate intensities, after which it stabilizes (Laughlin, M.H., Cardiovascular response to exercise. Am J Physiol, 1999. 277(6 Pt 2): p. S244-59). Although there are many promising and attractive features of using pulse oximeters for vital sign monitoring, currently they are mainly used on stationary patients. This is because motion artifacts (MAs) result in unreliable HR and SpO_2 estimation (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Clinicians have cited motion artifacts in pulse oximetry as the most common cause of false alarms, loss of signal, and inaccurate readings (Jubran, A., Pulse oximetry. Crit Care, 1999. 3(2): p. R11-r17). During physical activities, MA contamination in PPG signals seriously interferes with HR estimation. The MAs are mainly caused by ambient light leaking into the gap between the PPG sensor surface and skin surface. Besides, the change in blood flow due to movements is another MA source (Maeda, Y., M. Sekine, and T. Tamura, Relationship between measurement site and motion artifacts in wearable reflected photoplethysmography. J Med Syst, 2011. 35(5): p. 969-76). In practice, MAs are difficult to remove because they do not have a predefined narrow frequency band and their spectrum often overlaps that of the desired signal (Thakor, N.V. and Y.S. Zhu, Applications of adaptive filtering to ECG analysis: noise cancellation and arrhythmia detection. IEEE Trans Biomed Eng, 1991. 38(8): p. 785-94). Consequently, development of methods capable of reconstructing the corrupted signal and removing artifacts is challenging. There are a number of general techniques used for artifact detection and removal. One of the methods used to remove motion artifacts is adaptive filtering (Diniz, P., Adaptive filtering: algorithms and practical implementation.

2008: . Springer Science, Business Media L.L.C., Kalman, R.E., A New Approach to Linear Filtering and Prediction Problems Transactions of the ASME – Journal of Basic Engineering, 1960. Series D(82); Morbidi, F., et al., Application of Kalman Filter to Remove TMS-Induced Artifacts from EEG Recordings. Control Systems Technology, IEEE Transactions on, 2008. 16(6): p. 1360-1366; Seyedtabaii, S.S.a.L., Kalman filter based adaptive reduction of motion artifact from photoplethysmographic signal. World Academy of Science, Engineering and Technology, 2008. 37). An adaptive filter is easy to implement and it also can be used in real-time applications, though the requirement of additional sensors to provide reference inputs is the major drawback of such methods. There are many motion and noise artifact reduction techniques based on the concept of blind source separation (BSS). The aim of BSS is to estimate a set of uncorrupted signals from a set of mixed signals which is assumed to contain both the clean and noisy sources (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263). Some of the popular BSS techniques are independent component analysis (ICA) (Comon, P., Independent component analysis, A new concept? Signal Processing, 1994. 36(3): p. 287-314), canonical correlation analysis (CCA) (Thompson, B., Canonical Correlation Analysis: Uses and Interpretation. 1984: SAGE Publications), principle component analysis (PCA) (Jolliffe, I.T., Principal Component Analysis. 2 ed. Springer Series in Statistics. 2002: Springer-Verlag New York. 488), and singular spectrum analysis (SSA) (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263; Elsner, J.B. and A.A. Tsonis, Singular Spectrum Analysis: A New Tool in Time Series Analysis. 1996: Springer). Kim and Yoo (Kim, B.S. and S.K. Yoo, Motion artifact reduction in photoplethysmography using independent component analysis. IEEE Trans Biomed Eng, 2006. 53(3): p. 566-8) suggested using a basic ICA method and block interleaving to remove MA. Krishnan et al. (Krishnan, R., B. Natarajan, and S. Warren, Two-Stage Approach for Detection and Reduction of Motion Artifacts in Photoplethysmographic Data. Biomedical Engineering, IEEE Transactions on, 2010. 57(8): p. 1867-1876) later proposed using frequency-domain-based ICA. However, the key assumption in ICA, namely statistical independence or uncorrelation, does not hold in PPG

signals contaminated by MA (Yao, J. and S. Warren, A short study to assess the potential of independent component analysis for motion artifact separation in wearable pulse oximeter signals. Conf Proc IEEE Eng Med Biol Soc, 2005. 4: p. 3585-8). Salehizadeh et al. (Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263) proposed a motion artifact removal method using SSA. In Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263, SSA is used to decompose the corrupted segment adjacent to the clean segment and the SSA components are chosen in the corrupted segment that have a similar frequency range to that of the adjunct clean components. Although Salehizadeh, S.M.A., et al., Photoplethysmograph Signal Reconstruction based on a Novel Motion Artifact Detection-Reduction Approach. Part II: Motion and Noise Artifact Removal. Annals of Biomedical Engineering, 2014. 42(11): p. 2251-2263 reports good performance, the method cannot be applied in scenarios where the HR and SpO_2 are varying rapidly due to corruption and movement. Acceleration data are also shown to be helpful to remove MA. For example, Fukushima et al. (Fukushima, H., et al., Estimating heart rate using wrist-type Photoplethysmography and acceleration sensor while running. Conf Proc IEEE Eng Med Biol Soc, 2012. 2012: p. 2901-4) suggested a spectral subtraction technique to remove the spectrum of acceleration data from that of a PPG signal. Acceleration data can be also used to reconstruct the observation model for Kalman filtering (Boreom Lee, J.H., Hyun Jae Baek, Jae Hyuk Shin, Kwang Suk Park and Won Jin Yi, Improved elimination of motion artifacts from a photoplethysmographic signal using a Kalman smoother with simultaneous accelerometry. Physiological Measurement, 2010. 31(12): p. 1585) to remove MA.

[0065] Two noteworthy methods are TROIKA and JOSS (Zhilin, Z., P. Zhouyue, and L. Benyuan, TROIKA: A General Framework for Heart Rate Monitoring Using Wrist-Type Photoplethysmographic Signals During Intensive Physical Exercise. Biomedical Engineering, IEEE Transactions on, 2015. 62(2): p. 522-531; Zhang, Z., Photoplethysmography-Based Heart Rate Monitoring in Physical Activities via Joint Sparse Spectrum Reconstruction. Biomedical Engineering, IEEE Transactions on, 2015. PP(99): p. 1-1) in which sparsity-based spectrum estimation and spectral peak tracking with verification, are used to estimate