DocCode – S

SCORE Placeholder Sheet for IFW Content

Application Number: 15010345 Document Date: 01/29/2016

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

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT 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
	Ki	H.	Chon	

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

City	Worcester	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Worcester Polytechnic Institute
Address 2	100 Institute Road

City	Worcester	State/Province	MA
Postal Code	01609	Country	US

Inventor 2 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jowoon		Chong	

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

City	Worcester	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Worcester Polytechnic Institute
Address 2	100 Institute Road

City	Worcester	State/Province	MA
Postal Code	01609	Country	US

Inventor 3 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Duy		Dao	

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

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS	

City	Malden	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Worcester Polytechnic Institute
Address 2	100 Institute Road

City	Worcester	State/Province	MA
Postal Code	01609	Country	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Hamed		Salehizadeh	

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

City	Worcester	State/Province	MA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Worcester Polytechnic Institute
Address 2	100 Institute Road

City	Worcester	State/Province	MA
Postal Code	01609	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	26486		
Email Address	docketing@burnslev.com	Add Email	Remove Email

Application Information:

Title of the Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS		
Attorney Docket Number	30210-216	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	8	Suggested Figure for Publication (if any)	

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS	

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.

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	26486		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
Present	non provisional of	62109183	2015-01-29

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(d). 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(h)(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).

Remove

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

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS	

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.

Authorization to Permit Access:

Authorization to Permit Access to the Instant Application by the Participating Offices
If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application. In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application. In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

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.

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS	

If the Assignee is an Organization check here. ☐

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

Mailing Address Information For Non-Applicant Assignee:

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

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

Signature:

Remove

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

Signature	/Orlando Lopez/			Date (YYYY-MM-DD)	2016-01-29
First Name	Orlando	Last Name	Lopez	Registration Number	46880

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

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.**

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Co o p eration Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and benefit of U.S. Provisional Application No. 62/109,183, filed January 29, 2015, entitled MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM SIGNALS, the contents of which are incorporated by reference herein in their entirety for all purposes.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made partially with U.S. Government support from the United States Army under Grant No. W81XWH-12-1-054. The U.S. Government has certain rights in the invention.

BACKGROUND

[0003] These teachings relate generally to pulse oximeters and, more specifically, to pulse oximeters with algorithms embedded for real-time detection of motion and noise artifacts.

[0004] A pulse oximeter (PO) is a non-invasive, low cost device that is widely used in hospitals and clinics to monitor heart rate (HR) and arterial oxygen saturation (SpO2). Recently, there have been efforts to derive other physiological parameters from Photoplethysmogram (PPG), as recorded by a PO. The fluctuations observed in a PPG are influenced by arterial, and venous blood, as well as autonomic and respiratory systems of the peripheral circulation. Such information could be used to more comprehensively phenotype cardiovascular health. Due to increasing health care costs, a single sensor from which multiple clinical datapoints can be derived such as a PO is very attractive from a financial perspective. Moreover, utilizing a PO as a multipurpose vital sign monitor has a clinical appeal, since the device is widely accepted by clinicians and patients because of its ease of use, comfort and accuracy in providing reliable vital signs. Knowledge of respiratory rate and HR patterns would provide useful clinical information in many situations where a PO is the sole available monitor. However, extraction of the above mentioned vital signs and other physiological parameters using PO is predicated on artifact-free PPG data. It is well known that the PPG is highly sensitive to artifacts, particularly those

generated while the patient is in motion. This imposes a huge limitation on the usability of the PPG for ambulatory monitoring applications. Motion and noise artifacts (MNA) distorting PPG recordings can cause erroneous estimation of HR and SpO2. Although the intelligent design of sensor attachment, form factors and packaging can help to reduce the impact of motion disturbances by making sure that the sensor is securely mounted, they are not sufficient for complete MNA removal. Combating MNA in PPG has been the core focus of research for many years.

[0005] Although there are techniques which have been proposed to alleviate the effects of MNA, solutions to this problem still remain unsatisfactory in practice. Several algorithm-based MNA reduction methods have been proposed, such as time and frequency domain filtering, power spectrum analysis, and blind source separation techniques. These techniques reconstruct noise contaminated PPG such that a noise-reduced signal is obtained. However, the reconstructed signal typically contains incomplete dynamic features of the uncorrupted PPG signal and some algorithms are solely designed to capture only the HR and SpO2 information instead of the signal's morphology and its amplitudes, which are needed for other physiological derivations. Moreover, these reconstruction algorithms operate even on clean PPG portions where MNA reduction is not needed. This introduces unnecessary computation burden and distorts the signal integrity of the clean portion of the data. Hence, an accurate MNA detection algorithm, which identifies clean PPG recordings from corrupted portions, is essential for the subsequent MNA reduction algorithm so that it does not distort the non-corrupted data segments.

[0006] MNA detection methods are mostly based on a signal quality index (SQI) which quantifies the severity of the artifacts. Some approaches quantify the SQI using waveform morphologies or filtered output , while other derive the SQI with the help of additional hardware such as accelerometer and electrocardiogram. Statistical measures, such as skewness, kurtosis, Shannon entropy, and Renyi's entropy, have been shown to be helpful in determining the SQI. These statistical algorithms differentiate the distribution of amplitudes between PPG segments with an assumption that clean and corrupt segments would form two separate groups. However, PPG waveforms vary among patients, thus yielding multitude of amplitude distributions. Therefore, it would be difficult to obtain high accuracy from these algorithms in practice. A recently published MNA detection method uses time-domain features such as variability in heart rate, amplitude, and waveform morphology with the help of the support vector machine (SVM)

classifier for detection. The algorithm, which was termed time-domain variability SVM (TDV-SVM) is shown to be more robust than other statistical-based algorithms as it uses successive difference and variability measures. However, this method is highly dependent on accuracy of the peak amplitude detection. Unlike the electrocardiogram (ECG), the PPG waveform does not have distinctive peaks which make accurate peak detection challenging. The dependency on a peak detection subroutine is a drawback of the TDV-SVM algorithm and inevitably affects its performance. Time-frequency (TF) techniques such as Smoothed Pseudo Wigner-Ville, Short Time Fourier Transform, Continuous Wavelet Transform, Hilbert-Huang Transform, and Variable Frequency Complex Demodulation (VFCDM) received considerable attention as means to analysis the signal of interest in both temporal and spectral domains.

[0007] While PPG signals are obtained from a pulse oximeter, other devices can produce signals that behave like PPG signals. For example, color video images obtained from handheld mobile devices (such as smartphones) behave as reflection PPG images

[0008] There is therefore a need to provide a pulse oximeter with real-time detection of MNA to mitigate false readings of heart rates and oxygen saturation values during body movements, which can lead to a wider use of pulse oximeter device for ambulatory applications.

[0009] There is therefore also a need there is, therefore, to provide a device that uses signals that behave as PPG signals, where the device has a component for real-time detection of MNA to mitigate false readings of heart rates and oxygen saturation values during body movements, which can lead to a wider use of the device for ambulatory applications.

BRIEF SUMMARY

[0010] Disclosed herein are methods that can be embedded, in a pulse oximeter or a device that provides signals equivalent to PPG signals, for real-time detection of MNA to mitigate false readings of heart rates and oxygen saturation values during body movements.

[0011] In one or more embodiments, the method of these teachings for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal includes obtaining a time frequency spectrum of a segment of the PPG or equivalent signal, obtaining, from the time frequency spectrum, a noise quality index for the segment and applying a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

Petitioner Ex-1004, 0010

[0012] In one instance, the statistical learning methods includes using a Support Vector Machine (SVM).

[0013] In one or more embodiments, the system of these teachings for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal includes a processor configured to obtain a time frequency spectrum of a segment of the PPG or equivalent signal, obtain, from the time frequency spectrum, a noise quality index for the segment and apply a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

[0014] A number of other embodiments are disclosed herein below.

[0015] For a better understanding of the present teachings, together with other and further needs thereof, reference is made to the accompanying drawings and detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIGS. 1A-D are graphs of the VFCDM-TFS of the present approach;

[0017] FIGS. 2A-B illustrate trace-back strategy to determine the start and end points of MNA;

[0018] FIG. 3 illustrates examples of the trace-back mechanism;

[0019] FIGS. 4A-C are examples of MNA detection using VFCDM;

[0020] FIG. 5 is a graph of noise quality index (noiseQI) computed from the additive white-noise-corrupted PPG data at various signal-to-noise ratios (SNR);

[0021] FIG. 6 is an example of MNA detection using the present VFCDM method versus other methods;

[0022] FIGS. 7A-B are graphs of receiver-operative-curves (ROCs) of all the features used in MNA detection algorithms; and

[0023] FIG. 8 is a schematic block diagram representation of one embodiment of the system of these teachings.

DETAILED DESCRIPTION

[0024] The following detailed description presents the currently contemplated modes of carrying out the disclosure. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the disclosure.

[0025] As used herein, the singular forms “a,” “an,” and “the” include the plural reference unless the context clearly dictates otherwise.

[0026] 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.”

[0027] The following definitions are provided herein in order to facilitate elucidation of these teachings.

[0028] “Photoplethysmogram (PPG) or equivalent signal," as used herein, refers to signals obtained from a pulse oximeter or other devices that produce signals that behave like PPG signals obtained from the pulse oximeter.

[0029] In one or more embodiments, the method of these teachings for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal includes obtaining a time frequency spectrum of a segment of the PPG or equivalent signal, obtaining, from the time frequency spectrum, a noise quality index for the segment and applying a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

[0030] In one instance, obtaining the noise quality index includes determining a dominant frequency in the time frequency spectrum of the segment and normalizing the time frequency spectrum to the total power in a narrow band centered at the dominant frequency.

[0031] In one embodiment, the method of these teachings also includes determining a first trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at the dominant frequency, determining a second trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at twice the dominant frequency, determining a third trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at three times the dominant frequency, subtracting the first, second and third traces of amplitudes from the time frequency spectrum and obtaining, after subtracting, a total power remaining in the time frequency spectrum; the total power remaining hereinafter referred to as a residual noise power.

[0032] In another embodiment, the method of these teachings also includes determining a difference in frequency between the first trace and the second and third traces; the difference in frequency referred to as the projected difference.

[0033] In yet another embodiment, the method of these teachings also includes determining a difference between the dominant frequency and a heart rate obtained from peak to peak intervals from the PPG or equivalent signal in the time domain; the difference between the dominant frequency and the heart rate obtained from peak to peak intervals hereinafter referred to as a heart rate frequency difference.

[0034] In one instance, the noise quality index is a weighted sum of the residual noise power, the projected difference and the heart rate frequency difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment. Embodiments in which one or two of the weights are zero are also within the scope of these teachings.

[0035] In one or more instances, and in the exemplary embodiment presented below, the statistical learning method is a Support Vector Machine (SVM). It should be noted that other statistical learning methods are also within the scope of these teachings.

[0036] In one or more embodiments, the system of these teachings for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal includes a processor configured to obtain a time frequency spectrum of a segment of the PPG or equivalent signal, obtain, from the time frequency spectrum, a noise quality index for the segment and apply a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

[0037] In other embodiments of the system of these teachings, the processor is configured to perform the method of these teachings.

[0038] In one or more embodiments, the computer program product of these teachings includes tangible (also referred to as non-transitory) computer usable media having computer readable code embodied there in which, when executed by one or more processors, causes the one or more processors to perform the method of these teachings.

[0039] In order to further elucidate these teachings, an exemplary embodiment is presented herein below. It should be noted that these teachings are not limited only to the exemplary embodiment.

[0040] Example 1

[0041] Experimental Protocol and Preprocessing

[0042] PPG data were collected from healthy subjects in lab-controlled environment and also from patients enrolled in an emergency room. For the laboratory-controlled environment, both forehead and finger worn PO sensor data were collected from healthy subjects to have more control over the duration of MNA generated data to ensure that the detection algorithms were tested on a wide range of MNA durations. Data from participants recruited from the emergency room environment provided more realistic information about MNA in practice since participants in the lab-controlled study were allowed to move freely as long as the sensors were positioned properly. PPG data were collected by custom-made reflectance-type forehead and a transmission-type finger POs.

[0043] In laboratory-controlled head and finger movement data, motion artifacts were induced by head and finger movements for specific time intervals in both horizontal and vertical directions. For head movement data, 11 healthy volunteers were asked to wear the PO on the forehead along with a reference Masimo Radical (Masimo SET®) finger type transmittance pulse oximeter. After baseline recording for 5 minutes without any movement, subjects were instructed to introduce motion artifacts for specific time intervals varying from 10 to 50% within a 1 minute segment. For example, if a subject was instructed to perform left-right random movements for 6 seconds, 1 min segment of data would contain 10% noise. The finger laboratory movement data were recorded in a similar setup as the head data using a custom-made PPG finger sensor.

[0044] The patient PPG data were recorded from 10 subjects admitted to emergence rooms. Similar to the laboratory-controlled dataset, each patient was fitted with custom-made sensors (both forehead and finger) and the Masimo POs on the forehead and fingers, respectively. The patients were admitted due to pain related symptoms and were not restrained from movements. Therefore, they were expected to generate different MNA characteristics in the recorded PPG.

[0045] To further evaluate the robustness of the present algorithm, Gaussian white-noise of 5 minute duration was added to the clean forehead and finger PPG data with varying signal-to-noise ratios (SNR) ranging from 40dB to -5dB. All PPG data were pre-processed by a 6^{th} order infinite impulse response (IIR) band pass filter with cut-off frequencies of 0.1 Hz and 10 Hz. (Other bandpass filters are within the scope of these teachings) Zero-phase forward and reverse filtering was applied to account for the non-linear phase of the IIR filter. Human visual inspection was also used to establish a MNA reference for the datasets. Three inspectors

individually marked MNA corrupted portions of the PPG data. Disagreements of the marked portions were resolved by majority votes.

[0046] VFCDM Features from PPG Signals

[0047] VFCDM is a method for estimating time-frequency spectrum (TFS) of a time-varying signal (see, for example, Wang H, Siu K, Ju K, Chon KH. A high resolution approach to estimating time-frequency spectra and their amplitudes. Ann Biomed Eng. 2006 Feb;34(2):326-38, which is incorporated by reference herein in its entirety and for all purposes). This method was shown to provide concomitant high time and frequency resolution as well as preservation of the amplitude distribution of the signal. VFCDM has two phases: (1) constructing an initial TFS (iTFS) using a method termed fixed frequency complex modulation (FFCDM); (2) the centered frequencies of the iTFS are used for further complex demodulation (CDM) to obtain even more accurate TFS and amplitude of the TFS. The VFCDM methodology is detailed as followed.

[0048] VFCDM

[0049] 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 $dc(t)$:

$$x(t) = dc(t) + A(t)\cos\left(\int_0^t 2\pi f(\tau)d\tau + \phi(t)\right) \quad (1)$$

For a given center frequency, the instantaneous amplitude information $A(t)$ and phase information $\phi(t)$ can be extracted by multiplying (3) by $e^{-\int_0^t 2\pi f(\tau)d\tau}$ which results in the following:

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

From (2), if $z(t)$ is filtered with an ideal low-pass filter (LPF) with a cutoff frequency $f_c < f_0$, then the filtered signal $z_{lp}(t)$ will contain only the component of interest:

$$z_{lp}(t) = \frac{A(t)}{2}e^{j\phi(t)} \quad (3)$$

The instantaneous frequency is given by $f(t) = f_0 + \frac{1}{2\pi}\frac{d\phi(t)}{dt}$

where f_0 is the centered frequency of interest. By changing the centered frequency followed by

using the variable frequency approach as well as the LPF, the signal,x(t), will be decomposed into the sinusoid modulation by the CDM technique as follows:

$$x(t) = \sum_i d_i$$
$$= dc(t) + \sum_i A_i(t) \cos\left(\int_0^t 2\pi f_i(\tau)d\tau + \phi_i(t)\right) \quad (4)$$

The instantaneous frequency and amplitude of d_i can be calculated using the Hilbert transform

$$A(t) = 2\left|z_{lp}(t)\right| = [X^2(t) + Y^2(t)]^{1/2} \quad (5A)$$
$$X(t) = \text{real}(z_{lp}(t))$$
$$Y(t) = \text{imag}\left(z_{lp}(t)\right) = H[X(t)] = \frac{1}{\pi}\int \frac{X(t')}{t-t'}dt'$$
$$\phi(t) = \arctan\left(\frac{\text{imag}\left(z_{lp}(t)\right)}{\text{real}\left(z_{lp}(t)\right)}\right) = \arctan\left(\frac{Y(t)}{X(t)}\right) \quad (5B)$$

FFCDM operates by performing CDM on fixed frequency f_0 within confined bandwidth and repeat it over entire frequency band. In order to obtain even higher resolution TFS, center frequencies in iTFS obtained from FFCDM were used for subsequent CDM with finer bandwidth.

[0050] MNA Discriminative Feature from VFCDM-TFS

[0051] An example of VFCDM-TFS is shown in FIGS. 1A-D. The HR trace and two of its harmonic traces are termed as FM_1, FM_2, FM_3, respectively, with the corresponding amplitudes AM_1, AM_2, AM_3. The algorithm first determines the dominant frequency in the PPG segment termed f_{HR}. The TFS of the data segment is normalized by the total power in the f_{HR} band. It then extracts AM_1 from a narrow band spectrum of the TFS centered at the dominant frequency $AM_1 \in [f_{HR} - BW, f_{HR} + BW]$. In one instance, the bandwidth of the band, BW, is about 0.2 Hz (other values of the bandwidth are within the scope of these teachings). The maximal power in each time instance is taken to form AM_1 in the segment. Once located, AM_1 is removed from the TFS. Similarly, $AM_2 \in [2f_{HR} - BW, 2F_{HR} + BW]$ and $AM_3 \in [3f_{HR} - BW, 3f_{HR} + BW]$ are found and removed. From the extracted TFS, FMs and AMs, three features were derived to quantify the noise level between clean versus corrupted PPG segments.

[0052] Residual noise power (P_{noise})

[0053] After extracting the first three dominant traces, remaining power in the TFS is considered the residual noise power P_{noise} and is denoted as:

$$P_{noise} = P_{TFS} - \sum_{i=1}^{3} \sum_{j} AM_{i,j} \quad (6)$$

where P_{noise} is the total power in the TFS after extracting the first three dominant traces. In a clean PPG segment, the first three harmonics would be located within the predetermined narrow band. Thus extracting their power would effectively remove most of the spectral power from the TFS. The remaining noise power would be negligibly small. On the other hand, artifacts in the corrupted PPG segment produce spectral power at various frequency locations which are often not associated with the harmonics' frequency bands. Some of these spectral power would not be extracted which in turn yields high P_{noise} level.

[0054] Projected frequency modulation difference (df_{FM})

[0055] Projected difference is defined as the difference in frequency between the fundamental HR trace and its harmonic traces and is computed as:

$$df_{FM} = \sum_{i=2}^{3} \sum_{j} FM_{1,j} - i \times FM_{i,j} \quad (7)$$

Similar to the previous assumption, frequency location of the harmonic traces are expected to be proportional to that of the fundamental trace, which would result in a low df_{FM} for a clean segment. For artifact corrupted segment, the proportionality in the frequency of the harmonics would no longer hold, thus driving df_{FM} value to be high.

[0056] Heart rate frequency difference (df_{HR})

[0057] Heart rate frequency difference is defined as the difference between the fundamental frequency modulation FM_1 and HR computed from time-domain peak calculation and is computed as:

$$df_{HR} = FM_1 - \frac{1}{\Delta peak} \quad (8)$$

where $\Delta peak$ (sec) is the HR computed from the peak-to-peak intervals within a PPG segment. In one instance, a median of the peak-to-peak intervals within a PPG segment is used as the HR computed from time-domain peak calculation.

[0058] The three features P_{noise}, df_{FM}, and df_{HR} are combined into a weighted sum that represents noise quality index, noiseQI in a PPG segment.

$$noiseQI = c_1 P_{noise} + c_2 df_{FM} + c_3 df_{HR} \quad (9)$$

where c_i is the weight of each feature and is determined empirically such that each weighted

feature contributes no more than 5% in the clean PPG segments (other predetermined percentages are also within the scope of these teachings). In the instance where the predetermined percentage is 5%, a typical MNA-free PPG segment should not have *noiseQI* greater than 0.15.

[0059] The noiseQI is very sensitive as noise dynamics contained in only 1 second duration in a 4-second data segment is classified as noise corrupted. This is because the noise region introduces many frequencies and spectral dynamics that are distinctively dissimilar than the clean signal. Hence, as noted above, P_{noise}, df_{FM}, df_{HR}, and consequently the noiseQI of the MNA corrupted segment will all be significantly larger and distinct from the clean signal's values.

[0060] SVM-based Detection of Motion/Noise Artifacts

[0061] Feature extraction from PPG

[0062] The preprocessed PPG was used to extract the noiseQI, as mentioned above. A sliding window of length L_1 = 8 second with 50% overlap was used to extract the raw PPG signal. The signal was band-pass filtered at 0.1 – 20 Hz and then down-sampled to 20Hz. Only the middle portion of length $L_2 = 4$ second of the resulting TFS was considered for further processing. This is because, as shown below, the middle 4 second data length from the initial L_1 = 8 second for the subsequent VFCDM analysis provided the best accuracy in detection of MNA.

[0063] To accurately pinpoint the time occurrence of MNA, a trace-back strategy was implemented, which is triggered when the noiseQI value changes its state as illustrated in FIGS. 2A-B. When noiseQI goes from lower than a threshold value of 0.2 to greater than 0.2 (it should be noted that others threshold values are within the scope of these teachings; for example, a threshold value of 0.15 would be within the scope of these teachings), the trace-back algorithm computes a new noiseQI three times with shifting backward a second at each time instant. For example, in FIG. 2A, noiseQI changes to a value that is greater than 0.2 at time duration 4-8 seconds. The trace-back scheme would call the VFCDM routine to compute new noiseQI values for the back-shifted segments at time durations starting at 3-7 seconds, 2-6 seconds, and ending at 1-5 seconds. The threshold noiseQI $= 0.2$ was empirically determined to represent the presence of MNA. As detailed above, the VFCDM algorithm is designed to indicate that a segment is corrupted even if only 1 second of the 4 second duration data contain MNA. Hence, since the 3-7 second segment is determined to be corrupted, it allows deduction that the 8th

second time point is corrupted. The same logic applies to the 2-6 and 1-5 second segments. If MNA starts at the 5th second, it is expected that the updated noiseQI values would be low prior to the 5th second while remain high for the segments after the 5th second. Similarly, MNA end point is determined by applying the trace-back algorithm when noiseQI goes from higher than 0.2 to lower than 0.2. An example of the track-back strategy on an actual PPG signal is illustrated in FIG. 3.

[0064] Classification by Support Vector Machine (SVM)

[0065] SVM was applied to build a decision boundary to classify the MNA segment from the clean PPG data. SVM is widely used for classification and regression analysis due to its accuracy and robustness to noise. The SVM consists of training and test phases as briefly described in the following sections (see, for example, CHRISTOPHER J.C. BURGES, A Tutorial on Support Vector Machines for Pattern Recognition, which is incorporated by reference herein in its entirety and for all purposes).

[0066] The SVM takes a priori determined classification parameter values of the clean and corrupted PPG segments as a training data set, finds the support vectors among the training data set which maximize the margin (or the distance) between different classes, and then builds a decision boundary. If the estimated decision is different from its known label, the decision is regarded as a training error. A soft-margin SVM can set the boundary even when the data sets are mixed and cannot be separated. In the soft-margin SVM algorithm, slack variables are introduced to minimize the training error while maximizing the margin. Soft-margin SVM uses the following equation to find the support vectors.

$$\text{Minimize } C\sum_{sv=1}^{N}\delta_{sv}+\frac{1}{2}\langle \mathbf{w}_s,\mathbf{w}_s\rangle,$$

$$\text{Subject to } T_{sv}(\langle \mathbf{w}_s,\mathbf{y}_{sv}\rangle+b_s)\geq \delta_{sv}$$

$$\text{for } sv=1,2,\ldots,N \quad \text{and} \quad \delta\_sv\geq 0 \tag{10}$$

where C is a regulation parameter, N is the number of vectors, δ_{sv} is the slack variable, $\mathbf{w}_s$ is weight vector and $\langle\cdot,\cdot\rangle$ is the inner product operation. The T_{sv} is the sv^{th} target variable, $\mathbf{y}_{sv}$ is the sv^{th} input vector data, and b_s is the bias. The SVM decision boundary F_{sv} is derived as

$$F_{sv}=\langle \mathbf{w}_s^*,\mathbf{y}\rangle+b_s^*=0 \tag{11}$$

where w_s^* and b_s^* are weight factor and bias, respectively, obtained from Eq. (20) and $\mathbf{y}$ is the input point. By transforming the $\mathbf{y}_{sv}$ and $\mathbf{y}$ terms to $\mathbf{y}_{sv}\rightarrow\Phi(\mathbf{y}_{sv})$ and $\mathbf{y}\rightarrow\Phi(\mathbf{y})$, the non-linear

SVM can be transformed to a linear SVM. For nonlinear SVM, Eq. (20) is modified as

$$T_{sv}(\langle \mathbf{w}_s, \Phi(\mathbf{y}_{sv})\rangle + b_s) \geq 1 \quad (12)$$

To facilitate the operation in nonlinear SVM, a kernel function $K_s(\cdot,\cdot)$, which is a dot-product in the transformed feature space is used as the following:

$$K_s(\mathbf{y}_{sv}, \mathbf{y}_{sv'}) = \langle \Phi(y_{sv}), \Phi(y_{sv'})\rangle \quad (13)$$

where $sv' = 1,2, \ldots, N$. Once the training phase is completed, the optimal support vectors for training data are determined. These vectors are then used to classify the testing data so that the optimal solution of mutually exclusive boundaries can be determined.

[0067] Results

[0068] The performance of the VFCDM-based MNA detection algorithm was evaluated for various types (laboratory controlled, and hospital patients) of motion-corrupted PPGs to validate its performance for a wide range of scenarios. K-fold cross validation was adopted to evaluate the performance of the present algorithm. Specifically, for a dataset of N subjects, data from N-1 subjects were used for training and the unused subject data were used for testing. The train-test cycle was repeated N times, each time with a different test subject. The regularization parameter value $C = 10$ was optimized for the linear kernel SVM by minimizing the training error. FIGS. 4A-C show representative illustrations of the performance of the present approach. FIG. 4A displays the filtered PPG signal containing both clean and MNA which is corrupted with varying levels of amplitude fluctuations. FIG. 4B depicts the corresponding noiseQI which was obtained according to Eq. (9). As shown, the noiseQI has low values for the clean portion of the data whereas it is high where the MNA occurs. The noiseQI is used for the SVM classifier to determine whether the given segment is clean or corrupted. FIG. 4C shows the classification results via the present approach along with the trained experts' decision of the occurrence of the MNA for comparison. For this example, it was observed that the present approach has a high sensitivity and specificity in detecting MNA.

[0069] The optimal window length was determined by varying L_2 from 3 to 6 sec while keeping L_1 constant at 8 sec. Detection performance was evaluated by comparing the classification results to the MNA reference (as determined visually by the experts) to yield accuracy, sensitivity, and specificity. Table I shows performance statistics in terms of accuracy (Acc), sensitivity (Sen), and specificity (Spe) of the present MNA detection algorithm at various window lengths (L_2) for the laboratory collected dataset. The window length of 4 sec ($L_2 =$

4 second) yielded the best performance in term of accuracy among the various window lengths examined.

TABLE I. MEAN ± STD. DEVIATION OF PERFORMANCE METRICS OF THE PRESENT VFCDM USING VARIOUS WINDOW LENGTH

L		3s	4s	5s	6s
Lab. Head	Acc	86.9 ± 5.5	96.9 ± 1.4	87.2 ± 4.2	84.1 ± 9.3
	Sen	81.8 ± 9.7	96.3 ± 2.4	80.3 ± 6.8	75.5 ± 16.4
	Spe	89.4 ± 6.2	97.7 ± 2.0	80.3 ± 3.1	89.3 ± 8.0

[0070] The noiseQI value indicates the amount of noise present in the PPG segment. It is of interest to evaluate how well this parameter correlates with the actual noise at various levels. Therefore, the noiseQI values were computed for simulated data consisting of clean forehead and finger PPG data corrupted by additive white noise of varying SNR levels. The results are shown in FIG. 5. As shown, the noiseQI is consistently low for PPG signals with high SNR values and high for PPG signals with low SNR values with reaching a unity value for SNR less than 0 dB for both finger and forehead PPG data.

[0071] The present algorithm was compared with three other recently published MNA detection algorithms: 1) Hjorth features (Hjorth), 2) time-domain variability SVM (TDV-SVM) approach, and 3) Kurtosis-Shannon Entropy (KSE) features. A representative example of the MNA detection comparing all of the aforementioned methods is illustrated in FIG. 6. Performance results of each method are presented in Table II.

TABLE II. MEAN ± STD. DEVIATION OF PERFORMANCE METRICS OF THE PRESENT VFCDM, OTHER METHODS

		VFCDM	Hjorth		TDV		KSE	
Lab. Head	Acc	96.9 ± 1.4	72.5 ± 10.7	*	93.4 ± 3.5	*	83.1 ± 7.3	*
	Sen	96.3 ± 2.4	47.2 ± 28.8	*	88.8 ± 7.9	*	56.6 ± 17.9	*
	Spe	97.7 ± 2.0	84.4 ± 4.6	*	96.7 ± 3.0		91.5 ± 1.1	*
Umass. Head	Acc	95.5 ± 2.2	69.5 ± 21.8	*	89.8 ± 1.4	*	85.1 ± 8.3	*
	Sen	91.1 ± 3.5	53.8 ± 26.1	*	84.6 ± 2.9	*	68.7 ± 17.7	*
	Spe	96.3 ± 1.4	84.5 ± 8.8	*	94.3 ± 4.0		86.4 ± 7.8	*
Lab. Finger	Acc	97.7 ± 1.4	91.1 ± 6.9	*	94.4 ± 3.3	*	58.5 ± 20.7	*
	Sen	96.3 ± 2.6	83.5 ± 21.0	*	94.7 ± 3.4		34.6 ± 12.2	*
	Spe	98.2 ± 1.4	96.2 ± 3.0		94.7 ± 3.0	*	86.3 ± 15.7	*
Umass. Finger	Acc	95.5 ± 2.4	71.0 ± 19.0	*	89.6 ± 2.3	*	88.3 ± 2.7	*
	Sen	89.2 ± 2.0	41.1 ± 27.6	*	85.2 ± 3.8	*	71.5 ± 8.8	*
	Spe	97.2 ± 2.1	88.4 ± 7.5	*	95.1 ± 0.8		93.6 ± 1.5	*

(*) indicate statistical significance ($p<0.01$) between the present method versus the others

[0072] Two-sample one-sided Welch's t-tests at 95% confidence interval was performed to assess the significance of the accuracy, sensitivity, and specificity results from the K-fold cross-validation. In order to measure and compare the detection powers, receiver operative characteristic (ROC) curves were generated for all the features used in the present VFCDM algorithm and other detection algorithms. Areas under these curves (AUCs) represent the strength of these features. In FIG. 7, ROC curves with highest AUC values were shown. The VFCDM-derived features obtained the highest AUC values among all methods compared.

[0073] In addition to accurate MNA detection, the other attractive feature of the present algorithm is that it is able to accurately locate the start and end points of MNA occurrences. Accurate detection of the start and end time of the MNA is important for the subsequent reconstruction of the MNA-corrupted data in order not to miss the MNA portion of data for reconstruction or avoid having to reconstruct the noisy portion of the PPG signal when the data segment is designated to be clean. To evaluate the algorithm's effectiveness in pinpointing the start and end time of the MNA, the time difference of start and end points was computed between the visual reference and detection algorithms' results. The time difference is termed detection transition time, DTT, which reflects how accurate on average the MNA algorithm detects the start and end time of the MNA. Table III provides DTT comparison of the VFCDM algorithm and other detection algorithms. As shown in Table III, the algorithm's detection

accuracy of the duration of the MNA is significantly better than three other methods compared. The algorithm is off by less than 1 second whereas the second best algorithm, the Hjorth, is off by more than 2 seconds and the least accurate method, the KSE, is off by more than 4 seconds.

TABLE III. MEAN ± STD. DETECTION OF TRANSITION TIME, DTT OF THE VFCDM METHOD AND OTHER METHODS.

Algorithm	DTT (sec)
VFCDM	0.94 ± 0.65
Hjorth	2.17 ± 0.37 *
KSE	4.24 ± 2.42 *
TDV	2.75 ± 0.96 *

(*) indicate statistical significance ($p<0.01$) between the present method versus the others

[0074] Discussion

[0075] Disclosed is a pulse oximeter using a novel MNA detection method that uses dynamic characteristics of the corrupted PPG derived via the VFCDM. The efficacy of the detection method was validated using contrived motion data from healthy subjects and unconstrained MNA data from participants recruited from a hospital setting. In this study, several key features associated with MNA, derived from the VFCDM-based time-frequency spectrum, were utilized for detection of MNA. By transforming the PPG time series into the time-frequency domain, time-varying characteristics were better captured of the MNA. Specifically, it was recognized that PPG's clean signal dynamics are largely concentrated at the heart rate and its harmonic frequency bands. Hence, the presence of large amplitudes in the other frequency bands must be associated with MNA. This is clearly seen in FIG. 1B as VFCDM results from a clean PPG signal yields distinct peaks across all times at the HR frequencies and its two successive harmonic frequencies. Therefore, the TFS was divided into three narrow band spectra and tracked down these amplitude traces accordingly. In a clean PPG segment (shown in FIGs. 1A-B) most of the spectral power is concentrated in the FM_1, FM_2, and FM_3 traces since the signal is sinusoidal-like and periodic in nature. In a MNA corrupted PPG segment shown in FIGs. 1C-D, however, the signal is disturbed by inconsistent changes in the signal amplitude due to motion. These changes are typically irregular thus creating various spectral contents in the resulting TFS

and eventually yielding high noiseQI values as defined in Eq. (8). Hence, the noiseQI values provide a quantitative measure of the MNA that is present in the PPG signal.

[0076] Results in FIG. 5 indicate that if the SNR cutoff threshold is set at 15dB to discriminate between the clean and corrupted PPG data segments, then the corresponding noiseQI cutoff threshold would be around 0.14, and 0.22 for the head and finger data, respectively. Finger PPG waveforms for some people contain prominent traces of the dicrotic notch, which results in additional high frequency components. The VFCDM algorithm assumes that the HR cycle is the dominant component of the PPG waveform and the remaining components are considered as noise. Therefore, the noiseQI values of the finger PPG are higher than of the head PPG due to additional high frequency components introduced by the dicrotic notch. It can also be speculated that PPG recorded from peripheral regions (e.g., finger) is modulated at a higher intensity compared to forehead, which may explain the higher noiseQI values for the former location. Hence, due to the intrinsic difference in morphological properties of PPG recorded from the finger and forehead, training for MNA detection needs to be done separately for these two measurement locations.

[0077] The detection accuracy on both lab-controlled and UMMC datasets using the present methods outperformed the other three detection methods: Hjorth, TDV-SVM, and KSE. Each method's detectability was first compared based on their own unique feature selection by evaluating the area under the ROC curve. The AUCs showed that the noiseQI feature provided the highest value at 0.986 for both finger and forehead recorded PPG, as shown in FIG. 7. Concomitantly, the accuracy, sensitivity and specificity values of the present method were significantly higher than all other methods as indicated in Table II.

[0078] The eventual aim of the present algorithm is to detect MNA in real time. The algorithm only takes 33.3ms to compute noiseQI for a 4s PPG window length using Matlab running on a PC with the Intel Xeon processor operating at 3.6GHz. Therefore, it would be straightforward to optimize the algorithm for real time detection of MNA in a PPG signal.

[0079] In conclusion, the present approach is an accurate MNA detection algorithm that utilizes both time and spectral features to classify between a clean and corrupted PPG data segments. Comparison of the algorithm to existing methods using two datasets far better performance of the algorithm that other contemporary MNA detection algorithms. The algorithm also showed superiority with respect to detecting onset and offset of MNA. Moreover, the algorithm is real-

time realizable and it is applicable to either transmission (finger) or reflectance (forehead) recorded PPG signals.

[0080] In one embodiment, the system of these teachings includes one or more processors and one or more computer usable media having computer readable code embodied therein, the computer readable code causing the one or more processors to execute the method of these teachings, shown in Fig. 8. Referring to Fig. 8, in the embodiment shown there in, one or more processors 110 are operatively connected to computer usable media 120 that has computer readable code embodied therein, which, when executed by the one or more processors 110, causes the one or more processors to perform the method of these teachings. An input device 130 is operatively connected to the one or more processors 110 and to the computer usable media 120 and enables the inputs of the PPG data segments. The one or more processors 110, the computer readable media 120 and the input device 130 are operatively connected by means of a computer connection component 125 (such as a computer bus).

[0081] The capability to extract accurate PPG equivalent signals, HR signals, heart rate variability dynamics, the respiratory rates and oxygen saturation information directly from the green, red, and blue band signals from a smart phone is detailed in a recently published paper (see also PCT Publication No. WO2012100175, corresponding to PCT/US2012/022049, PHYSIOLOGICAL PARAMETER MONITORING WITH A MOBILE COMMUNICATION DEVICE, filed on January 20, 2012, and corresponding U.S. Published application 2012190947, PHYSIOLOGICAL PARAMETER MONITORING WITH A MOBILE COMMUNICATION DEVICE, which are incorporated by reference herein in their entirety and for all purposes).

[0082] The following is a disclosure by way of example of a device configured to execute functions (hereinafter referred to as computing device) which may be used with the presently disclosed subject matter. The description of the various components of a computing device is not intended to represent any particular architecture or manner of interconnecting the components. Other systems that have fewer or more components may also be used with the disclosed subject matter. A communication device may constitute a form of a computing device and may at least include a computing device. The computing device may include an inter-connect (e.g., bus and system core logic), which can interconnect such components of a computing device to a data processing device, such as a processor(s) or microprocessor(s), or other form of partly or completely programmable or pre-programmed device, e.g., hard wired and or application

specific integrated circuit ("ASIC") customized logic circuitry, such as a controller or microcontroller, a digital signal processor, or any other form of device that can fetch instructions, operate on pre-loaded/pre-programmed instructions, and/or followed instructions found in hard-wired or customized circuitry to carry out logic operations that, together, perform steps of and whole processes and functionalities as described in the present disclosure.

[0083] In this description, various functions, functionalities and/or operations may be described as being performed by or caused by software program code to simplify description. However, those skilled in the art will recognize what is meant by such expressions is that the functions result from execution of the program code/instructions by a computing device as described above, e.g., including a processor, such as a microprocessor, microcontroller, logic circuit or the like. Alternatively, or in combination, the functions and operations can be implemented using special purpose circuitry, with or without software instructions, such as using Application-Specific Integrated Circuit (ASIC) or Field-Programmable Gate Array (FPGA), which may be programmable, partly programmable or hard wired. The application specific integrated circuit ("ASIC") logic may be such as gate arrays or standard cells, or the like, implementing customized logic by metallization(s) interconnects of the base gate array ASIC architecture or selecting and providing metallization(s) interconnects between standard cell functional blocks included in a manufacturer's library of functional blocks, etc. Embodiments can thus be implemented using hardwired circuitry without program software code/instructions, or in combination with circuitry using programmed software code/instructions.

[0084] Thus, the techniques are limited neither to any specific combination of hardware circuitry and software, nor to any particular tangible source for the instructions executed by the data processor(s) within the computing device. While some embodiments can be implemented in fully functioning computers and computer systems, various embodiments are capable of being distributed as a computing device including, e.g., a variety of forms and capable of being applied regardless of the particular type of machine or tangible computer-readable media used to actually effect the performance of the functions and operations and/or the distribution of the performance of the functions, functionalities and/or operations.

[0085] The memory may include any tangible computer-readable media, which may include but are not limited to recordable and non-recordable type media such as volatile and non-volatile memory devices, such as volatile RAM (Random Access Memory), typically implemented as

dynamic RAM (DRAM) which requires power continually in order to refresh or maintain the data in the memory, and non-volatile ROM (Read Only Memory), and other types of non-volatile memory, such as a hard drive, flash memory, detachable memory stick, etc. Non-volatile memory typically may include a magnetic hard drive, a magnetic optical drive, or an optical drive (e.g., a DVD RAM, a CD ROM, a DVD or a CD), or other type of memory system which maintains data even after power is removed from the system.

[0086] At least some aspects of the disclosed subject matter can be embodied, at least in part, utilizing programmed software code/instructions. That is, the functions, functionalities and/or operations techniques may be carried out in a computing device or other data processing system in response to its processor, such as a microprocessor, executing sequences of instructions contained in a memory, such as ROM, volatile RAM, non-volatile memory, cache or a remote storage device. In general, the routines executed to implement the embodiments of the disclosed subject matter may be implemented as part of an operating system or a specific application, component, program, object, module or sequence of instructions usually referred to as "computer programs," or "software." The computer programs typically comprise instructions stored at various times in various tangible memory and storage devices in a computing device, such as in cache memory, main memory, internal or external disk drives, and other remote storage devices, such as a disc farm, and when read and executed by a processor(s) in the computing device, cause the computing device to perform a method(s), e.g., process and operation steps to execute an element(s) as part of some aspect(s) of the method(s) of the disclosed subject matter.

[0087] A tangible machine readable medium can be used to store software and data that, when executed by a computing device, causes the computing device to perform a method(s) as may be recited in one or more accompanying claims defining the disclosed subject matter. The tangible machine readable medium may include storage of the executable software program code/instructions and data in various tangible locations, including for example ROM, volatile RAM, non-volatile memory and/or cache. Portions of this program software code/instructions and/or data may be stored in any one of these storage devices. Further, the program software code/instructions can be obtained from remote storage, including, e.g., through centralized servers or peer to peer networks and the like. Different portions of the software program code/instructions and data can be obtained at different times and in different communication sessions or in a same communication session. The software program code/instructions and data

can be obtained in their entirety prior to the execution of a respective software application by the computing device. Alternatively, portions of the software program code/instructions and data can be obtained dynamically, e.g., just in time, when needed for execution. Alternatively, some combination of these ways of obtaining the software program code/instructions and data may occur, e.g., for different applications, components, programs, objects, modules, routines or other sequences of instructions or organization of sequences of instructions, by way of example. Thus, it is not required that the data and instructions be on a single machine readable medium in entirety at any particular instance of time.

[0088] In general, a tangible machine readable medium includes any tangible mechanism that provides (i.e., stores) information in a form accessible by a machine (i.e., a computing device, which may be included, e.g., in a communication device, a network device, a personal digital assistant, a mobile communication device, whether or not able to download and run applications from the communication network, such as the Internet, e.g., an I-phone, Blackberry, Droid or the like, a manufacturing tool, or any other device including a computing device, comprising one or more data processors, etc.

[0089] 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 representation may vary from a stated reference without resulting in a change in the basic function of the subject matter at issue.

[0090] Although these 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.

[0091] What is claimed is:

CLAIMS

1. A computer implemented method for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal, the computer implemented method comprising:

obtaining a time frequency spectrum of a segment of the PPG or equivalent signal;

obtaining, from the time frequency spectrum, a noise quality index for the segment; the noise quality index being used to determine whether a segment is corrupted by motion and noise artifacts; and

applying a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

2. The computer implemented method of claim 1 wherein obtaining a noise quality index comprises:

determining a dominant frequency in the time frequency spectrum of the segment; and

normalizing the time frequency spectrum to a total power in a narrow band centered at the dominant frequency.

3. The computer implemented method of claim 2 further comprising:

determining a first trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at the dominant frequency;

determining a second trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at twice the dominant frequency;

determining a third trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at three times the dominant frequency;

subtracting the first, second and third traces of amplitudes from the time frequency spectrum; and

obtaining, after subtracting, a total power remaining in the time frequency spectrum; the total power remaining hereinafter referred to as a residual noise power.

4. The computer implemented method of claim 3 wherein the noise quality index is the residual noise power.

Petitioner Ex-1004, 0029

5. The computer implemented method of claim 4 wherein the statistical learning method is a Support Vector Mahine (SVM).

6. The computer implemented method of claim 3 further comprising:

determining a difference in frequency between the first trace and the second and third traces; the difference in frequency referred to as a projected difference.

7. The computer implemented method of claim 6 wherein the noise quality index is a weighted sum of the residual noise power and the projected difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

8. The computer implemented method of claim 7 wherein the statistical learning method is a Support Vector Machine (SVM).

9. The computer implemented method of claim 6 further comprising determining a difference between the dominant frequency and a heart rate obtained from peak to peak intervals from the PPG or equivalent signal in a time domain; the difference between the dominant frequency and the heart rate obtained from peak to peak intervals hereinafter referred to as a heart rate frequency difference.

10. The computer implemented method of claim 9 wherein the noise quality index is a weighted sum of the residual noise power, the projected difference and the heart rate frequency difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

11. The computer implemented method of claim 10 wherein the statistical learning method is a Support Vector Machine (SVM).

12. The computer implemented method of claim 3 further comprising determining a difference between the dominant frequency and a heart rate obtained from peak to peak intervals

from the PPG or equivalent signal in a time domain; the difference between the dominant frequency and the heart rate obtained from peak to peak intervals hereinafter referred to as a heart rate frequency difference.

13. The computer implemented method of claim 12 wherein the noise quality index is a weighted sum of the residual noise power and the heart rate frequency difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

14. The computer implemented method of claim 13 wherein the statistical learning method is a Support Vector Machine (SVM).

15. The computer implemented method of claim 1 wherein the PPG or equivalent signal is preprocessed before obtaining the time frequency spectrum.

16. The computer implemented method of claim 15 wherein the PPG or equivalent signal is preprocessed by filtering with a bandpass filter of predetermined bandwidth.

17. The computer implemented method of claim 1 wherein the time frequency spectrum is obtained using variable frequency complex demodulation.

18. A system for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal, the system comprising:

a processor configured to:

receive the PPG or equivalent signal;

obtain a time frequency spectrum of a segment of the PPG or equivalent signal;

obtain, from the time frequency spectrum, a noise quality index for the segment; the noise quality index being used to determine whether a segment is corrupted by motion and noise artifacts; and

apply a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

Petitioner Ex-1004, 0031

19. The system of claim 18 wherein, for obtaining a noise quality index, the processor is configured to:

determine a dominant frequency in the time frequency spectrum of the segment; and

normalize the time frequency spectrum to the total power in a narrow band centered at the dominant frequency.

20. The system of claim 19 wherein the processor is further configured to:

determine a first trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at the dominant frequency;

determine a second trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at twice the dominant frequency;

determine a third trace of amplitudes in a narrow band spectrum of the time frequency spectrum centered at three times the dominant frequency;

subtract the first, second and third traces of amplitudes from the time frequency spectrum; and

obtain, after subtracting, a total power remaining in the time frequency spectrum; the total power remaining hereinafter referred to as a residual noise power.

21. The system of claim 20 wherein the noise quality index is the residual noise power.

22. The system of claim 21 wherein the statistical learning method is a Support Vector Machine (SVM).

23. The system of claim 20 wherein the processor is further configured to determine a difference in frequency between the first trace and the second and third traces; the difference in frequency referred to as a projected difference.

24. The system of claim 23 wherein the noise quality index is a weighted sum of the residual noise power and the projected difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

25. The system of claim 24 wherein the statistical learning method is a Support Vector Machine (SVM).

26. The system of claim 23 wherein the processor is further configured to determine a difference between the dominant frequency and a heart rate obtained from peak to peak intervals from the PPG or equivalent signal in a time domain; the difference between the dominant frequency and the heart rate obtained from peak to peak intervals hereinafter referred to as a heart rate frequency difference.

27. The system of claim 26 wherein the noise quality index is a weighted sum of the residual noise power, the projected difference and the heart rate frequency difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

28. The system of claim 27 wherein the statistical learning method is a Support Vector Machine (SVM).

29. The system of claim 20 wherein the processor is further configured to determine a difference between the dominant frequency and a heart rate obtained from peak to peak intervals from the PPG or equivalent signal in a time domain; the difference between the dominant frequency and the heart rate obtained from peak to peak intervals hereinafter referred to as a heart rate frequency difference.

30. The system of claim 29 wherein the noise quality index is a weighted sum of the residual noise power and the heart rate frequency difference; weights being selected such that each weighted factor represents less than a predetermined percentage of power in an uncorrupted segment.

31. The system of claim 30 wherein the statistical learning method is a Support Vector Machine (SVM).

32. The system of claim 18 wherein the processor is further configured to preprocess the PPG or equivalent signal before obtaining the time frequency spectrum.

33. The system of claim 32 wherein the processor is configured to preprocess the PPG or equivalent signal by filtering with a bandpass filter of predetermined bandwidth.

34. The system of claim 18 wherein the processor is configured to obtain the time frequency spectrum using variable frequency complex demodulation.

35. A computer program product comprising:

tangible computer usable media, having computer readable code embodied therein, the computer readable code, when executed by the one or more processors, causes the one or more processors to:

obtain a time frequency spectrum of a segment of a PPG or equivalent signal;

obtain, from the time frequency spectrum, a noise quality index for the segment; the noise quality index being used to determine whether a segment is corrupted by motion and noise artifacts; and

apply a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts.

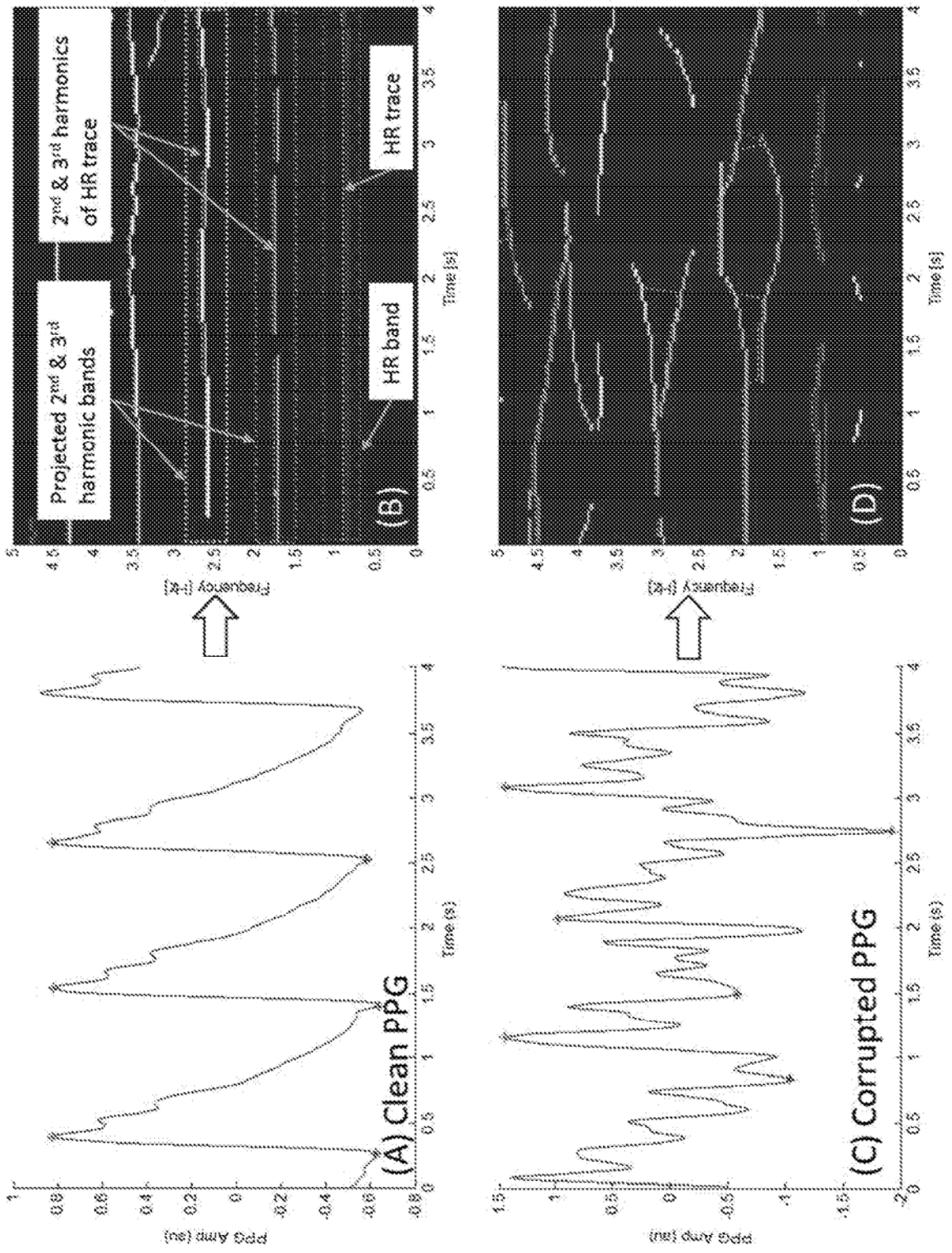
36. The computer program product of claim 35 wherein the statistical learning method is a Support Vector Machine (SVM).

ABSTRACT

A pulse oximeter embedded with a novel motion and noise artifact (MNA) detection algorithm based on extraction of time-varying spectral features that are unique to the clean and corrupted components.

4833-4625-4125.2

Petitioner Ex-1004, 0035


(A) Clean PPG
PPG Amp (au)
Time (s)
(B)
Projected 2nd & 3rd harmonic bands
2nd & 3rd harmonics of HR trace
HR band
HR trace
Frequency (Hz)
Time (s)
(C) Corrupted PPG
PPG Amp (au)
Time (s)
(D)
Frequency (Hz)
Time (s)

FIGS. 1A-D

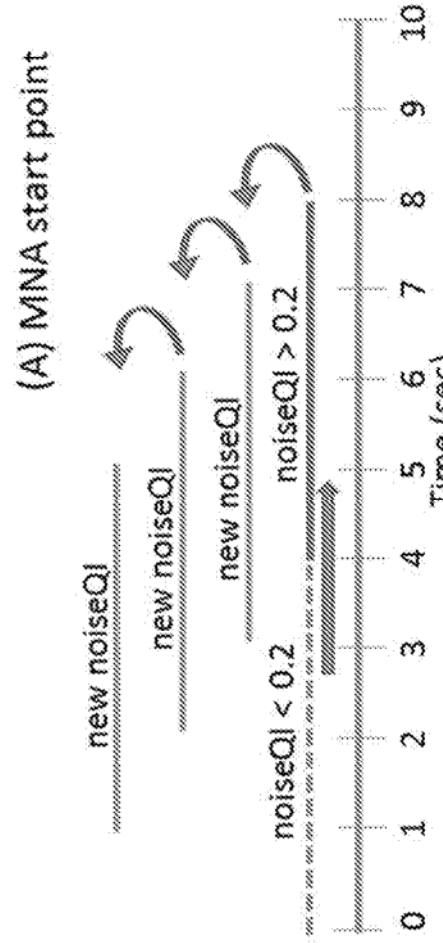

(A) MNA start point
new noiseQI
new noiseQI
new noiseQI
noiseQI < 0.2
noiseQI > 0.2
0 1 2 3 4 5 6 7 8 9 10
Time (sec)

FIG. 2A

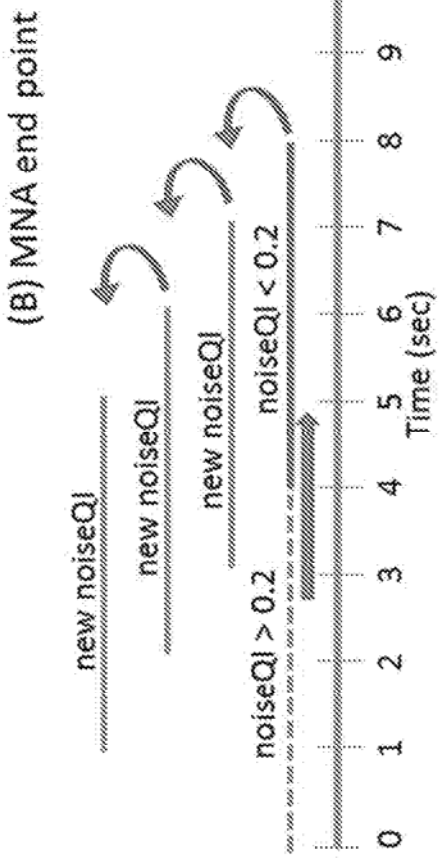

(B) MNA end point
new noiseQI
new noiseQI
new noiseQI
noiseQI > 0.2
noiseQI < 0.2
0 1 2 3 4 5 6 7 8 9 10
Time (sec)

FIG. 2B

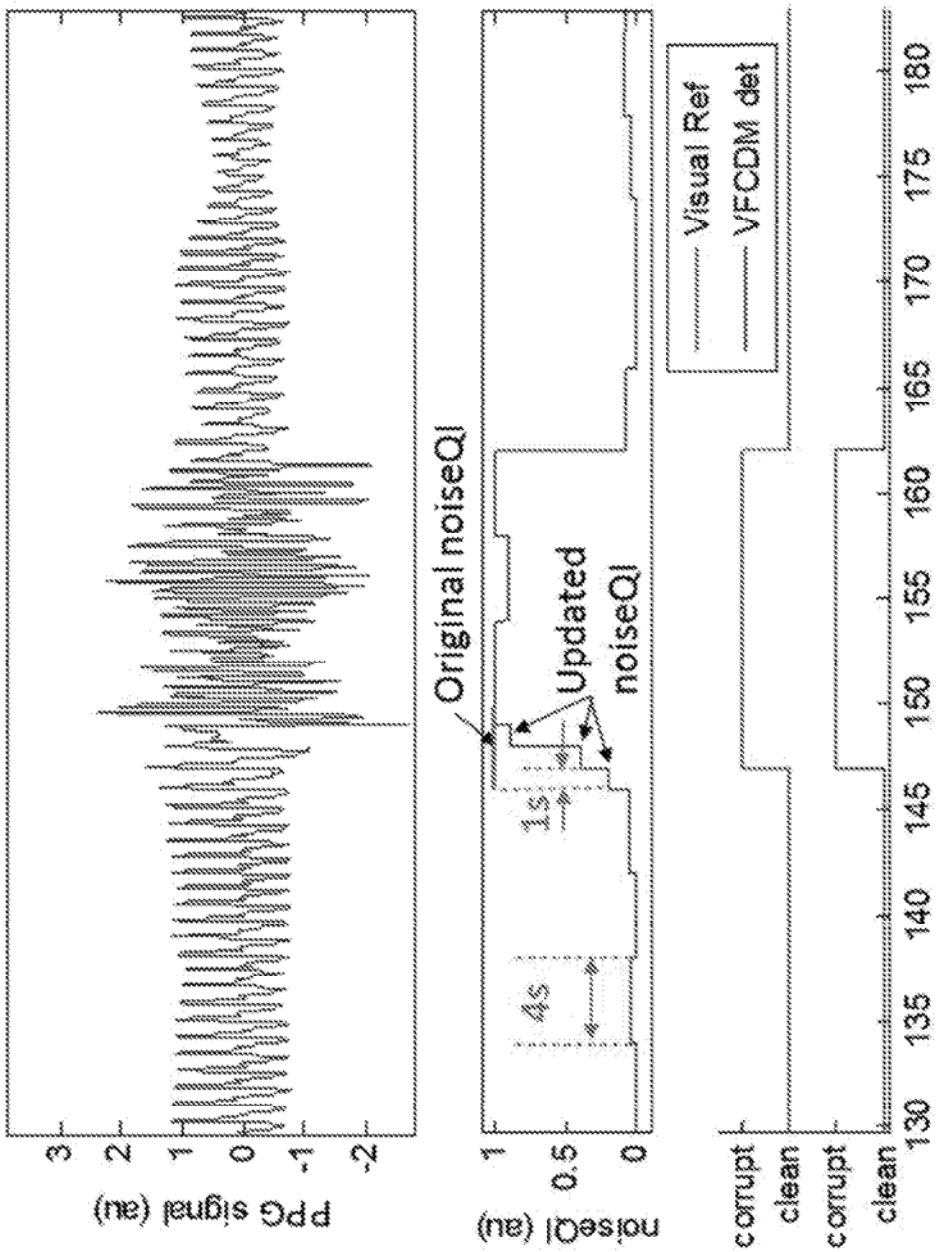
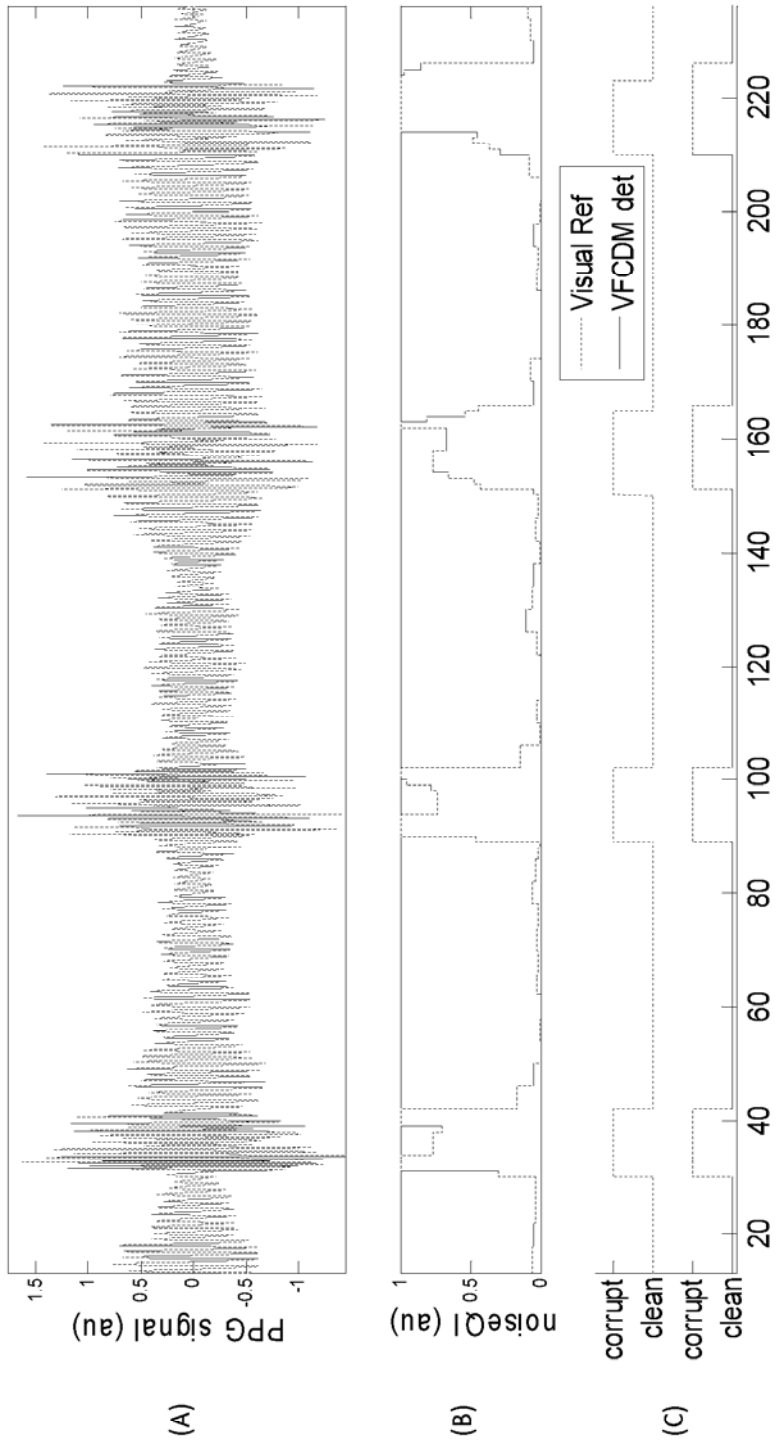

PPG signal (au)
3
2
1
0
-1
-2
noiseQI (au)
1
0.5
0
Original noiseQI
Updated noiseQI
4s
1s
Visual Ref
VFCDM det
corrupt
clean
corrupt
clean
130
135
140
145
150
155
160
165
170
175
180
Time (s)

FIG. 3


(A)
PPG signal (au)
1.5
1
0.5
0
-0.5
-1
(B)
noiseQI (au)
1
0.5
0
(C)
corrupt
clean
corrupt
clean
Visual Ref
VFCDM det
20
40
60
80
100
120
140
160
180
200
220

FIGS. 4A-C

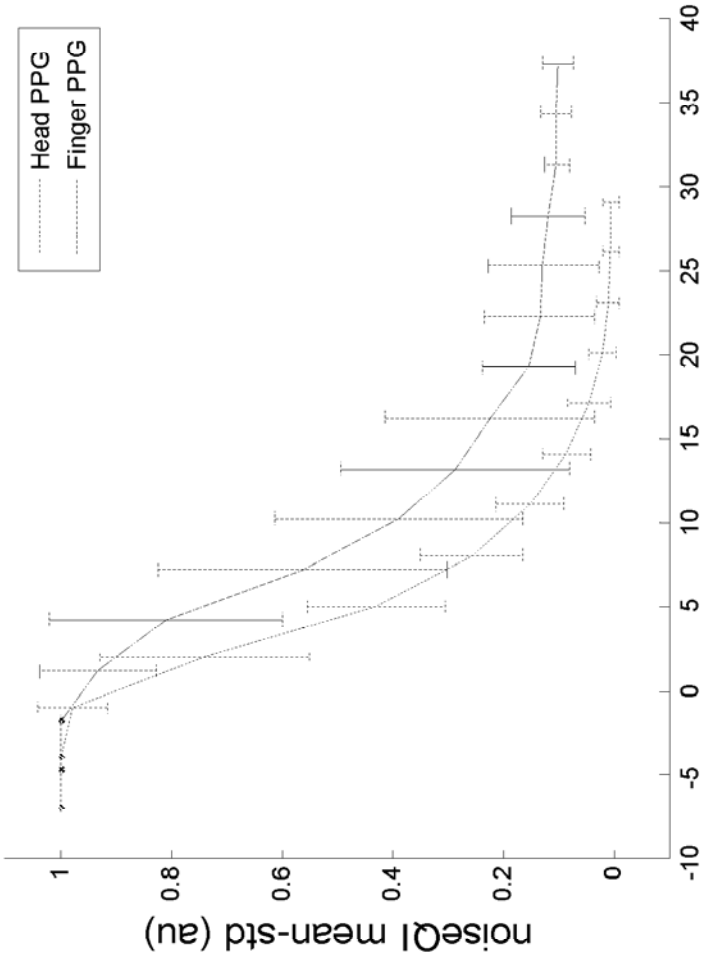

Head PPG
Finger PPG
noiseQI mean-std (au)
SNR (dB)
1
0.8
0.6
0.4
0.2
0
-10
-5
0
5
10
15
20
25
30
35
40

FIG. 5

PPG Amplitude (au)
2
1.5
1
0.5
0
-0.5
-1
-1.5
Visual Ref
VFCDM
Hjorth
KSE
TDV
MNA Detection
corrupt
clean
20
40
60
80
100
120
140
160
180

FIG. 6

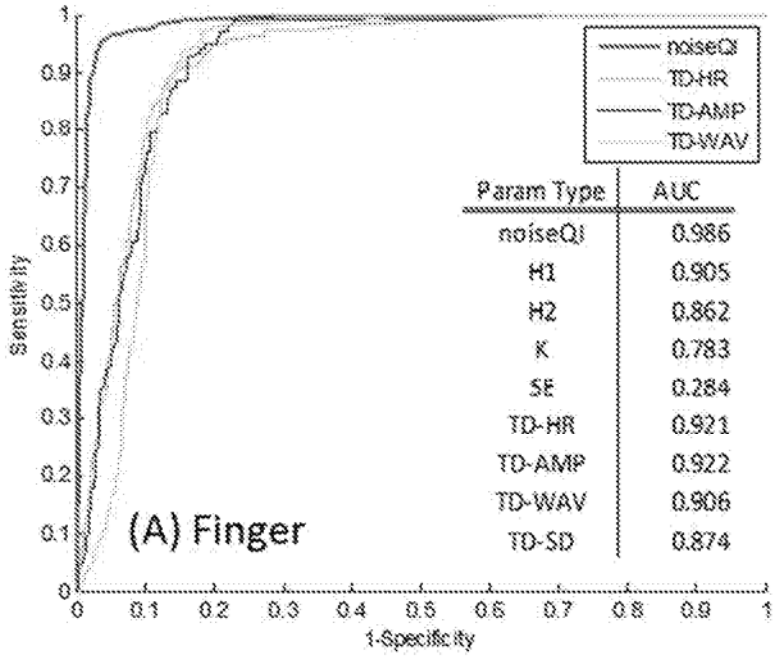

noiseQI
TD-HR
TD-AMP
TD-WAV
Param Type | AUC
noiseQI | 0.986
H1 | 0.905
H2 | 0.862
K | 0.783
SE | 0.284
TD-HR | 0.921
TD-AMP | 0.922
TD-WAV | 0.906
TD-SD | 0.874
(A) Finger
Sensitivity
1-Specificity
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

FIG. 7A

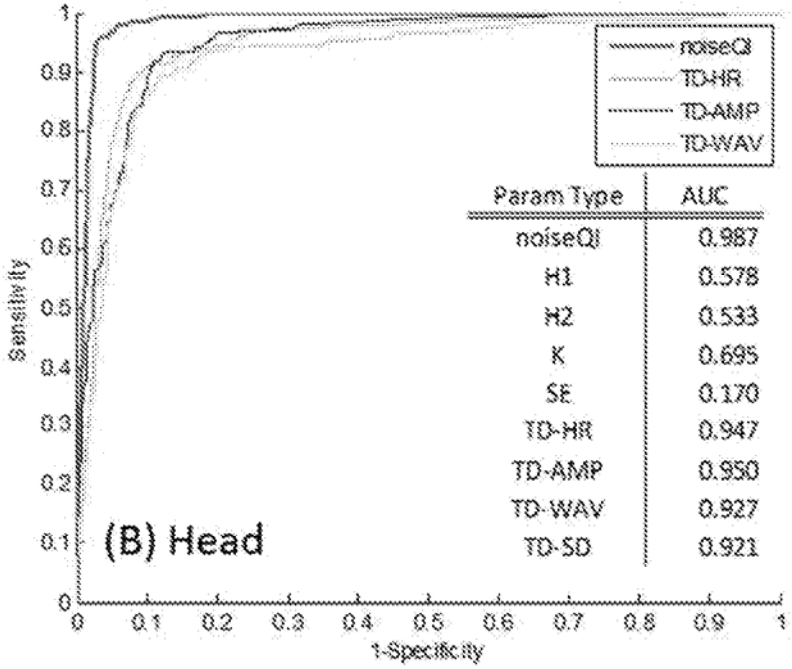

noiseQI
TD-HR
TD-AMP
TD-WAV
Param Type | AUC
noiseQI | 0.987
H1 | 0.578
H2 | 0.533
K | 0.695
SE | 0.170
TD-HR | 0.947
TD-AMP | 0.950
TD-WAV | 0.927
TD-SD | 0.921
(B) Head
Sensitivity
1-Specificity
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

FIG. 7B

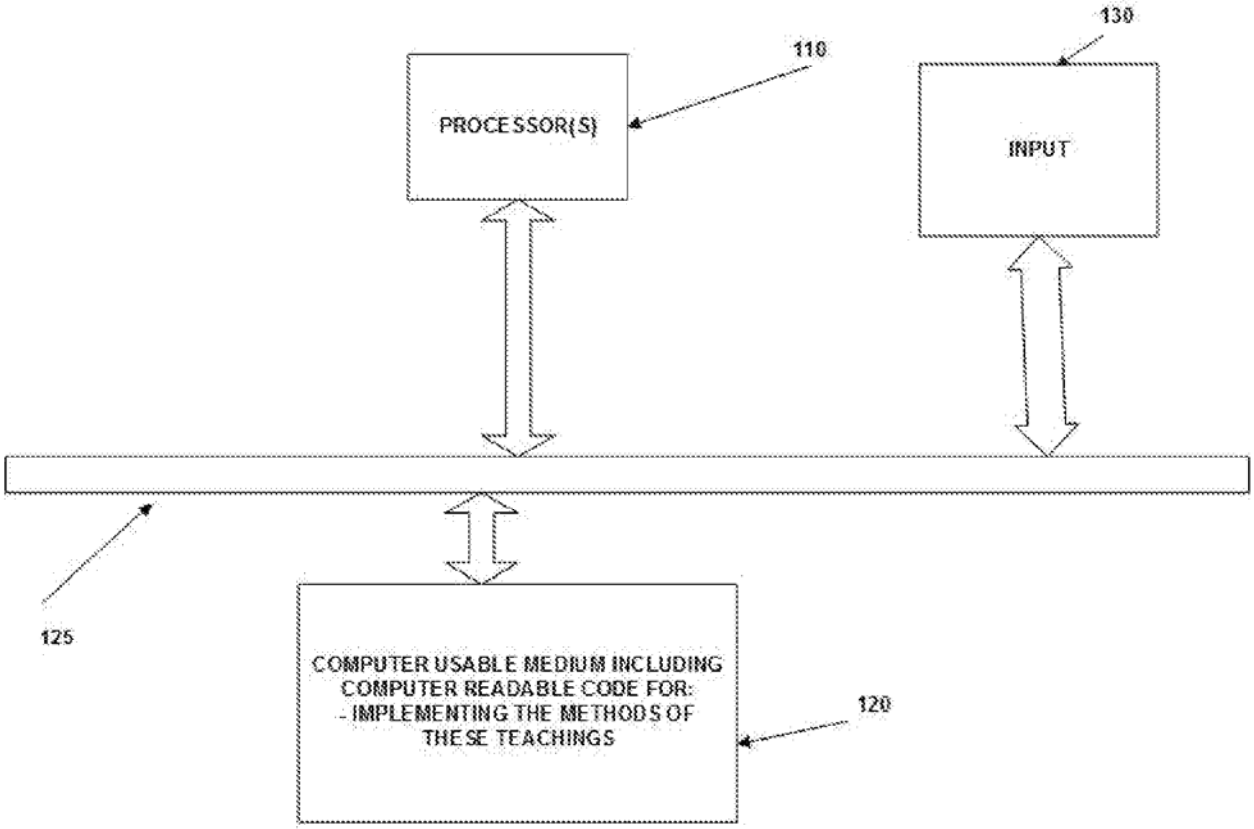

130
110
PROCESSOR(S)
INPUT
125
COMPUTER USABLE MEDIUM INCLUDING
COMPUTER READABLE CODE FOR:
- IMPLEMENTING THE METHODS OF
THESE TEACHINGS
120

FIG. 8

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS
First Named Inventor/Applicant Name:	Ki H. Chon
Filer:	Marlo Schepper Grolnic
Attorney Docket Number:	30210-216

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	16	40	640
Miscellaneous-Filing:				
Petition:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1370**

Electronic Acknowledgement Receipt

EFS ID:	24766661
Application Number:	15010345
International Application Number:	
Confirmation Number:	2095
Title of Invention:	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS
First Named Inventor/Applicant Name:	Ki H. Chon
Customer Number:	26486
Filer:	Marlo Schepper Grolnic
Filer Authorized By:	
Attorney Docket Number:	30210-216
Receipt Date:	29-JAN-2016
Filing Date:	
Time Stamp:	14:39:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$1370
RAM confirmation Number	632
Deposit Account	032410
Authorized User	LOPEZ, ORLANDO

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 1.16 (National application filing, search, and examination fees)

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

Charge any Additional Fees required under 37 CFR 1.19 (Document supply fees)

Charge any Additional Fees required under 37 CFR 1.20 (Post Issuance fees)

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	Application Data Sheet	216ADS.pdf	1514523 52b41e1f806ee071de40d00ca9d291e85a2831b2	no	7
Warnings:					
Information:					
2		216AppFnl.pdf	254976 e34047110d203b4f2b142769b6ce56e0f85258ee	yes	28

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Specification	1	21
Claims	22	27
Abstract	28	28

Warnings:					
Information:					
3	Drawings-other than black and white line drawings	216Figures.pdf	817282 09ba97d92d397b983c04e686c4318aba69ba17f2	no	8
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	36675 190e3debe6039d33f830198e240509c932e25a15	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2623456	

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.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 02/23/2016

VVAN11 SALE #00000059 Mailroom Dt: 01/29/2016 032410 15010345
01 FC : 2051 70.00 DA

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/010,345	01/29/2016	Ki H. Chon	30210-216

CONFIRMATION NO. 2095

26486
BURNS & LEVINSON, LLP
125 SUMMER STREET
BOSTON, MA 02110

INFORMAL NOTICE

OC000000080901318

Date Mailed: 02/26/2016

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):
  Ki H. Chon
  Jowoon Chong
  Duy Dao
  Hamed Salehizadeh

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**.

/wtsige/

Petitioner Ex-1004, 0050

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/010,345

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))	36 minus 20 =	* 16	x 40 =	640	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	1370		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	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
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.

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
15/010,345	01/29/2016	3777	1440	30210-216	36	3

CONFIRMATION NO. 2095

26486
BURNS & LEVINSON, LLP
125 SUMMER STREET
BOSTON, MA 02110

FILING RECEIPT

OC000000080901317

Date Mailed: 02/26/2016

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)

Ki H. Chon, Worcester, MA;
Jowoon Chong, Worcester, MA;
Duy Dao, Malden, MA;
Hamed Salehizadeh, Worcester, MA;

Applicant(s)

Ki H. Chon, Worcester, MA;
Jowoon Chong, Worcester, MA;
Duy Dao, Malden, MA;
Hamed Salehizadeh, Worcester, MA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 62/109,183 01/29/2015

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: No

Permission to Access Search Results: No

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: 02/24/2016
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/010,345**
Projected Publication Date: 08/04/2016
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT 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.

Petitioner Ex-1004, 0055

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15010345
Filing Date	2016-01-29
First Named Inventor	Ki H. Chon
Art Unit	3777
Examiner Name	TBD
Attorney Docket Number	30210-216

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20110077484	A1	2011-03-31	Van Slyke et al.	
	2	20080287815	A1	2008-11-20	Chon et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	1998042250	WO	A1	2000-02-02	NELLCOR PURITAN BENNETT INC.		

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	15010345
Filing Date	2016-01-29
First Named Inventor	Ki H. Chon
Art Unit	3777
Examiner Name	TBD
Attorney Docket Number	30210-216

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	COUCEIRO, R. et al., "Detection of motion artifacts in photoplethysmographic signals based on time and period domain analysis", THE EFFECT OF APPLI ED COMPRESSIVE LOADING ON TISSUE-ENGI NEERED CARTILAGE CONSTRUCTS CULTURED WITH TGF-BETA3, IEEE, 28 August 2012 (2012-08-28), pages 2603-2606.	
	2	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, vol. 16, no. 1, 23 December 2015 (2015-12-23), page 10.	
	3	The International Search Report And The Written Opinion for PCT/US16/15650 dated May 17, 2016.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	15010345
	Filing Date	2016-01-29
	First Named Inventor	Ki H. Chon
	Art Unit	3777
	Examiner Name	TBD
	Attorney Docket Number	30210-216

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the 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 the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification 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 the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Orlando Lopez/	Date (YYYY-MM-DD)	2016-06-03
Name/Print	Orlando Lopez	Registration Number	46880

This collection of information is required by 37 CFR 1.97 and 1.98. 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 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	26054518
Application Number:	15010345
International Application Number:	
Confirmation Number:	2095
Title of Invention:	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS
First Named Inventor/Applicant Name:	Ki H. Chon
Customer Number:	26486
Filer:	Marlo Schepper Grolnic
Filer Authorized By:	
Attorney Docket Number:	30210-216
Receipt Date:	14-JUN-2016
Filing Date:	29-JAN-2016
Time Stamp:	09:58:01
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	216IDSLtr.pdf	62802 a39278638bbfc3fc6fcaf9603b50e3adc450869a	no	1

Warnings:	
Information:	

2	Foreign Reference	WO9842250A1.pdf	1094684 dcc1a2e18ac355d0421d26cf9860e3e1c7a05f3b	no	29
Warnings:					
Information:					
3	Non Patent Literature	Salehizadeh.pdf	748147 90d171f4c47a47e6d86e6772ace95c6545dfabea	no	10
Warnings:					
Information:					
4	Non Patent Literature	Couceiro.pdf	251010 5324acada0f74c92e2c3d70e624afc2eabd6eb0f	no	2
Warnings:					
Information:					
5	Other Reference-Patent/App/Search documents	216ISRWo.pdf	793429 ca1268861153dd4e98bf4c65f12b92285dc3bc01	no	13
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	216IDSForm.pdf	1035567 091d90437e2774401955dc51d1f8f32ba711fefb	no	4
Warnings:					
Information:					
			Total Files Size (in bytes):	3985639	

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.

PATENT APPLICATION
Attorney Docket No. 30210-216

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Ki H. Chon et al.
Application No.: 15/010,345
Filed: January 29, 2016
For: MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS

Examiner: TBD
Group Art Unit: TBD
Confirm. No.: 2095

BURNS & LEVINSON LLP
125 Summer Street
Boston, MA 02110
(617) 345-3000

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

INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement (Form PTO/SB/08a) (including copies of foreign references and non-patent literature) is submitted under 37 CFR 1.97(b)(3), before the mailing of a first office action on the merits.

In view thereof, no fee is believed to be required. However, in the event fees are required, please charge any underpayment or credit any overpayment of fees to Deposit Account No. 03-2410, Order No. 30210-216.

Respectfully submitted,
Ki H. Chon et al., Applicants

Dated: June 13, 2016

By: /Orlando Lopez/
Orlando Lopez, Ph.D.
Reg. No. 46,880
Attorney for Applicants

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/00, 5/024

A1

(11) International Publication Number: **WO 98/42250**

(43) International Publication Date: 1 October 1998 (01.10.98)

(21) International Application Number: PCT/IB97/00290

(22) International Filing Date: 21 March 1997 (21.03.97)

(71) Applicant: NELLCOR PURITAN BENNETT INC. [US/US]; 4280 Hacienda Drive, Pleasanton, CA 94588 (US).

(72) Inventors: BAKER, Clark, R., Jr.; 18493 Magee Way, Castro Valley, CA 94546 (US). YORKEY, Thomas, J.; 3072 Bernard Avenue, San Ramon, CA 94583 (US).

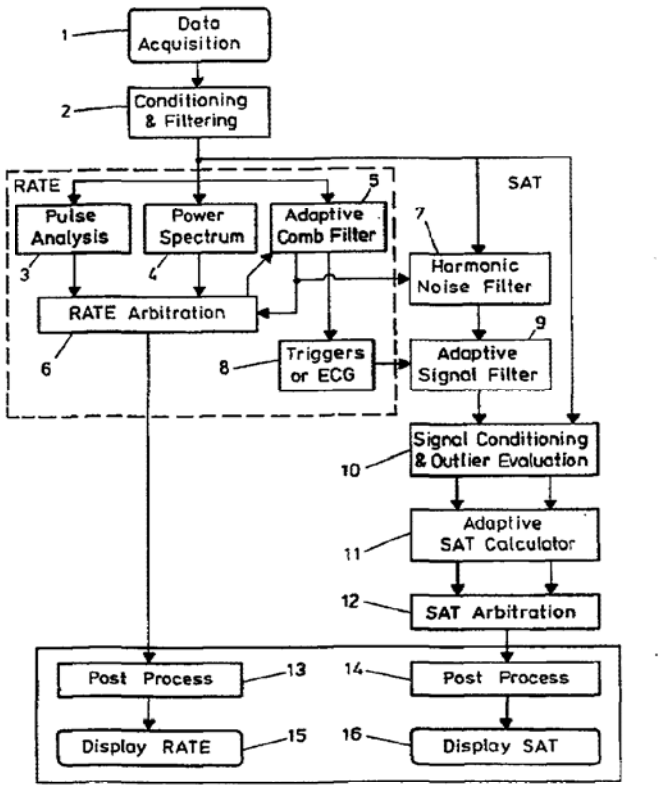
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT).

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR MEASURING PULSE RATE AND SATURATION

(57) Abstract

A method of generating a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient comprises (a) defining a comb filter to isolate signal energy in the data corresponding to a fundamental frequency and related higher frequency components thereof; (b) determining a particular frequency which optimizes energy at an output of the comb filter; and (c) generating a filtered pulse rate corresponding to the particular frequency.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

METHOD AND APPARATUS FOR MEASURING PULSE RATE AND SATURATION

This invention relates to a method and apparatus for measuring physiological parameters, in particular for reducing noise effects, including effects arising from motion, in a system for measuring the pulse rate of a patient. It relates in particular to a method and apparatus for measuring pulse rate and saturation. The invention involves the application of filtering techniques.

It is known to determine pulse rate from the optical plethysmograph waveform is by counting zero crossings. If there is no motion and no other noise, the optical plethysmograph signal is very clean and a pulse rate can be determined by accurately counting zero crossings. During motion, a zero-crossing approach will count transients from the motion and display an artificially high rate.

It is also known to determine pulse rate using a template of the plethysmograph signal corresponding to a single pulse, and then counting the number of matches with this template. However, motion effects can lead to the appearance of the signal differing significantly from that of the template; as a result, no pulse counting occurs.

The present invention provides a technique for reducing noise effects in a system for measuring pulse rate, by use of a comb filter to isolate signal energy which corresponds to fundamental and related frequencies.

Accordingly, in one aspect, the invention provides a method of generating a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, the method comprising the steps of:

(a) defining a comb filter to isolate signal energy in the data corresponding to a fundamental frequency and related higher frequency components thereof;

(b) determining a particular frequency which optimizes energy at the output of the comb filter; and

(c) generating a filtered pulse rate corresponding to the particular frequency.

In another aspect, the invention provides apparatus for generating a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, comprising:

(a) a comb filter for isolating signal energy in the data corresponding to a fundamental frequency and related higher frequency components thereof;

(b) means for determining a particular frequency which optimizes energy at an output of the comb filter; and

(c) means for generating a pulse rate corresponding to the particular frequency.

The technique of the present invention estimates the frequencies and amplitudes of sinusoids in noise. A procedure to find the frequencies and then the amplitudes and phases of a given number of arbitrary sinusoids in noise is disclosed in *A Minimal Parameter Adaptive Notch Filter with Constrained Poles and Zeros* (Nehorai A), volume 33 of the IEEE Transactions on Acoustics, Speech, and Signal Processing (1985). This approach has been extended specifically to look for the fundamental frequency and then the amplitudes and phases of a harmonic signal in noise, as disclosed in *Adaptive Comb Filtering for Harmonic Signal Enhancement* (Nehorai A and Porat B), volume 34 of the IEEE Transactions on Acoustics, Speech,

and Signal Processing (1986). A numerically more efficient procedure for finding the fundamental frequency based on this approach is the subject of *Computation of Harmonic Comb Filter Weights* (Hendry S D), volume 41 of the IEEE Transactions on Acoustics, Speech, and Signal Processing (1993). Subject matter disclosed in these papers is incorporated herein by reference.

The technique employed by the present invention is referred to herein as Adaptive Comb Filtering (ACF). The pulse rate is calculated from the optical absorbance signal.

When viewed as a spectrogram (frequency versus time), the energy in a typical human plethysmograph signal is distributed in a few stable, clearly defined bands corresponding to the harmonics of the pulse rate. Adaptive comb filtering first finds the fundamental frequency by defining a comb filter to notch out the energy of the signal, leaving only noise. The number of notches or signal harmonics in the signal is a matter of choice. For normal heart rates, four harmonics can be preferred, but other numbers may be preferred depending on the application, processor, computation power, and the low pass cutoff frequency of a bandpass filter. The ACF finds the harmonic frequency that defines the comb filter to cause the output noise outside the fundamental and chosen harmonics to have the smallest energy. The ACF searches for the fundamental by estimating derivatives of the squared noise with respect to the fundamental to perform a Newton-Raphson search which is the classic approach to nonlinear minimization as discussed in the Nehorai and Porat (1986) and Hendry (1993) documents referred to above.

To formalize the minimization description, let y be the measured signal, x the harmonic signal, and n the noise

$$y(t) = x(t) + n(t)$$

$$= \sum_{k=1}^{N} C_k \sin(k\omega t + \phi_k) + n(t)$$

In the z-transform domain, the comb filter is

$$H(z^{-1}) = \frac{\prod_{k=1}^{N} (1 + \alpha_k z^{-1} + z^{-2})}{\prod_{k=1}^{N} (1 + \rho\alpha_k z^{-1} + \rho^2 z^{-2})}$$

where

$$\alpha_k = -2\cos k\omega_0$$

The parameter ω_0 is the fundamental frequency normalized by the sample rate. Each quadratic in the numerator of H introduces a zero on the unit circle at $\pm k\omega_0$. With $\rho<1$, the denominator introduces a pole inside the unit circle at $\pm k\omega_0$. The bandwidth of the notches is $\pi(1-\rho)$.

When a reliable estimate of the fundamental frequency has been determined, it is preferred to at least occasionally calculate the harmonic amplitudes. A description of a technique for calculating the harmonic amplitudes follows.

It is useful to know the amplitudes of the harmonics. The power of each of the first $n = 4$ harmonics is estimated by taking an RMS of the output of a comb filter having only one "tooth" tuned to the frequency of that harmonic. This allows the power of the harmonics to be estimated with a minimal number of computations. This process can be performed independently of the adaptive comb filter provided the heart

rate estimate is made available to this process. For each harmonic k, the steps in the harmonic estimation are:

1. Calculate **a** for $k\omega_0$

$$a_1 = -2\cos k\omega_0, \quad a_0 = a_2 = 1$$

2. Calculate the output of the "single toothed" comb filter at $k\omega_0$

$$\varepsilon(t) = y(t) + \sum_{i=1}^{2} y(t-i)\,a_i - \sum_{i=1}^{2} \bar{\varepsilon}(t-i)\,\rho^i a_i$$

3. Estimate the bandpass gain of the "single toothed" comb filter at $k\omega_0$ as the gain at DC

$$K(t) = \frac{\sum_{i=0}^{2} a_i}{\sum_{i=0}^{2} \rho^i a_i}$$

4. Estimate the harmonic signal at $k\omega_0$ as the difference between the measured signal and the output of the "single toothed" comb filter.

$$x(t) = y(t) - \varepsilon(t)/K(t)$$

5. Estimate the power (*pwr*) in the harmonic at $k\omega_0$ using a cascaded IIR filter

$$pwr(t) = \lambda pwr(t-1) + (1-\lambda)\,x(t)^2$$

$$pwr'(t) = \lambda pwr'(t-1) + (1-\lambda)\,pwr(t)^2$$

where λ represents the degree of acceptable variability

There are times when the ACF by itself is not sufficient to track a patient's heart rate. This is the case with arrhythmias, where the energy is not concentrated in a few trackable harmonics. Also, a patient's heart rate can change more rapidly than the ACF is capable of tracking, or change dramatically during a period of motion in which the ACF failed to correctly track the change. An alternative pulse rate calculator is therefore included in the present invention that does not require a harmonic signal, and is not based on an adaptive algorithm. This alternative rate calculator is not as robust during motion as the rate calculator described above, but is intended to be used when the ACF cannot track the rate.

A feature that is common to all human pulses is that they go up and down and have some minimum period corresponding to about 250 beats per minute, i.e., 240 msec. Given this model of a human pulse, there is a crest during each pulse such that the current value of the pulse waveform is the maximum value that has been seen for the past 240 msec followed by a trough during that same pulse where the current value is the minimum value that has been seen for the past 240 msec. The pattern matcher provided by the present invention identifies sequences of crests and troughs that preferably do not trigger any motion detection criterion (discussed below), and computes the rate from the average period of all such patterns which have been identified in the past 10 seconds. In one embodiment, the pattern matcher uses a minimum period of 210 msec instead of 240 msec to make allowances for limited motion artifact and an oximeter sampling rate of about 57 Hz. The pattern matching rate is updated each time such a pattern is identified. In some preferred embodiments, motion detection criterion based on the shape of the pulse have been adapted to reject pulses which are potentially contaminated by motion artifact.

Preferably, the step referred to above of determining a pattern matching pulse rate includes the steps of:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;
(b) averaging a number of successive waveform periods to determine an average waveform period; and
(c) determining the alternate pulse rate from the average waveform period.

The method can include a step of comparing the data to a predetermined waveform template prior to the identification step.

Preferably, the motion detection criteria require the calculation of the maxima, minima, and average for the current and previous detected patterns. Motion is detected when any of the following criteria are met:

a) the maximum of the current pattern is significantly further away from the average of the current pattern than the minimum is;
b) criterion a) failed on the last detected pattern;
c) the maximum of the current pattern is significantly further away from the average of the current pattern than the average of the current pattern is from the average of the current and previous minima; or
d) the difference between the average of the current and previous patterns is greater than half the difference between the current maximum and minimum (big DC shift).

A motion flag is set whenever any of the motion detection criteria are met and is cleared whenever none are met for two consecutive patterns.

In a preferred embodiment, two pattern matching rate calculators are run in parallel. One receives the bandpassed normalized waveform as input. The second receives a filtered

form of the first derivative of the plethysmograph. The use of two inputs with different characteristics minimizes the time that motion is incorrectly reported. Each pattern matcher stores the proportion of patterns for which its motion metrics indicate motion. The pattern matcher that reports the least motion over the last ten seconds is used for the pattern matching rate. This dual pattern matcher reports that motion is present only when the motion metrics for each of its two pattern matchers indicates motion.

As discussed above, the adaptive comb filter (ACF) employed by the present invention tracks a signal having N harmonics. It sometimes happens that motion artifact causes the ACF to track the wrong rate, and when the motion stops, the "teeth" on the comb may be on a harmonic rather than the fundamental. For example, the fundamental of the ACF could be tracking the second harmonic of the plethysmograph, or the second harmonic for the ACF could be tracking the fundamental of the plethysmograph. These situations would cause the ACF to report twice or half the correct pulse rate, respectively. This could happen if the ACF was initialized to the wrong rate and settled on a harmonic or subharmonic, or if the rate changed more suddenly than the ACF could track. In general, the ACF is quite stable, and several minutes of prolonged, vigorous motion may be required before it locks onto a harmonic or subharmonic of the pulse rate. However, because of the potential for false reporting, according to a preferred embodiment a number of rules are used to calculate a more accurate rate.

A simple model of most plethysmographs may be compared to a sawtooth-like pattern for which the amplitude of the harmonics of the plethysmograph fall off by a factor of two for each harmonic. Thus, for most plethysmographs, the falloff is fairly rapid. However, some patients have nearly half the energy of their pulses contained in the second harmonic. Other physiological plethysmograph patterns may contain significant amounts of energy at multiples of one-half the pulse rate,

while still others may have strong respiratory components at one-half the pulse rate, although the signal at the pulse rate should still be dominant. Arrhythmias may have no repeating pattern, thus violating the model assumed by the ACF. When the ACF locks onto a subharmonic, or some superharmonic, the "tooth" on the comb that passes the greatest amount of energy will not correspond to the fundamental frequency estimated by the ACF.

For most patients, where there is little or no motion, all the energy in the plethysmograph is at the fundamental or a harmonic of the pulse rate. Although pulse rates will vary cyclically in response to various mechanisms, plateaus in the pulse rate will be long enough, and frequent enough, that the autocorrelation has a very high value at the fundamental of the pulse rate at these times. Where there is significant energy at a subharmonic of the pulse rate, the autocorrelation at the subharmonic may be higher than at the pulse rate, but the autocorrelation function will still have a strong local maxima at the pulse rate.

For an arrhythmia with a non-repeating pattern, the autocorrelation may not have any strong local maxima. However, if a patient is not moving, the plethysmograph will be modulated only by the patient's pulse, and will thus be completely correlated in the IR and red channels. Motion artifact, however, causes the IR and red channels to become less correlated. This crosscorrelation can thus be used as a rough indicator of the degree of motion and therefore the reliability of the rate reported by the pattern matching.

In view of the foregoing, a concise set of rules is desirable that reliably enables the ACF to resume tracking the correct pulse rate when motion has stopped, and which does not increase the chance that ACF will track the wrong pulse rate. An "uncorrelation" metric is calculated which is defined as:

$$\sqrt{1-crosscorrelation(IR,red)^2},$$

where the crosscorrelation is currently calculated over about 10 seconds of normalized data.

The magnitude of each of the harmonics is estimated each second, and the magnitude information is used to calculate a measure of the validity of the pulse. In addition to estimating the pulse rate, the ACF also calculates filtered signal and noise waveforms, X and ϵ using the comb filter, which enables the calculation of a signal to noise (S/N) ratio. The S/N ratio is expected to be high for non-arrhythmic patients who are not moving, and low during motion or arrhythmias. It is also low if the fundamental of the heart rate does not match any of the harmonics being tracked by the ACF. In various embodiments, the S/N may be calculated by differentiating, filtering in derivative space, and then integrating the plethysmographs, with the best S/N ratio being used.

A preferred valid plethysmograph will have the energy in consecutive harmonics falling off exponentially. If a majority of the energy in the plethysmograph is calculated to be in one of the harmonics instead of the fundamental, the standard deviation for the exponential decay will probably be large enough to drive the validity measure negative.

The following mechanisms can be used to assure that the ACF is tracking the right rate. A Fast Fourier Transform (FFT) (power spectrum) can be performed on the IR plethysmograph and each peak in the spectrum may be evaluated prospectively to find the rate which would give the highest confidence measure for the ACF (the formulas used to combine various metrics into a confidence measure for the ACF rate are described below). This is possible because the magnitude of each of the harmonics that would be tracked by the ACF at a given rate can be estimated by

adding up the energy in several adjacent frequencies of the FFT.

The ACF rate is reset to this FFT rate if the FFT rate is considered more reliable than the ACF rate. Ideally, the ACF rate should not be reported until it has been initialized by this mechanism.

The determining step can minimise or maximise the energy at the output of the comb filter, according to the selected operation of the ACF.

Preferably, the determining step of the method of the invention comprises:

(a) calculating squared noise for the data;
(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
(c) performing a Newton-Raphson search to determine the particular frequency.

Preferably, the method includes the steps of:

(a) comparing selected samples of the pulse rate to an expected measurement characteristic;
(b) assigning a variable weight to each selected sample based on the comparing step, thereby generating a plurality of differently weighted samples of the pulse rate;
(c) averaging a first number of the weighted samples to obtain a filtered sample of the pulse rate, the first number preferably varying in response to the variable weights assigned in the assigning step; and
(d) generating a filtered pulse rate from a plurality of filtered samples.

Preferably, before the defining step of the method, it includes the steps of:

(a) taking the logarithm of a signal representative of at least one wavelength of electromagnetic energy, thereby generating a first signal;
(b) band pass filtering the first signal, thereby generating a second signal;
(c) normalizing the second signal, thereby generating a third signal; and
(d) taking the derivative of the third signal, thereby generating the data.

There will generally be a confidence level associated with the pulse rate, the confidence level being based on at least one quality metric selected from the group comprising pulse signal shape, signal-to-noise ratio, and correlation between at least two wavelengths of electromagnetic energy.

Preferably, the method includes the steps of:

(a) determining an alternate pulse rate using an alternate rate finder; and
(b) selectively setting the pulse rate to the alternate pulse rate.

The alternate pulse rate can be determined by:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency;
(b) generating an alternate pulse rate corresponding to the fundamental frequency; and
(c) calculating a confidence level for the alternate pulse rate.

The method can include the step of generating an initial pulse rate corresponding to the alternate pulse rate in the setting step.

The step of determining an alternate pulse rate can be arranged to occur periodically, the setting step only then occurring where at least one condition is met. That condition can be selected from the group comprising:

(a) a confidence level corresponding to the filtered pulse rate is less than a first value;
(b) the confidence level corresponding to the alternate pulse rate is greater than or equal to the first value;
(c) a signal-to-noise ratio corresponding to the alternate pulse rate is greater than or equal to a second value;
(d) the alternate pulse rate corresponds to a local maxima on an autocorrelation curve corresponding to the data; and
(e) the alternate pulse rate is within a third value of a previously determined alternate pulse rate, the previously determined alternate pulse rate having been determined within a first interval.

The method can be performed such that conditions (a) to (e) above are met before the pulse rate is set to the alternate pulse rate.

The technique of the present invention can be used in conjunction with a technique for calculating oxygen saturation levels in haemoglobin, providing information relating to pulse rate. Techniques for determining oxygen saturation which can be used in the present invention are disclosed in International patent applications nos. IB96/ and IB96/ , entitled METHOD AND APPARATUS FOR ADAPTIVELY AVERAGING DATA SIGNALS, and METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA, which are

filed with the present application and which bear the references P21977A and P21977D. Information concerning these features of the present invention that is disclosed in those documents is incorporated in the specification of the present application by this reference.

The invention can involve reduction of noise effects when measuring a physiological parameter. It can include apparatus for reducing the noise effects which comprises:

means for generating a plurality of measurements derived from at least one wavelength of electromagnetic energy transmitted through living tissue;

means for providing a signal indicative of the at least one wavelength of electromagnetic energy;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements for each wavelength, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the system to measure the physiological parameter in response to the signal indicative of the at least one wavelength of electromagnetic energy.

The invention also includes a monitor for measuring a physiological parameter, the monitor being for use with a sensor having emitting means for emitting at least one wavelength of electromagnetic energy, sensing means for sensing the electromagnetic energy and for generating a first signal representative thereof, means for detachably coupling the sensor to

the oximeter and for providing communication of signals between the sensor and the oximeter, and means for providing a second signal indicative of the at least one wavelength of electromagnetic energy, the monitor comprising:

means for generating a plurality of measurements derived from the first signal;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the monitor to measure the physiological parameter in response to the second signal.

The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic representation of apparatus for measuring a physiological parameter such as oxygen saturation of haemoglobin of a patient;

Figure 2 is a block diagram illustrating the flow of data in apparatus such as that shown in Figure 1;

Referring to the drawings, Figure 1 shows apparatus for measuring physiological parameters such as oxygen saturation of haemoglobin of a patient. A sensor/oximeter combination 60 comprises a sensor 61 and an oximeter monitor 62. Sensor 61 includes LEDs 63 and 64 typically having wavelength emission characteristics in the infrared and red ranges of the spectrum,

respectively. Photodiode sensor 65 receives the light transmitted by LEDs 63 and 64. Resistor 66 (or a similar electrical impedance reference) is chosen to correspond to a specific wavelength or combination of wavelengths as specified by a table relating impedance values to wavelengths. Decoding means 67 determines the impedance value of resistor 66, and appropriate extinction coefficients are generated which correspond to the transmission characteristics of the particular sensor 61. Thus, the oximeter may be used with a variety of sensors having LEDs which emit varying wavelengths of light without recalibration. The sensor 61 is detachably coupled to oximeter monitor 62 via connector 68. An example of such a sensor/oximeter combination is disclosed in US-4621643.

The data received from the sensor is processed according to the scheme shown in Figure 2. It can be processed using apparatus of the type disclosed in US-5348004. In initial process step 2, the natural logarithm of the data (usually from red and infra red LEDs) is taken, and the data is band pass filtered with an infinite impulse response (IIR) filter that has a high pass cutoff frequency at 0.5 Hz (that is 30 beats per minute) and a low pass rolloff from 10 to 20 Hz. The filtered data can then processed by algorithms for calculation of pulse rate as discussed in detail above.

In the illustrated arrangement, data are sent to two different algorithms for calculation of the patient's pulse rate. According to one algorithm, the derivative of the data is taken 2 as described above, and the fundamental frequency of the pulse rate is tracked using an adaptive comb filter (ACF) 5 as discussed below. The ACF 5 supplies its pulse rate directly to a harmonic filter 7. The ACF 5 can also provide a trigger for an algorithm for calculating oxygen saturation as disclosed in the related application referred to above. ACF 5 is a robust pulse rate tracker, but not a good pulse rate finder. Therefore, the frequency power spectrum of the data is calculated periodically 4 to determine whether ACF 5 is tracking the

fundamental rather than a super- or subharmonic of the pulse rate.

The normalized data is also supplied to a pattern matching algorithm 3 which recognizes sequences of crests and troughs in the data and calculates an average period of the plethysmograph over a set number of samples. This algorithm is preferably used primarily to track the pulse rate for an arrhythmic pulse rate during periods where no motion is detected. A rate arbitration algorithm 6 then arbitrates between the pulse rates calculated by ACF 5 (as updated by frequency power spectrum 4) and pattern matching algorithm 3 using confidence levels associated with each, which are based on various metrics. After appropriate post processing 13, the pulse rate data is output to the display 15. The data is post processed using available metrics to determine the reliability of the pulse rate and to determine whether and how it is to be displayed. Details of techniques for assessing the reliability of physiological parameters are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES AND REJECTING HARMONICS, which bears the reference P21977C. Information concerning these features of the present invention that is disclosed in that document is incorporated in the specification of the present application by this reference.

CLAIMS:

1. A method of generating a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, the method comprising the steps of:

(a) defining a comb filter to isolate signal energy in the data corresponding to a fundamental frequency and related higher frequency components thereof;

(b) determining a particular frequency which optimizes energy at an output of the comb filter; and

(c) generating a filtered pulse rate corresponding to the particular frequency.

2. A method as claimed in claim 1, in which the determining step minimizes the energy at the output of the comb filter.

3. A method as claimed in claim 1, in which the determining step maximizes the energy at the output of the comb filter.

4. A method as claimed in claim 1, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the particular frequency.

5. A method as claimed in claim 1, which includes the steps of:

(a) comparing selected samples of the pulse rate to an expected measurement characteristic;

(b) assigning a variable weight to each selected sample based on the comparing step, thereby generating a plurality of differently weighted samples of the pulse rate;

(c) averaging a first number of the weighted samples to obtain a filtered sample of the pulse rate; and

(d) generating a filtered pulse rate from a plurality of filtered samples.

6. A method as claimed in claim 5, in which the first number varies in response to the variable weights assigned in the assigning step.

7. A method as claimed in claim 1, in which, preceding the defining step, the method further comprises the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;

(b) band pass filtering the first signal, thereby generating a second signal;

(c) normalizing the second signal, thereby generating a third signal; and

(d) taking the derivative of the third signal, thereby generating the data.

8. A method as claimed in claim 1, in which there is a confidence level associated with the pulse rate, the confidence level being based on at least one quality metric selected from

the group comprising pulse signal shape, signal-to-noise ratio, and correlation between at least two wavelengths of electromagnetic energy.

9. A method as claimed in claim 1, which includes the steps of:

(a) determining an alternate pulse rate using an alternate rate finder; and

(b) selectively setting the pulse rate to the alternate pulse rate.

10. A method as claimed in claim 9, in which the step of determining an alternate pulse rate comprises the steps of:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency;

(b) generating an alternate pulse rate corresponding to the fundamental frequency; and

(c) calculating a confidence level for the alternate pulse rate.

11. A method as claimed in claim 10, which includes the step of generating an initial pulse rate, the initial pulse rate being set to the alternate pulse rate in the setting step.

12. A method as claimed in claim 9, in which the step of determining an alternate pulse rate comprises the steps of:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;

(b) averaging a number of successive waveform periods to determine an average waveform period; and

(c) determining the alternate pulse rate from the average waveform period.

13. A method as claimed in claim 11 or claim 12, in which the step of determining an alternate pulse rate occurs periodically, the setting step occurring only where at least one condition is met.

14. A method as claimed in claim 13, in which the at least one condition is selected from the group comprising:

(a) a confidence level corresponding to the filtered pulse rate is less than a first value;

(b) the confidence level corresponding to the alternate pulse rate is greater than or equal to the first value;

(c) a signal-to-noise ratio corresponding to the alternate pulse rate is greater than or equal to a second value;

(d) the alternate pulse rate corresponds to a local maxima on an autocorrelation curve corresponding to the data; and

(e) the alternate pulse rate is within a third value of a previously determined alternate pulse rate, the previously determined alternate pulse rate having been determined within a first interval.

15. A method as claimed in claim 14, in which conditions (a) to (e) are met before the pulse rate is set to the alternate pulse rate.

16. Apparatus for generating a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, comprising:

(a) a comb filter for isolating signal energy in the data corresponding to a fundamental frequency and related higher frequency components thereof;

(b) means for determining a particular frequency which optimizes energy at an output of the comb filter; and

(c) means for generating a pulse rate corresponding to the particular frequency.

17. A method for calculating oxygen saturation of haemoglobin in arterial blood using data corresponding to a plurality of wavelengths of electromagnetic energy transmitted through tissue of a patient, the method comprising the steps of:

determining extinction coefficients corresponding to the plurality of wavelengths; and

calculating values proportional to total hemoglobin and oxygenated hemoglobin directly from the data and the extinction coefficients.

18. A method as claimed in claim 17, which includes the step of calculating a value corresponding to oxygen saturation of haemoglobin from the values proportional to total haemoglobin and oxygenated haemoglobin.

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	30210-216
	Application Number	
Title of Invention	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS	

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. ☐

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

Mailing Address Information For Applicant:

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

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

Non-Applicant Assignee Information:

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

Assignee 1

Complete this section only if non-applicant assignee information is desired to be included on the patent application publication in accordance with 37 CFR 1.215(b). Do not include in this section 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), as the patent application publication will include the name of the applicant(s).

Remove

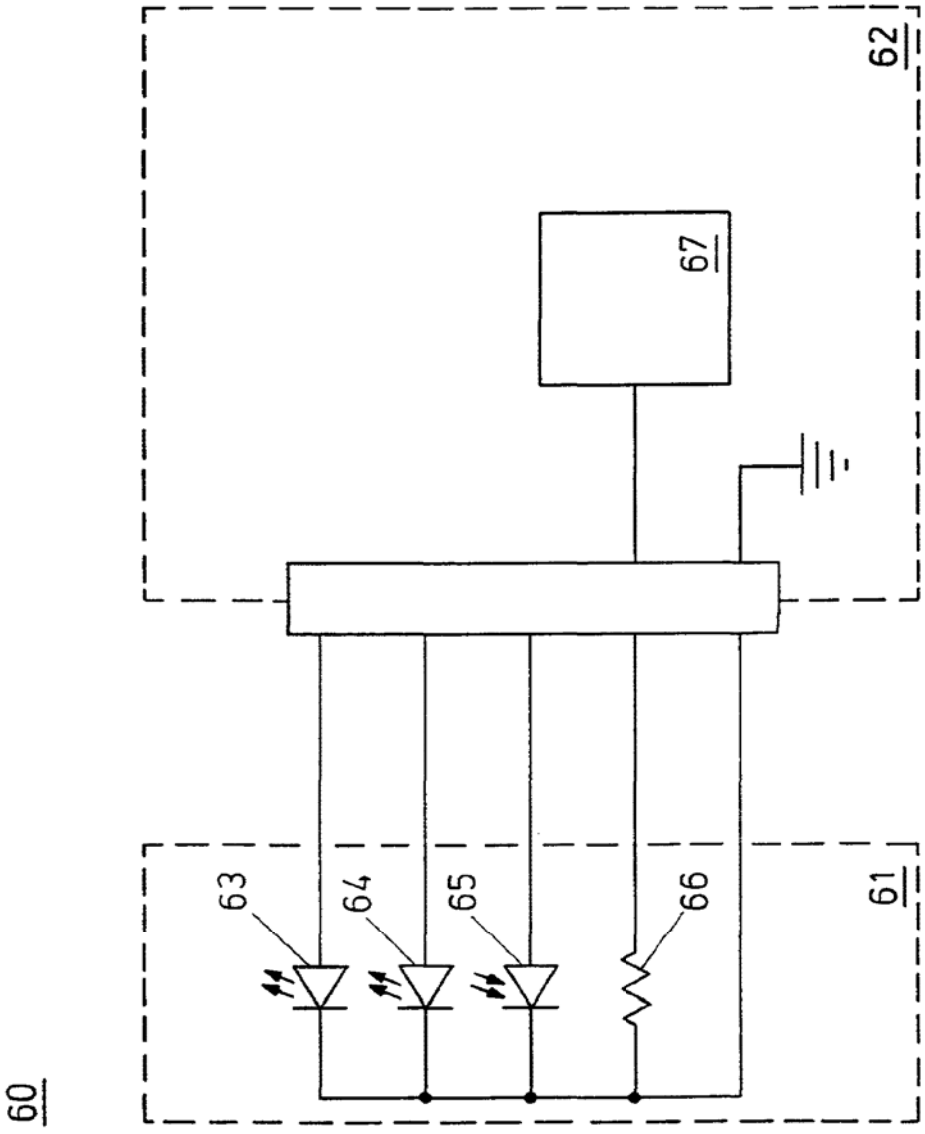


FIG. 1

Petitioner Ex-1004, 0088

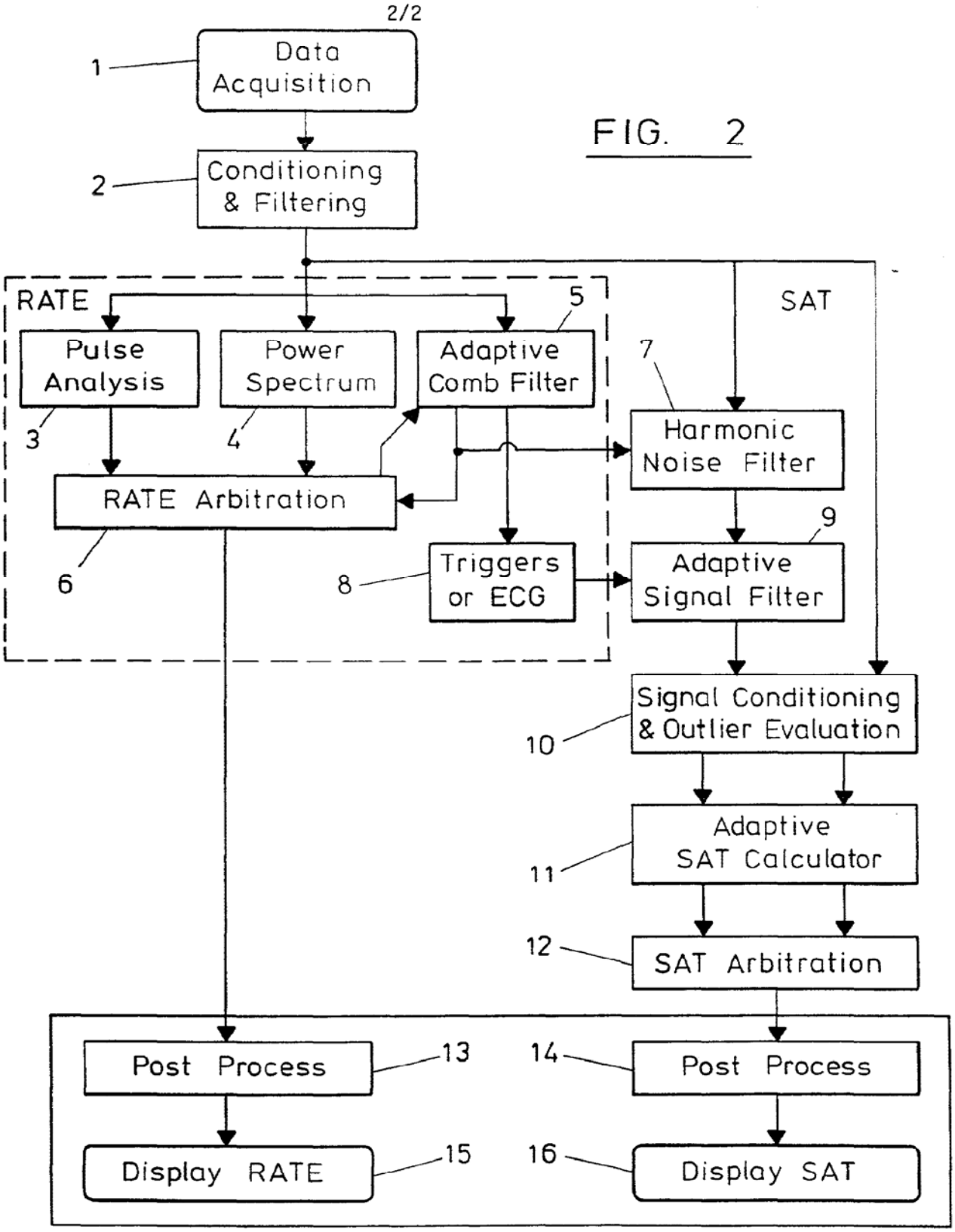


FIG. 2

Petitioner Ex-1004, 0089

INTERNATIONAL SEARCH REPORT

Inte .onal Application No
PCT/IB 97/00290

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00 A61B5/024

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 6 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 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	DE 31 46 063 A (STEPHENS) 1 June 1983 see the whole document ---	1-3,8, 16-18
X	WO 95 10038 A (BLOCK) 13 April 1995 see page 7, line 16 - line 26 see page 13, line 12 - line 27 see page 16, line 3 - line 10 ---	1-3,8,16
A	WO 97 00041 A (YORKEY) 3 January 1997 see the whole document --- -/--	1-8,17, 18

[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

1

Date of the actual completion of the international search	Date of mailing of the international search report
28 November 1997	05/12/1997

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	Lemercier, D

Form PCT/ISA/210 (second sheet) (July 1992)

Petitioner Ex-1004, 0090

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/IB 97/00290

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	NEHORAI A ET AL: "ADAPTIVE COMB FILTERING FOR HARMONIC SIGNAL ENHANCEMENT" IEEE TRANSACTIONS ON ACOUSTICS, SPEECH AND SIGNAL PROCESSING, vol. ASSP-34, no. 5, October 1986, pages 1124-1138, XP000676140 cited in the application	1,4-6
A	HENDRY S D: "COMPUTATION OF HARMONIC COMB FILTER WEIGHTS" IEEE TRANSACTIONS ON SIGNAL PROCESSING, vol. 41, no. 4, April 1993, pages 1677-1680, XP000676141 cited in the application	1,4-6
A	EP 0 335 357 A (NELLCOR) 4 October 1989 see page 6, line 43 - page 9, line 51	1,9-15
A	EP 0 555 553 A (BOC) 18 August 1993 see the whole document	1,9-15

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

Petitioner Ex-1004, 0091

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 97/00290

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 3146063 A	01-06-83	NONE	
WO 9510038 A	13-04-95	US 5434412 A	18-07-95
		AU 7842894 A	01-05-95
		CA 2173200 A	13-04-95
		EP 0721579 A	17-07-96
		JP 9503585 T	08-04-97
		US 5424545 A	13-06-95
		US 5672875 A	30-09-97
WO 9700041 A	03-01-97	US 5645060 A	08-07-97
		AU 6279196 A	15-01-97
EP 335357 A	04-10-89	US 4911167 A	27-03-90
		AT 137648 T	15-05-96
		CA 1323432 A	19-10-93
		DE 68926405 D	13-06-96
		DE 68926405 T	05-09-96
		JP 2045041 A	15-02-90
		US 4934372 A	19-06-90
		US RE35122 E	19-12-95
EP 555553 A	18-08-93	CA 2087475 A	08-08-93
		JP 5269116 A	19-10-93
		US 5297548 A	29-03-94

PATENT COOPERATION TREATY

RECEIVED
MAY 19 2016
PCT
By

From the INTERNATIONAL SEARCHING AUTHORITY

To:
Lopez, Orlando
BURNS & LEVINSON, LLP
125 Summer Street
Boston, MA 02110
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 30210-216PCT	Date of mailing *(day/month/year)* 17 May 2016 (17-05-2016)
International application No. PCT/US2016/015650	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
Applicant WORCESTER POLYTECHNIC INSTITUTE	International filing date *(day/month/year)* 29 January 2016 (29-01-2016)

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

   How? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Fascimile No.: (41-22) 338.82.70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   [ ] the protest together with the decision thereon has been transmitted to the International Bureau together with any applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   [ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **19 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer WILLIS, Peggy Tel: +49 (0)30 25901-749

Petitioner Ex-1004, 0093

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
30210-216PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2016/015650	29 January 2016 (29-01-2016)	29 January 2015 (29-01-2015)

Applicant

WORCESTER POLYTECHNIC INSTITUTE

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the international Bureau.

This international search report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

[X] the international application in the language in which it was filed

[ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [ ] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant

[ ] the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**

a. the figure of the **drawings** to be published with the abstract is Figure No. 5

[X] as suggested by the applicant

[ ] as selected by this Authority, because the applicant failed to suggest a figure

[ ] as selected by this Authority, because this figure better characterizes the invention

b. [ ] none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/015650

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/024 A61B5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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,P	SEYED SALEHIZADEH 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, vol. 16, no. 1, 23 December 2015 (2015-12-23), page 10, XP055270036, CH ISSN: 1424-8220, DOI: 10.3390/s16010010 the whole document ***** ~/~~	1-36

[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
4 May 2016	17/05/2016

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	Trachterna, Morten

Petitioner Ex-1004, 0095

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/015650

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 2011/077484 A1 (VAN SLYKE BRADDON M [US] ET AL) 31 March 2011 (2011-03-31)	1-6,8,9, 11, 13-23, 25,26, 28,29, 31-36
A	paragraphs [0074] - [0089]	7,10,12, 24,27,30
X	COUCEIRO R ET AL: "Detection of motion artifacts in photoplethysmographic signals based on time and period domain analysis", THE EFFECT OF APPLIED COMPRESSIVE LOADING ON TISSUE-ENGINEERED CARTILAGE CONSTRUCTS CULTURED WITH TGF-BETA3, IEEE, 28 August 2012 (2012-08-28), pages 2603-2606, XP032463474, ISSN: 1557-170X, DOI: 10.1109/EMBC.2012.6346497	1-6,8,9, 11, 13-23, 25,26, 28,29, 31-36
A	/* III Methods p. 2604-2606 */	7,10,12, 24,27,30
X	EP 0 975 446 A1 (NELLCOR PURITAN BENNETT INC [US]) 2 February 2000 (2000-02-02)	1-6,8,9, 11, 13-23, 25,26, 28,29, 31-36
A	paragraphs [0007] - [0018], [0023] - [0030]	7,10,12, 24,27,30
A	US 2008/287815 A1 (CHON KI H [US] ET AL) 20 November 2008 (2008-11-20) paragraphs [0021] - [0024]	1-35

Petitioner Ex-1004, 0096

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/015650

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011077484 A1	31-03-2011	CA 2772536 A1	07-04-2011
		EP 2482718 A1	08-08-2012
		US 2011077484 A1	31-03-2011
		WO 2011041216 A1	07-04-2011
EP 0975446 A1	02-02-2000	AT 251863 T	15-11-2003
		AU 720609 B2	08-06-2000
		CA 2283853 A1	01-10-1998
		DE 69725616 D1	20-11-2003
		DE 69725616 T2	19-08-2004
		EP 0975446 A1	02-02-2000
		ES 2208877 T3	16-06-2004
		HK 1026861 A1	08-04-2004
		JP 3763480 B2	05-04-2006
		JP 2001518822 A	16-10-2001
		WO 9842250 A1	01-10-1998
US 2008287815 A1	20-11-2008	US 2008287815 A1	20-11-2008
		US 2013172760 A1	04-07-2013

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2016/015650

TITLE: MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS

APPLICANT: WORCESTER POLYTECHNIC INSTITUTE

IPC CLASSIFICATION: A61B5/024, A61B5/00

EXAMINER: Trachterna, Morten

CONSULTED DATABASES: NPL, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/02416, A61B5/7257, A61B5/7207

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
noise detection
PPG signals
time frequency analysis
fundamental frequency
harmonics

EPO FORM P0443

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2016/015650	29.01.2016	29.01.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/024 A61B5/00

Applicant
WORCESTER POLYTECHNIC INSTITUTE

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Trachterna, Morten Telephone No. +49 30 25901-0

Petitioner Ex-1004, 0099

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-17, 19-34, 36
	No:	Claims	1, 18, 35
Inventive step (IS)	Yes:	Claims	7, 10, 12, 24, 27, 30
	No:	Claims	1-6, 8, 9, 11, 13-23, 25, 26, 28, 29, 31-36
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

1 Reference is made to the following documents:

D1 US 2011/077484 A1 (VAN SLYKE BRADDON M [US] ET AL) 31 March 2011

D2 COUCEIRO R ET AL: "Detection of motion artifacts in photoplethysmographic signals based on time and period domain analysis", THE EFFECT OF APPLIED COMPRESSIVE LOADING ON TISSUE-ENGINEERED CARTILAGE CONSTRUCTS CULTURED WITH TGF-BETA3, IEEE, 28 August 2012 (2012-08-28), pages 2603-2606, XP032463474, ISSN: 1557-170X, DOI: 10.1109/EMBC.2012.6346497

D3 EP 0 975 446 A1 (NELLCOR PURITAN BENNETT INC [US]) 2 February 2000

D4 US 2008/287815 A1 (CHON KI H [US] ET AL) 20 November 2008

2 The application does not meet the requirements of Article 6 PCT, because claims 1-36 are not clear.

2.1 Claims 1,18, 35 are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description and drawings. The description discloses a sophisticated algorithm adapted to reduce motion artifacts within corrupted PPG signals. Furthermore, it cannot be reasonably assumed that any available "noise quality index" is suitable to achieve the desired effect (for instance a "noise quality index" indicative for the 50 or 60 Hz power-line frequency is also included in claim 1).

2.2 Furthermore the independent claims do not establish a clear relation between the noise quality index (which is functionally defined as being somehow "used to determine whether a segment is corrupted") and the application of a statistical learning method.

In any case, the application of a statistical learning method for the determination whether a segment is corrupted appears to be contradictory because the determination whether a segment is corrupted or not can only be made by a trained classifier.

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 18, 35 is not new in the sense of Article 33(2) PCT.

3.1 The document D1 discloses (the references in parentheses applying to this document): A computer implemented method (par. 76) for detection of motion and noise artifacts in a Photoplethysmogram (PPG) or equivalent signal (par. 87, 89), the computer implemented method comprising:
obtaining a time frequency spectrum of a segment of the PPG or equivalent signal (par. 79);
obtaining, from the time frequency spectrum, a noise quality index for the segment; the noise quality index being used to determine whether a segment is corrupted by motion and noise artifacts (par. 89: (scalogram magnitude)); and
applying a statistical learning method to determine whether the segment is corrupted by motion and noise artifacts or not corrupted by motion and noise artifacts (par. 89 (neural network)).

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

3.2 For the sake of completeness it is pointed out, that the objection of lack of novelty for claim s set out above could also have been substantiated on document D2 (p. 2604: 2) Period domain analysis and p. 2606: E. Classification)

3.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 18, 35, which therefore are also considered not new.

4 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 18, 35 does not involve an inventive step in the sense of Article 33(3) PCT.

As far as understood the invention as defined in claims 1-33, 18-20 merely consists in determining the presence of noise based on the power contained in those parts of the spectrum which do not correspond to the fundamental frequency of the measured signal and its harmonics.

Since it is well known that the information on heart rate is contained in the fundamental frequency and the harmonics, see D3 (par. 10), no inventive step can be seen in determining the presence of the amount of noise based on the power of the remaining signal components

5 Further dependent claims 2-6, 8, 9, 11, 13-17, 19-23, 25, 26, 28, 29, 31-34, 36 contain either additional features known per se from the prior art or being slight constructional changes which come within the scope of the customary practice followed by the persons skilled in the art.

In particular the dependent claims do not define a relationship between the determined parameters and the defined noise quality index and/or the decision step (statistical learning method). Due to this lack of consistency it can not be determined whether or how these parameters should contribute to the determination of motion or noise artifacts. The features of these claims do thus not contribute to inventive step Art. 33(3) PCT.

Thus also dependent claims 2-6, 8, 9, 11, 13-17, 19-23, 25, 26, 28, 29, 31-34, 36 do not meet the requirements of Art. 33(1) PCT with respect to inventive step (Art. 33(3) PCT).

6 The combination of the features of dependent claims 7, 10, 12, 24, 27 or 30 is neither known from, nor rendered obvious by, the available prior art.

Re Item VI

The applicant should further be aware of the following document:

D5 SEYED SALEHIZADEH 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, vol. 16, no. 1, 23 December 2015, ISSN: 1424-8220, DOI: 10.3390/s16010010

Re Item VII

1 The independent claims are not drafted in the two part form as required by Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

2 The features of the claims are not provided with reference signs placed in parentheses as required by Rule 6.2(b) PCT.

3 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D3 is not mentioned in the description, nor are these documents identified therein.

Bitte beachten Sie, dass angeführte Nichtpatentliteratur (wie z. B. wissenschaftliche oder technische Dokumente) je nach geltendem Recht dem Urheberrechtsschutz und/oder anderen Schutzarten für schriftliche Werke unterliegen könnte. Die Vervielfältigung urheberrechtlich geschützter Texte, ihre Verwendung in anderen elektronischen oder gedruckten Publikationen und ihre Weitergabe an Dritte ist ohne ausdrückliche Zustimmung des Rechtsinhabers nicht gestattet.

Veuillez noter que les ouvrages de la littérature non-brevets qui sont cités, par exemple les documents scientifiques ou techniques, etc., peuvent être protégés par des droits d'auteur et/ou toute autre protection des écrits prévue par les législations applicables. Les textes ainsi protégés ne peuvent être reproduits ni utilisés dans d'autres publications électroniques ou imprimées, ni rediffusés sans l'autorisation expresse du titulaire du droit d'auteur.

Please be aware that cited works of non-patent literature such as scientific or technical documents or the like may be subject to copyright protection and/or any other protection of written works as appropriate based on applicable laws. Copyrighted texts may not be copied or used in other electronic or printed publications or re-distributed without the express permission of the copyright holder.

XS CPRTENFRDE

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
15/010,345	01/29/2016	Ki H. Chon	30210-216

CONFIRMATION NO. 2095

26486
BURNS & LEVINSON, LLP
125 SUMMER STREET
BOSTON, MA 02110

PUBLICATION NOTICE

OC000000084854785

Title:MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS

Publication No.US-2016-0220188-A1
Publication Date:08/04/2016

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ki H. Chon
Examiner: MALLARI, PATRICIA C
Application No.: 15/010,345
Confirm. No.: 2095
Filed: 01-29-2016
Art Unit: 3735
For: MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS

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

SUPPLEMENTAL AMENDMENT

Sir/Ms.:

Applicants submit the following supplemental amendment to the specification.

Amendments to the specification begin on page 2 of this paper.

Amendments to the specification:

Please revise paragraph **[0002]** with the following amended paragraph:

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] This invention was made ~~partially~~ with U.S. Government support from the United States Army Medical Research and Material Command under Grant No. W81XWH-12-1-0541. The U.S. Government has certain rights in the invention.

REMARKS

If the Examiner has any further questions regarding this amendment, he/she is invited to call Applicant's attorney at the number listed above.

The Director of Patents and Trademarks is hereby authorized to charge any underpayment of fees, or credit any overpayments to Deposit Account 03-2410 (Order No. 30210-216).

Respectfully submitted,

Dated: December 28, 2017

By: / Orlando Lopez/
Orlando Lopez, Ph.D.
Reg. No. 46,880
Attorney for Applicant
617-345-3243

4833-5256-2521.1

Electronic Acknowledgement Receipt

EFS ID:	31355152
Application Number:	15010345
International Application Number:	
Confirmation Number:	2095
Title of Invention:	MOTION AND NOISE ARTIFACT DETECTION AND RECONSTRUCTION ALGORITHMS FOR PHOTOPLETHYSMOGRAM AND EQUIVALENT SIGNALS
First Named Inventor/Applicant Name:	Ki H. Chon
Customer Number:	26486
Filer:	Orlando Lopez/Susan Jones Oujli
Filer Authorized By:	Orlando Lopez
Attorney Docket Number:	30210-216
Receipt Date:	28-DEC-2017
Filing Date:	29-JAN-2016
Time Stamp:	14:37:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		SupplAmend.pdf	72781 68e5e23269187e2003de4d97e8641ddd50e1e2d7	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Supplemental Response or Supplemental Amendment	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	72781	

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/010,345	01/29/2016	Ki H. Chon	30210-216	2095

26486 7590 09/14/2018

BURNS & LEVINSON, LLP
125 SUMMER STREET
BOSTON, MA 02110

EXAMINER	
SHOSTAK, ANDREY	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
09/14/2018	ELECTRONIC

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

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

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

docketing@burnslev.com

Office Action Summary	Application No. 15/010,345	Applicant(s) Chon et al.	
	Examiner ANDREY SHOSTAK	Art Unit 3735	AIA Status Yes

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 12/28/2017.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-36 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-36 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☑ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 01/29/2016 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

Drawings

2. The drawings are objected to because at least Figs. 1B, 1D, 3, 4A-4C, 5, 6, 7A, and 7B contain unreadable graphical and/or textual elements (e.g. unreadable white lines on a black background, and no distinction between traces and unclear legends such that the legends are not usable). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of

any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: The use of the terms MASIMO, MASIMO RADICAL, INTEL, XEON, and MATLAB, which are trade names or marks used in commerce, has been noted in this application. They should be (1a) in ALL CAPS or (1b) accompanied by the appropriate symbol (™, ℠, or ®) wherever they appear, and be (2) accompanied by the generic terminology. See MPEP 608.01(v).

Although the use of trade names and marks used in commerce (i.e., trademarks, service marks, certification marks, and collective marks) are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as commercial marks.

Appropriate correction is required.

4. The abstract of the disclosure is objected to because it uses the term "novel," which is redundant because the term is already implied. The abstract is meant to include that which is new in the art to which the invention pertains. Correction is required. See MPEP § 608.01(b).

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claim 5 is objected to because of the following informalities: the recitation of "Mahine" is a typographical error and should instead read --Machine--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):

> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 1-36 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.**

9. **Regarding claims 1, 9, 12, 15, 16, 18, 26, 29, 32, 33, and 35,** they each recite "equivalent signal," which is a relative phrase which renders the claim indefinite. The phrase "equivalent signal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, it is unclear what kind of signal would be considered an equivalent. ¶ 0028 of the specification defines them as signals which behave like PPG signals, but it is unclear what behavior/signal qualities are intended or encompassed.

10. **Regarding claims 3, 6, 9, 12, 20, 23, 26, and 29,** they each recite "hereinafter referred to as" or "referred to as," which are narrative recitations that fail to particularly point out the invention at least because reference is made to subsequent claims. The terms should be defined first.

11. **Regarding claims 1, 3, 6, 7, 9, 10, 12, 13, 18, 20, 23, 24, 26, 27, 29, 30, and 35,** the separation and interoperability of elements is unclear because the claims use a semicolon, instead of e.g. a comma, to further detail particular elements (see e.g. line 5 of