Docket No.: MAS.1007C1 Page 1 of 1

REQUEST FOR CERTIFICATE OF CORRECTION

First Inventor Ammar Al-Ali

App. No. 16/226249

Filed December 19, 2018

Patent No. 10,470,695

Issue Date November 12, 2019

Title ADVANCED PULSE OXIMETRY SENSOR

Conf. No. 1002

Commissioner for Patents Office of Data Management

Attention: Certificates of Correction Branch

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Commissioner:

Enclosed for filing is a Certificate of Correction in connection with the above-identified patent.

Some of the errors cited in the Certificate of Correction appear to have been incurred through the fault of the PTO (see 35 USC § 254, 37 CFR § 1.322, and MPEP § 1480). However, because this may not apply to each item in the Certificate of Correction, the \$150 fee under 37 CFR § 1.20(a) is submitted herewith. Please charge any additional fees to our Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 10, 2020 By: /Jarom Kesler/

> Jarom D. Kesler Registration No. 57,046 Registered Practitioner

(949) 760-0404

1

33262661

APPLE 1002

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

PATENT NO. : 10,470,695 Page 1 of 1

APPLICATION NO. : 16/226249

ISSUE DATE : November 12, 2019

INVENTOR(S) : Ammar Al-Ali

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

On Page 9, Column 1, Item (56), Line 30, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 1, Item (56), Line 35, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 1, Item (56), Line 39, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 6, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 8, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 9, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 10, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 11, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 12, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 13, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 14, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 15, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Page 9, Column 2, Item (56), Line 16, under U.S. Patent Documents, delete "Ai" and insert -- Al--.

On Sheet 7 of 7, FIG. 8, Reference Number 810, Line 2 (Approx.),

delete "PROCESOR" and insert -- PROCESSOR ---.

In Column 1, Line 39, delete " $\mu_{a,\lambda}$ " and insert -- $\mu_{\alpha,\lambda}$ --.

In Column 1, Line 42 (Approx.), delete " $\mu_{a,\lambda}$ " and insert -- $\mu_{\alpha,\lambda}$ --.

In Column 7, Line 52, delete "(also" and insert -- also--.

In Column 8, Line 1, delete "Gausian" and insert -- Gaussian--.

In Column 12, Line 37, delete "light emitting" and insert --light-emitting--.

MAILING ADDRESS OF SENDER:

Jarom D. Kesler KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, 14th Floor Irvine, California 92614

DOCKET NO. MAS.1007C1

| Electronic Patent Application Fee Transmittal | | | | | | | |
|---|----------------------------------|-----------|----------|--------|-------------------------|--|--|
| Application Number: | 16 | 226249 | | | | | |
| Filing Date: | 19 | -Dec-2018 | | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | | |
| Filer: | Jarom D. Kesler/Lorraine Yoo Lin | | | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | | | |
| Filed as Large Entity | | | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) | | |
| Basic Filing: | | | | | | | |
| Pages: | | | | | | | |
| Claims: | | | | | | | |
| Miscellaneous-Filing: | | | | | | | |
| Petition: | | | | | | | |
| Patent-Appeals-and-Interference: | | | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | | | |
| CERTIFICATE OF CORRECTION | | 1811 | 1 | 150 | 150 | | |
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| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------|----------|-----------|--------|-------------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| | Tot | al in USD | (\$) | 150 |
| | | | | |

| Electronic Acknowledgement Receipt | | | | |
|--------------------------------------|--------------------------------------|--|--|--|
| EFS ID: | 40237895 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Jarom D. Kesler/Elizabeth Rutherford | | | |
| Filer Authorized By: | Jarom D. Kesler | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 10-AUG-2020 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 14:43:20 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | yes |
|--|----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$150 |
| RAM confirmation Number | E202080E43460435 |
| Deposit Account | 111410 |
| Authorized User | Elizabeth Rutherford |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing | | | | | |
|--------------------|---------------------------------------|-----------------------------|---|---------------------|---------------------|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
| 1 | Request for Certificate of Correction | 1007C1.pdf | 36064 6627fcfc4404999932ca0ace6a8903afb706 5675 | no | 2 |
| Warnings: | | | • | | |
| Information: | | | | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30127 c253164ccee834a79943210e325ac76d510 47ed7 | no | 2 |
| Warnings: | | | | | |
| Information: | | | | | |
| | | Total Files Size (in bytes) | 6 | 6191 | |

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | ISSUE DATE | PATENT NO. | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|------------|---------------------|------------------|
| 16/226 240 | 11/12/2010 | 10470605 | MAS 1007C1 | 1002 |

64735

7590

10/23/2019

KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

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

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

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

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

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

Ammar Al-Ali, San Juan Capistrano, CA; MASIMO CORPORATION, Irvine, CA;

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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit <u>SelectUSA.gov</u>.

IR103 (Rev. 10/09)



United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User: C46472

Sale Accounting Date:10/02/2019

Sale Item Reference Number Effective Date

16226249 09/30/2019

Document Number Fee Code Fee Code Description Amount Paid Payment Method 1201902841092646 1501 UTILITY APPL ISSUE FEE \$1,000.00 Salea

PART B - FEE(S) TRANSMITTAL Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web. By mail, send to: Mail Stop ISSUE FEE By fax, send to: (571)-273-2885 Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) Certificate of Mailing or Transmission 09/27/2019 I hereby certify that this Fee(s) Transmittal is being deposited with the United KNOBBE, MARTENS, OLSON & BEAR, LLP States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below. MASIMO CORPORATION (MASIMO) 2040 MAIN STREET (Typed or printed name FOURTEENTH FLOOR (Signature IRVINE, CA 92614 APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 16/226,249 12/19/2018 Ammar Al-Ali MAS.1007C1 1002 TITLE OF INVENTION: ADVANCED PULSE OXIMETRY SENSOR APPLN, TYPE ENTITY STATUS ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional UNDISCOUNTED \$1000 \$0.00 \$1000.00 \$0 12/27/2019 EXAMINER ART UNIT CLASS-SUBCLASS FARDANESH, MARJAN 3791 600-323000 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys Knobbe, Martens, or agents OR, alternatively, ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) The name of a single firm (having as a member a Olson & Bear, LLP registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is "Fee Address" indication (or "Fee Address" Indication form PTO/ listed, no name will be printed. SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) Irvine, CA Masimo Corporation Please check the appropriate assignee category or categories (will not be printed on the patent): 🗖 Individual 🚨 Corporation or other private group entity 🗖 Government **∑**Issue Fee 4a. Fees submitted: Publication Fee (if required) ☐Advance Order - # of Copies 4b. Method of Payment: (Please first reapply any previously paid fee shown above) Electronic Payment via EFS-Web Enclosed check Non-electronic payment by credit card (Attach form PTO-2038) The Director is hereby authorized to charge the required fec(s), any deficiency, or credit any overpayment to Deposit Account No. 11-1410

to be a notification of loss of entitlement to micro entity status. NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro Applicant changing to regular undiscounted fee status. entity status, as applicable. NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications. /Aaron S. Johnson/ September 30, 2019 Authorized Signature Date 74,164 Aaron S. Johnson Typed or printed name _ Registration No.

Page 2 of 3

OMB 0651-0033

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue

fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken

5. Change in Entity Status (from status indicated above)

Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

| Electronic Acknowledgement Receipt | | | | |
|--------------------------------------|---------------------------------------|--|--|--|
| EFS ID: | 37315738 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Aaron Samuel Johnson/ThuyQuyen Nguyen | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 30-SEP-2019 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 18:51:49 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | | | no | | | | |
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| File Listin | g: | | | | | | |
| Document Number | Document Description | | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) | |
| 1 | Issue Fee Payment (PTO-85B) | IS | SSUE-FEE MAS1007C1.PDF | 217542 | no | 1 | |
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| Information: | |
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| Total Files Size (in bytes): | 217542 |

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Best Available CoppreE(S) TRANSMITTAL

| Complete and send t | his form, together v | with applicable fee(s |), by mail or fax, | or via EFS-Web. | | | |
|--|---|--|---|--|----------------------------------|---|---|
| By mail, send to: | Mail Stop ISSUE | | | | | By fax, send to: | : (571)-273-2885 |
| | Commissioner for P.O. Box 1450 | Patents | | | | | 10 |
| | Alexandria, Virgin | nia 22313-1450 | | | | | XV |
| | | ansmitting the ISSUE FEI | | | | | |
| below or directed otherwi | ise in Block 1, by (a) spe | ecifying a new correspond | dence address; and/or | (b) indicating a separat | e "FEE ADD | RESS" for mainten | ance fee notifications. |
| CURRENT CORRESPONDE | ENCE ADDRESS (Note: Use Bi | lock I for any change of address) | | Fee(s) Transmittal. Th | is certificate al paper, such | cannot be used for as an assignment | domestic mailings of the any other accompanying or formal drawing, must |
| 64735 | | 7/2019 | | Ce | rtificate of N | failing or Transmi | |
| | RTENS, OLSON | | OPAR | States Postal Service v | with sufficier | it postage for first o | eposited with the United class mail in an envelope |
| 2040 MAIN STR | PORATION (MAS) REET | / | MAA | the USPTO via EFS-V | Stop ISSUE Veb or by fac | FEE address above simile to (571) 273- | e, or being transmitted to 2885, on the date below. |
| FOURTEENTH | | (\$ | SEP 3 0 2019 🗟 | | | | (Typed or printed name) |
| IRVINE, CA 92614 | | | | | | | (Signature) |
| | | · · | A TRADEMARK OFFICE | | | | (Date) |
| | | | | | | | |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVEN | TOR | ATTORNE | OCKET NO. | CONFIRMATION NO. |
| 16/226,249 | 12/19/2018 | | Ammar Al-Ali | | MAS | .1007C1 | 1002 |
| TITLE OF INVENTION: | ADVANCED PULSE | OXIMETRY SENSOR | | | | | |
| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE I | DUE PREV. PAID ISSU | JE FEE TO | TAL FEE(S) DUE | DATE DUE |
| nonprovisional | UNDISCOUNTED | \$1000 | \$0.00 | \$1000.00 | | \$0 | 12/27/2019 |
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| 1. Change of corresponde CFR 1.363). | ence address of indication | not ree Address (37 | (1) The names of | up to 3 registered pate | | , Knobbe, N | /lartens. |
| Change of corresponded Address form PTO/SB | ondence address (or Cha | nge of Correspondence | or agents OR, alte (2) The name of a | single firm (having as | a member a | * | |
| | • | | registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is | | | | |
| SB/47; Rev 03-09 or n Number is required. | cation (or "Fee Address nore recent) attached. U | se of a Customer | listed, no name wi | | | 3 | |
| 3. ASSIGNEE NAME AT | | | | | dentified belo | ow the document m | ust have been previously |
| recorded, or filed for r | ecordation, as set forth i | ed below, no assignee dat n 37 CFR 3.11 and 37 CF | FR 3.81(a). Completion | on of this form is NOT | a substitute fo | or filing an assignm | ent. |
| (A) NAME OF ASSIC | GNEE | | (B) RESIDENCE: (C | CITY and STATE OR | COUNTRY) | | |
| Masimo Coi | rporation | | Irvine, CA | | | | |
| Please check the appropri | ate assignee category or | categories (will not be pa | rinted on the patent): | Individual 🛚 Corp | oration or oth | er private group en | tity 🗖 Government |
| 4a. Fees submitted: | XIssue Fee Pub | olication Fee (if required) | Advance Ord | er - # of Copies | | | |
| 4b. Method of Payment: (| | · · · · · _ | | | | | |
| Electronic Paymen | | | | nt by credit card (Attac | | * | |
| The Director is her | reby authorized to charge | e the required fee(s), any | deficiency, or credit a | ny overpayment to Dep | osit Account | No11-14-10 | |
| 5. Change in Entity Stat | (6 | . 4 . 1 | | | | | |
| _ ` . | g micro entity status. Se | * | | | | | SB/15A and 15B), issue |
| | small entity status. See | | NOTE: If the applica | ation was previously un floss of entitlement to | ider micro en | tity status, checking | pplication abandonment. g this box will be taken |
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| NOTE: This form must be | | | entity status, as appl 3. See 37 CFR 1.4 for | | and certifica | tions. | |
| Authorized Signature | /A O . I - b | · · · · · · · · · · · · · · · · · · · | | | | r 30, 2019 | |
| Typed or printed name | | | | Registration 1 | 74,10 | 64 | |

Page 2 of 3 OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Registration No. _

Typed or printed name Aaron S. Johnson

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

64735 7590 09/27/2019
KNOBBE, MARTENS, OLSON & BEAR, LLP
MASIMO CORPORATION (MASIMO)
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
FARDANESH, MARJAN

ART UNIT PAPER NUMBER

3791

DATE MAILED: 09/27/2019

| | APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|-------------|----------------------|---------------------|------------------|
| - | 16/226.249 | 12/19/2018 | Ammar Al-Ali | MAS.1007C1 | 1002 |

TITLE OF INVENTION: ADVANCED PULSE OXIMETRY SENSOR

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED | \$1000 | \$0.00 | \$1000.00 | \$0 | 12/27/2019 |

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

Page 1 of 3

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web. Mail Stop ISSUE FEE By mail, send to: By fax, send to: (571)-273-2885 Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. Certificate of Mailing or Transmission 64735 09/27/2019 7590 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below. 2040 MAIN STREET (Typed or printed name FOURTEENTH FLOOR (Signatur IRVINE, CA 92614 APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 16/226.249 12/19/2018 MAS.1007C1 Ammar Al-Ali 1002 TITLE OF INVENTION: ADVANCED PULSE OXIMETRY SENSOR APPLN TYPE ENTITY STATUS ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional UNDISCOUNTED \$1000 \$0.00 \$1000.00 12/27/2019 EXAMINER ART UNIT CLASS-SUBCLASS FARDANESH, MARJAN 3791 600-323000 1. Change of correspondence address or indication of "Fee Address" (37 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is "Fee Address" indication (or "Fee Address" Indication form PTO/ listed, no name will be printed. SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) Please check the appropriate assignee category or categories (will not be printed on the patent) : 🗖 Individual 🗖 Corporation or other private group entity 🗖 Government 4a. Fees submitted: ☐Issue Fee ■Publication Fee (if required) Advance Order - # of Copies 4b. Method of Payment: (Please first reapply any previously paid fee shown above) 🗖 Electronic Payment via EFS-Web Enclosed check Non-electronic payment by credit card (Attach form PTO-2038) The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 5. Change in Entity Status (from status indicated above) NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue Applicant certifying micro entity status. See 37 CFR 1.29 fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken Applicant asserting small entity status. See 37 CFR 1.27 to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro

Date

Registration No.

entity status, as applicable

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

Page 2 of 3 OMB 0651-0033

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Applicant changing to regular undiscounted fee status.

Authorized Signature

Typed or printed name

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. | | |
|--------------------------------|-------------------------|-----------------------|------------------------|------------------|--|--|
| 16/226,249 | 12/19/2018 | Ammar Al-Ali | MAS.1007C1 | 1002 | | |
| 64735 75 | 590 09/27/2019 | EXAMINER | | | | |
| KNOBBE, MAR | TENS, OLSON & B | FARDANESH, MARJAN | | | | |
| MASIMO CORPO 2040 MAIN STRE | DRATION (MASIMO) EET | ART UNIT PAPER NUMBER | | | | |
| FOURTEENTH F | | | 3791 | | | |
| IRVINE, CA 9261 | 4 | | DATE MAILED: 09/27/201 | 9 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

| | Application No. 16/226,249 | Applicant(s Al-Ali, Amma | |
|--|---|---------------------------------|-------------------------------------|
| Notice of Allowability | Examiner MARJAN FARDANESH | Art Unit 3791 | AIA (FITF) Status Yes |
| The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS (herewith (or previously mailed), a Notice of Allowance (PTOL-85) of NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIC of the Office or upon petition by the applicant. See 37 CFR 1.313 at 1. This communication is responsive to IDS filed on 08/15/2019 | OR REMAINS) CLOSED in this app or other appropriate communication GHTS. This application is subject to and MPEP 1308. | lication. If not will be mailed | included in due course. THIS |
| ☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/ 2.☐ An election was made by the applicant in response to a restriction requirement and election have been incorporated | riction requirement set forth during t | he interview o | n; the |
| 3. ☑ The allowed claim(s) is/are 57-64,67-70,72-74,77-78,81-83, benefit from the Patent Prosecution Highway program at a application. For more information, please see http://www.us-PPHfeedback@uspto.gov. | 85 and 87-95. As a result of the allogation aparticipating intellectual property of | ffice for the co | rresponding |
| 4. Acknowledgment is made of a claim for foreign priority unde Certified copies: | er 35 U.S.C. § 119(a)-(d) or (f). | | |
| a) All b) Some *c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 5. CORRECTED DRAWINGS (as "replacement sheets") must including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1. sheet. Replacement sheet(s) should be labeled as such in the heet | e been received in Application Nocuments have been received in this of this communication to file a reply ENT of this application. be submitted. Amendment / Comment or in the Of 84(c)) should be written on the drawing cument and the submitted of the submit | national stage complying wi | th the requirements |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT F | IOLOGICAL MATERIAL must be su | | |
| Attachment(s) 1. Notice of References Cited (PTO-892) 2. Information Disclosure Statements (PTO/SB/08), | 5. ☑ Examiner's Amend 6. ☐ Examiner's Statem 7. ☐ Other | | - |
| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | /ERIC F WINAKUR/ Primary Examiner, Art | Unit 3791 | |

U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20190906

Application/Control Number: 16/226,249 Page 2

Art Unit: 3791

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.

2. The IDS filed on 08/15/2019 was fully considered and entered. Claims 57-64,67-70,72-74,77-78,81-83,85,87-95 are allowable for the reasons of record.

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571)272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

Application/Control Number: 16/226,249 Art Unit: 3791 Page 3

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC F WINAKUR/ Primary Examiner, Art Unit 3791

/MARJAN FARDANESH/ Examiner, Art Unit 3791

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali, Ammar |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| CPC | CPC | | | | | | | | |
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| Symbol | | | Туре | Version | | | | | |
| A61B | / 5 | 14552 | F | 2013-01-01 | | | | | |
| A61B | / 5 | / 6826 | I | 2013-01-01 | | | | | |
| A61B | / 5 | / 0002 | I | 2013-01-01 | | | | | |
| A61B | / 5 | J 02416 | I | 2013-01-01 | | | | | |
| A61B | / 5 | / 14532 | I | 2013-01-01 | | | | | |
| A61B | 5 | / 14546 | I | 2013-01-01 | | | | | |
| A61B | / 5 | / 4875 | I | 2013-01-01 | | | | | |
| A61B | 5 | <i>i</i> 7278 | I | 2013-01-01 | | | | | |
| A61B | / 5 | <i>l</i> 742 | 1 | 2013-01-01 | | | | | |
| A61B | 2562 | / 04 | A | 2013-01-01 | | | | | |

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| Symbol | Туре | Set | Ranking | Version | | | | | |
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| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 11 September 2019 | Total Claims Allowed: | | |
|---|-------------------|-----------------------|-------------------|--|
| (Assistant Examiner) | (Date) | 30 | | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 11 September 2019 | O.G. Print Claim(s) | O.G. Print Figure | |
| (Primary Examiner) | (Date) | 1 | 7 | |

U.S. Patent and Trademark Office

Part of Paper No.: 20190906

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali, Ammar |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| INTERNATIONAL CLASS | IFICATION | |
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| A61B | / 5 | <i>l</i> 1455 |
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| US ORIGINAL CLASSIFIC | CATION | |
| C | LASS | SUBCLASS |
| 600 | | 310 |

| CROSS REFERENCES(S) | | | | | | | | | | |
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| CLASS | | SUBCLASS (ONE SUBCLASS PER BLOCK) | | | | | | | | |
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| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 11 September 2019 | Total Claims Allowed: | | |
|---|-------------------|-----------------------|-------------------|--|
| (Assistant Examiner) | (Date) | 30 | | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 11 September 2019 | O.G. Print Claim(s) | O.G. Print Figure | |
| (Primary Examiner) | (Date) | 1 | 7 | |

U.S. Patent and Trademark Office

Part of Paper No.: 20190906

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali, Ammar |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| | Claims re | enumbe | ered in th | ie sam | e order a | s pres | ented by | applic | ant [|] CPA | √ | T.D. | R.1 | 1.47 | |
|-------|-----------|--------|------------|--------|-----------|--------|----------|--------|----------|-------|----------|-------|----------|-------|----------|
| CLAIM | S | | | | | | | | | | | | | | |
| Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original |
| 1 | 57 | | 66 | | 75 | | 84 | 28 | 93 | | | | | | |
| 2 | 58 | 9 | 67 | | 76 | 24 | 85 | 29 | 94 | | | | | | |
| 3 | 59 | 10 | 68 | 19 | 77 | | 86 | 30 | 95 | | | | | | |
| 4 | 60 | 11 | 69 | 20 | 78 | 25 | 87 | | | | | | | | |
| 5 | 61 | 12 | 70 | | 79 | 26 | 88 | | | | | | | | |
| 6 | 62 | | 71 | | 80 | 27 | 89 | | | | | | | | |
| 7 | 63 | 13 | 72 | 21 | 81 | 16 | 90 | | | | | | | | |
| 8 | 64 | 14 | 73 | 22 | 82 | 17 | 91 | | | | | | | | |
| | 65 | 15 | 74 | 23 | 83 | 18 | 92 | | | | | | | | |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 11 September 2019 | 11 September 2019 Total Claims Allowed: | |
|---|-------------------|---|-------------------|
| (Assistant Examiner) | (Date) | 30 | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 11 September 2019 | O.G. Print Claim(s) | O.G. Print Figure |
| (Primary Examiner) | (Date) | 1 | 7 |

U.S. Patent and Trademark Office

Part of Paper No.: 20190906

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|--------------|-------------------------|---|
| Search Notes | 16/226,249 | Al-Ali, Ammar |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| CPC - Searched* | | | | |
|----------------------------------|------------|------|--|--|
| Symbol Date Examin | | | | |
| EAST-See search history printout | 03/04/2019 | /mf/ | | |
| EAST-See search history printout | 07/19/2019 | /mf/ | | |
| EAST-See search history printout | 09/11/2019 | /mf/ | | |

| CPC Combination Sets - Searched* | | | | |
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| US Classification - Searched* | | | | |
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| Class Subclass Date Examiner | | | | |
| | | | | |

^{*} See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

| Search Notes | | |
|---------------------------|------------|----------|
| Search Notes | Date | Examiner |
| PALM-inventor name search | 03/04/2019 | /mf/ |

| Interference Search | | | | |
|------------------------|-----------------------------|------------|----------|--|
| US Class/CPC Symbol | US Subclass/CPC Group | Date | Examiner | |
| EAST- | See search history printout | 07/19/2019 | /mf/ | |
| EAST- | See search history printout | 09/11/2019 | /mf | |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | |
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EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|---|---|--|----------------------------------|---------------------|---------------------|---------------------|
| S1 | 6 | (("5513649") or ("7286871") or ("8538512") or ("20070167858") or ("20160157779") or ("20050288954")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 07:24 |
| S2 | 1 | (sweat) with subtract\$4 with EEG and A61B5/0006.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/09 07:32 |
| A61B5/\$.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 07:41 | |
| S4 0 (sweat) adj2 subtract\$4 and A61B5/0006.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 07:42 | |
| S5 1 (sweat) with subtract\$4 and A61B5/0006.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 07:42 | |
| S6 | S6 4 (sweat) adj artifact and A61B5/0006.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 07:46 |
| S7 | 1 "15782874" US- OR PGPUB; USPAT | | ON | 2019/09/09 08:17 | | |
| S8 | 0 | pulse and lee with rang.in. | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:50 |
| S9 | 10 | lee with rang.in. | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:50 |
| S10 | 373 | meridian.asn. | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:52 |
| S1 1 | 1537586 | meridian.asn. ans pulse | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:52 |
| S12 | 32 | meridian.asn. and pulse | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:52 |
| S13 | park.in. and stiffness | | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:53 |
| S14 | S14 0 park.in. and sarterial | | US- PGPUB; USPAT | OR | ON | 2019/09/09 09:53 |
| S15 | 1 | ("20130324859").PN. | US- PGPUB; USPAT; USOCR | | OFF | 2019/09/09 09:53 |

| S16 | 1 | normal adj notch and transient adj notch | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:00 |
|-----------------|---|---|----------------------------------|----|---------------------|---------------------|
| S17 | 143 | normal adj notch | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:00 |
| S18 | 38 | normal adj notch and pulse | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:01 |
| S19 | A61B5/7278.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:01 |
| S20 | notch and pulse and A61B5/7278.cpc. | | | OR | ON | 2019/09/09 10:01 |
| A61B5/7278.cpc. | | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:02 | |
| S22 | 51 | notch and pulse and peak\$4 and trough and A61B5/7278.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:02 |
| S23 | 4228 | notch and pulse and peak\$4 and trough and systolicand A61B5/7278.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:03 |
| S24 | 35 | notch and pulse and peak\$4 and trough and systolic and A61B5/7278.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:03 |
| S25 | 5585 | notch and pulse and peak\$4 and trough and systolic and onset]and A61B5/7278.cpc. | | OR | ON | 2019/09/09 10:04 |
| S26 | 21 | notch and pulse and peak\$4 and trough and systolic and onset and A61B5/7278.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:04 |
| S27 | 21 | notch and pulse and peak\$4 and trough and systolic and onset and A61B5/7278.cpc. and (normal transient dicrotic) | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:05 |
| S28 | 4 | notch and pulse and peak\$4 and trough and systolic and onset and A61B5/7278.cpc. and (normal transient dicrotic) and classif\$5 | US- PGPUB; USPAT | OR | ON | 2019/09/09 10:05 |
| S29 | S29 1 ("20100317940").PN. | | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 12:56 |
| S30 | 530 5 (("20100317940") or ("20020011568") or ("8175668") or ("4770536") or ("4443107")).PN. | | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 12:57 |
| S31 | 26 | 26 ("4114604" "4623248" "4776340" "4809697" "4944299" "5048524" "5061632" "5149503" "5282466" "6064474" "6103197" "6144444" "6181958" "6275734" "6711425" "6714805" "7029628").PN. OR ("8175668").URPN. | | OR | OFF | 2019/09/09 13:03 |
| S32 | 1 | ("20100041969").PN. | US- PGPUB; | OR | OFF | 2019/09/09 13:05 |

| | | | USPAT; USOCR | | | |
|-----|-----|--|----------------------------------|----|-----|---------------------|
| S33 | 1 | "15581803" | US- PGPUB; USPAT | OR | OFF | 2019/09/09 14:36 |
| S34 | 1 | "16312080" | US- PGPUB; USPAT | OR | OFF | 2019/09/09 14:54 |
| S35 | 1 | "15850755" | US- PGPUB; USPAT | OR | OFF | 2019/09/09 15:12 |
| S36 | 313 | fardanesh.xa. | US- PGPUB; USPAT | OR | OFF | 2019/09/09 15:13 |
| S37 | 920 | ("20010021803" "20010051767" "20020026109" "20020028990" "20020038078" "20020042558" "20020038878" "20020128544" "20020133067" "20020156354" "20020173706" "20020173709" "20020190863" "20020198442" "20030018245" "20030036690" "20030073890" "20030100840" "20030132495" "20030135099" "20030162414" "20030171662" "20030187337" "200301581799" "20030187337" "20030195402" "20030187337" "2003012316" "20030225323" "20030225337" "20030225323" "20030225337" "2004006261" "20040010188" "200400424297" "20040039272" "20040034293" "20040054269" "20040059210" "20040054269" "20040059210" "20040064020" "20040068164" "2004007797" "2004008809" "2004007665" "20040116788" "20040116789" "20040117891" "2004012300" "20040117891" "20040143172" "20040117821" "20040143172" "20040152302" "20040147824" "20040158135" "20040171948" "2004017920" "2004018133" "200401799063" "20040171948" "20040176671" "20040186358" "20040176671" "20040204636" "2004024639" "20040204636" "2004024639" "20040204638" "2004024639" "20040204638" "2004024639" "20040204638" "2004024639" "20040204638" "20040266161" "20040224880" "20040266161" "20040224980" "20040236196" "20040224980" "20040236196" "20040224980" "20040236196" "20040257557" "20040266161" "20040257557" "200402667104").PN. OR ("20040267140" "20050004479" "20040257557" "200402667104").PN. OR ("20040267140" "20050004479" "20040267103" "200402667104").PN. OR ("20040267140" "20050004479" "20050010092" | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 15:27 |

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| 1 | ("5007423" | , | _ | *************************************** | | | - |
| ******* | "5040539" | • | "5055671" | *************************************** | | | *************************************** |
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| | "5452717" | "5465714" | "5469845" | į l | | | |
| | "5482034" | "5482036" | "5483646" | j l | | | |
| , | "5485847" | "5490505") | .PN. OR | ' | | | |
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| | "5797841" | "5800348" | "5800349" | į į | | | |
| | "5803910" | "5807246" | "5807247" | į į | | | |
| | "5807248" | "5810723" | "5810724" | į l | | | |
| ļ | "5813980" | | "5817009" | j | | | |
| ì | "5817010" | "5818985" | "5820550" | j | | | |
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| | "6681454" | "6684090" | "6684091" | | | |
| | "6694160" i | i "6697653" i | "6697655" | i | | |
| | "6697656" | "6697658" | "6699194" | | | |
| | "6699199" | "6701170" | "6702752" | i | | |
| | "6707257" i | "6708049" | "6709402" | i l | | |
| | "6711424" | "6711425" | "6714803" | i l | | |
| | "6714804" | "6714805" | "6719686" | j l | | |
| | "6719705" i | "6720734" | "6721584" | j l | | |
| | "6721585" i | "6725074" | "6725075" | i | | |
| | "6731963" | "6731967" | "6735459" | | | |
| | "6745060" i | "6745061" | "6748253" | i l | | |
| | "6748254" | "6754515" | "6754516" | i l | | |
| | "6760607" i | i "6760609" i | "6760610" | i | | |
| | "6763255" i | "6763256" | "6770028" | i l | | |
| | "6771994" i | i "6773397" i | "6778923" | j l | | |
| | "6780158" | "6792300" | "6793654" | i | | |
| | "6801797" i | "6801798" | "6801799" | i | | |
| | "6801802" | "6802812" | "6805673" | i l | | |
| | "6810277" | "6813511" i | "6816741" | i | | |
| | "6819950" | | "6825619" | <u> </u> | | |
| | "6826419" | | "6830711" | j l | | |
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| | "6862091" | "6863652" | "6865407" | İ | | |
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| | "6898452" i | "6909912" | "6912413" | i l | | |
| | "6916289" | "6920345" | "6931269" | i | | |
| | "6934570" i | i "6939307" i | "6941162" | i l | | |
| | "6947781" | "6950687" | "6963767" | i | | |
| | "6971580" | "6983178" | "6985763" | j | | |
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| | 1, | 7027850" | "7035697" | ' ' | | |
| | "7039449" | | "7047054" | ' ; | | |
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| | | "7047055" "7047056" "7060035" "7062307" "7067893" "7072701" "7072702" "7079880" "7085597" "7096052" "7096054" "7107088" "7113815" "7123950" "7127278" "7130671" "7130672" "7132641" "7133711" "7139599" "7142901" "7162288" "7171065" "7190987" "7198778" "7209775" "7215984" "7225006" "7236811" "7236881" "7248910" "7254433" "7254434" "7263395" "7272426" "7280858" "7283242" "7295866" "7305262" "7313425" "7313426" "7313427" "7315753" "7319894" "7332784" "7341560" "7346378" "7355688" "7356365" "7376454" "7415298" "7424317" "8162503" "D393830" "H001039" "RE33643" "RE38492").PN. OR ("8577434").URPN. | | | | |
|-----|------|---|----------------------------------|----|-----|---------------------|
| S38 | | ("20170281074").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 15:35 |
| S39 | 1 | ("20070057004").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/09 15:59 |
| S40 | 3 | "15958620" and oxide and absorption | US- PGPUB; USPAT | OR | OFF | 2019/09/10 10:10 |
| S41 | 6483 | (UV ultraviolet) same wavelength\$1 and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/09/10 10:14 |
| S42 | 1771 | (UV ultraviolet) same wavelength\$1 and A61B5/1455\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/09/10 10:14 |
| S43 | 837 | ("380" "390" "400" "410") adj nm and A61B5/1455\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/09/10 10:28 |
| S44 | 222 | ("380" "390") adj nm and A61B5/1455\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/09/10 10:37 |
| S45 | 1 | ("9743864").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 13:04 |
| S46 | 29 | ("20020007113" "20030225321" "20030233036" "20050154269" "20060134004" "20060200013" "20080269580" "20100234704" "20110105868" "3958560" "5009230" "5433197" "5535743" "5820557" "5835215" "5879294" "6083158" "6152875" "6166807" "6181957" "6226089" "6424850" "6836337" "6999808" "7167736" "7627357" "7653424" "7769419" "RE40316").PN. OR ("9743864").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 13:05 |

| S47 | 1 | ("5638816").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 13:07 |
|-----|-----|--|----------------------------------|----|-----|---------------------|
| S48 | 2 | (("20140051955") or ("20140371601")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 14:01 |
| S49 | 324 | reflectance same transmittance and A61B5/\$.cpc. and (energiz\$4 driv\$4) with light | US- PGPUB; USPAT | OR | ON | 2019/09/10 14:38 |
| S50 | 26 | ("4114604" "4623248" "4776340" "4809697" "4944299" "5048524" "5061632" "5149503" "5282466" "6064474" "6103197" "6144444" "6181958" "6275734" "6711425" "6714805" "7029628").PN. OR ("8175668").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 14:45 |
| S51 | 16 | ("20060287589" "20070060807" "20070078309" "20070100218" "20070100219" "20070129613" "20080106792" "20080108886" "20090275841" "20090326346" "20100026995" "20100030040" "20100331640" "5817007").PN. OR ("8798702").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 14:53 |
| S52 | 139 | ("5074309" "5151590" "5348002" "5348003" "5579001" "5702284" "5786592").PN. OR ("6403944").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 14:54 |
| S53 | 35 | reflectance same transmittance same switch\$4 and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 14:55 |
| S54 | 920 | ("20010021803" "20010051767" "20020026109" "20020028990" "20020038078" "20020042558" "20020068859" "20020128544" "20020133067" "20020156354" "20020173706" "20020173709" "20020190863" "20020198442" "20030018243" "20030036690" "20030045785" "20030073889" "20030073890" "20030100840" "20030132495" "20030135099" "20030162414" "20030171662" "20030176776" "20030181799" "20030187337" "20030181799" "20030187337" "20030181799" "2003025323" "2003025337" "20030225323" "20030242316" "20030236452" "20030236647" "2004006261" "20040010188" "2004004297" "20040059209" "20040059210" "20040059209" "20040068164" "20040087846" "20040098009" "2004007065" "20040116788" "20040116789" "20040117891" "20040122300" "200401122302" "20040133087" | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 14:58 |

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| 31 ' | 14341" "4759369" | | |
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| | "4805623" I | . ' | ['] "4807631" | ı' | | | | |
| - | "4819646" | "4819752" | "4824242" | i | | | | |
| · · | "4825872" | "4825879" | "4830014" | į | | | | |
| - | "4832484" | "4846183" | "4848901" | i | | | | |
| - | "4854699" | "4859056" | "4859057" | i | | | | |
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| - | "4911167" | "4913150" | "4926867" | i i | | | | |
| - | "4927264" | "4928692" | "4934372" | <u> </u> | | | | |
| - | "4938218" | "4942877" | "4948248" | i | | | | |
| - | "4955379" | "4960126" | "4964408" | i | | | | |
| - | "4971062" | "4974591" | "5007423" | i | | | | |
| - | "5025791" | "5028787" | "5035243" | <u>'</u> | | | | |
| - | "5040539" | "5054488" | "5055671" | | | | | |
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| - | "5069213" | | "5084327" | , | | | | |
| - | "5088493" | "5090410" | "5094239" | <u>'</u> | | | | |
| · | "5094240" | "5099841" | "5099842" | i | | | | |
| · · · · · · | "5104623" | "5109849" | "5111817" | i | | | | |
| · | "5113861" | "5125403" | "5127406" | i | | | | |
| | "5131391" | "5140989" | "5152296" | i | | | | |
| man. | "5154175" | "5158082" | "5170786" | i | | | | |
| | "5188108" | "5190038" | "5193542" | j | | | | |
| · | "5193543" | "5203329" | "5209230" | İ | | | | |
| - | "5213099" | "5216598" | "5217012" | ĺ | | | | |
| | "5217013" | | "5224478" | İ | | | | |
| - | "5226417" | "5228440" | "5237994" | İ | | | | |
| - | "5239185" | "5246002" | "5246003" | İ | | | | |
| - | "5247931" | "5247932" | "5249576" | į | | | | |
| · · | "5253645" | "5253646" | "5259381" | j | | | | |
| - | "5259761" | "5263244" | "5267562" | İ | | | | |
| - | "5267563" | "5273036" | "5275159" | j | | | | |
| | "5279295" | "5285783" | "5285784" | İ | | | | |
| - | "5287853" | "5291884" | "5297548" | į | | | | |
| - | "5299120" | "5299570" | "5309908" | ĺ | | | | |
| - | "5311865" | "5313940" | "5323776" | j | | | | |
| - | "5329922" | "5337744" | "5339810" | ĺ | | | | |
| - | "5343818" | "5343869" | "5348003" | ĺ | | | | |
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| · · | "5353799" | | "5355882" | | | | | |
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| | "5482036" | "5483646" | "5485847" | ļ . | | | | |
| | "5490505" | "5490523" | "5491299" | | | | | |
| | "5494032" | "5497771" | "5499627" | ļ | | | | |
| · | "5503148" | "5505199" | "5507286" | ļ | | | | |
| | "5511546" | "5517988" | "5520177" | | | | | |
| | "5521851" | "5522388" | "5524617" | l | | | | |
| man. | "5529064" | | "5551423" | l | | | | |
| | "5551424" | "5553614" | "5553615" | l | | | | |
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| "5555882" | "5558096" | "5560355" | | | | |
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| "6018673" | "6018674" | "6022321" | j | | | |
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| "6031603" | | "6036642" | j | | | |
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| 1 | "6229856" | "6230035" | "6233470" | | | | | |
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| | "6253097" | "6253098" | "6256523" | | | | | |
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| | "6263222" | "6263223" | "6266546" | | | | | |
| | "6266547" | "6272363" | "6278522" | | | | | |
| | "6280213" | "6280381" | "6285894" | | | | | |
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| 1 | "6353569" | "6353750" | "6356774" | | | | | |
| 1 | "6360113" | "6360114" | "6361501" | | | | | |
| | "6363269" | "6370408" | "6370409" | | | | | |
| | "6374129" | "6377829" | "6381479" | i | | 1 | | |
| 1 | "6381480" | "6385471" | "6385821" | j | | | | |
| | "6388240" | "6393310" | "6397091" | j | | | | |
| | "6397092" | "6397093" | "6400971" | İ | | | | |
| | "6400972" | "6402690" | "6408198" | ĺ | | | | |
| | "6411832" | "6411833" | "6419671" | ĺ | | | | |
| | "6421549" | "6430423" | "6430513" | | | | | |
| | "6430525" | "6434408" | "6438399" | | | | | |
| | "6449501" | "6453183" | "6453184" | | | | | |
| | "6456862" | "6461305" | "6463310" | | | | | |
| | "6463311" | "6466808" | "6466809" | | | | | |
| | "6470199" | "6470200" | "6480729" | l | | | | |
| | "6490466" "CE01074" | "6496711" | "6498942" | | | | | |
| | "6501974" | "6501975" "6505133" | "6505060" | | | | | |
| | "6505061" "6510331" | "6505133" "6512937" | "6510329" "6515273" | | | | | |
| | "6519484" | "6512937 "6519486" | "6519487" | | | | | |
| , | "6525386" | "6526300"). | | l | | | | |
| | ("6526301" | ' | | 1 | | | | |
| | "6546267" | 6553241" | "6553242" | ı' | | | | |
| | "6553243" | | "6560470" | İ | | | | |
| | "6564077" | | "6571113" | j | | | | |
| | "6571114" | "6574491" | "6580086" | j | | | | |
| | "6584336" | "6587703" | "6587704" | | | | | |
| | "6589172" | "6591122" | "6591123" | | | | | |
| | "6594511" | "6594512" | "6594513" | | | | | |
| | "6597931" | "6597933" | "6600940" | ļ | | | | |
| | "6606510" | "6606511" | "6606512" | ļ | | | | |
| | "6615064" | "6615065" | "6618602" | | | | | |
| | "6622034" | "6628975" | "6631281" | | | | | |
| | "6643530" | "6643531" "6650017" | "6647279" | | | | | |
| | "6647280" | "6650917" | "6650918" | | | | | |
| , | "6654621" "6654624" | "6654622" "6658276" | "6654623" "6658277" | l I | | | | |
| | "6662033" | "6658276" "6665551" | "6668182" | l I | | | | |
| | "6668183" | 6663331 "6671526" | "6671528" | | | | | |
| | "6671530" | "6671526 "6671531" | "6671532" | | | | | |
| | "6675031" I | "6678543" | "6681126" | <u> </u> | | | | |
| | "6681128" | "6681454" | "6684090" | ' | | | | |
| | "6684091" | "6694160" | "6697653" | <u>'</u> | | | | |
| | "6697655" | | "6697658" | j | | | | |
| | "6699194" | ' | "6701170" | İ | | | | |
| | 1 | , | | | | | | |
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| S57 | 1389 | reflectance | with transmit | tance and | US- | OR | ON | 2019/09/10 |
|-----|-------------|----------------------------|--------------------------|--------------------------|---|----|---|---------------------|
| | | | "4714080") | | PGPUB; USPAT; USOCR | | | 15:07 |
| S56 | 171 | <u> </u> | | "4463762" | US- | OR | OFF | 2019/09/10 |
| | | "5297548" ("5524617") | "5372135"). | .PN. OR | USOCR | | | |
| | | "5226417" | "5277181" | "5285783" | USPAT; | | | |
| S55 | 157 | SI ' | | "5057695" "5218962" | US- PGPUB; | OR | OFF | 2019/09/10 15:05 |
| L | <u> </u> | ··· / | | 17310").URPN. | 116 | | l IOSE | 100101011 |
| | | "RE35122" | "RE36000" | "RE38476" | *************************************** | | | |
| | | 11 | | "RE33643" | | | | |
| | | "7305262" "7392074" | | | *************************************** | | *************************************** | |
| | | "7272426" | "7280858" | "7295866" | *************************************** | | | |
| | | "7254434" | | | | | | |
| | | "7209775" "7236811" | "7215984" "7248910" | "7225006" "7254433" | *************************************** | | | |
| | | 11 | "7190987" | | *************************************** | | | |
| | | "7133711" | "7139599" | "7142901" | | | | |
| | | "7107088" "7127278" | "7113815" "7130671" | "7123950" "7132641" | | | | |
| | | "7085597" | | "7096054" | | | | |
| | | "7072701" | | "7079880" | *************************************** | | | |
| | | "7047055" "7060035" | "7047056" "7062307" | "7048687" "7067893" | *************************************** | | | |
| | | 31 | "7039449" | "7043289" | *************************************** | | | |
| | | "7025728" | | "7027850" | | | | |
| | | "7006855" "7020507" | "7006856" "7024233" | "7016715" "7024235" | *************************************** | | | |
| | | "6999904" | | | *************************************** | | | |
| | | "6993371" | "6993372" | "6996427" | *************************************** | | | |
| | | 31 | "6992751" | "6992772" | | | | |
| | | 31 | "6971580" "6985763" | "6979812" "6985764" | *************************************** | | | |
| | | 31 | | "6950687" "6979812" | *************************************** | | | |
| | | "6931269" | "6934570" | "6939307" | | | | |
| | | 1 | | "6920345" | *************************************** | | | |
| | | 11 | | "6882874" "6909912" | | | | |
| | | \$1 | | "6863652" | *************************************** | | | |
| | | 31 | ' | "6850788" | | | | |
| | | | | "6839580" "6842635" | *************************************** | | | |
| | | 51 | "6830711"). | | | | | |
| | | "6822564" | "6825619" | "6826419" | *************************************** | | | |
| | | 1 | , | "6819950" | *************************************** | | | |
| | | 11 | ' | "6801802" "6810277" | *************************************** | | | |
| | | 31 | "6793654" | "6801797" | | | | |
| | | 31 | | "6791689" | | | | |
| | | 1 | "6771994" | | | | | |
| | | 1 | "6760607" "6763255" | "6760609" "6763256" | | | | |
| | | 1 | "6748254" | 1 | | | | |
| | | 11 | "6745060" | "6745061" | | | | |
| | | 31 | "6731963" | "6731967" | | | | |
| | | 31 | "6721585" | 1 | | | | |
| | | 11 | "6714804" "6719705" | | | | | |
| | | 51 | ' | "6711425" "6714805" | | | | |
| | \$ 1 | 51 | | "6708049" | - }} | 1 | | |

| | | A61B5/\$.cpc. | PGPUB; USPAT | | | 15:08 |
|-----|-----|---|----------------------------------|----|-----|---------------------|
| S58 | 58 | reflectance with transmittance with (switch\$4 select\$4 choos\$4 chos\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 15:08 |
| S59 | 203 | ("3463142" "3638640" "3958560" "4014321" "4169676" "4202339" "4223680" "4350163" "4408880" "4655225" "4704029" "4714080" "4785814" "4796636" "4840179" "4854699" "4882492" "4901728" "4975581" "5007423" "5054487" "5070874" "5086229").PN. OR ("5222495").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 15:12 |
| S60 | 35 | reflectance with transmittance same plurality and (driv\$4 energiz\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 15:13 |
| S61 | 314 | ("4766551" "4901728" "4975581" "5009230" "5028787" "5068536" "5070874" "5077476" "5086229" "5119819" "5121338" "5137023" "5139023" "5140985" "5204532" "5206701" "5223714" "5223715" "5242602" "5243546" "5252829" "5258825" "5267151" "5267152" "5299138" "5307263" "5313941" "5343044" "5348002" "5348003" "5349188" "5349189" "5360972" "5361758" "5362307" "5370114" "5379238" "5362307" "5370114" "5379238" "5362307" "5370114" "5379238" "5369377" "5459677" "5481476" "5498875" "5512751" "5515847" "5551422" "5568400" "556575644" "5582168" "5602755" "5606164" "5610836" "5615672" "5668320" "566956" "5668373" "5766283 "5710630" "5712481" "5712797" "5730714" "5740073" "5743262" "5747806" "5750994" "5788632" "5771891" "5782755" "58830133" "5840020" "5841523" "5782512" "5771891" "5782755" "5830133" "5840020" "5841523" "583062" "5798526" "5822219" "5783062" "5945676" "5933792" "5935062" "5945676" "5946128" "5946640" "5968760" "5985120" "60661582" "6064065" "6064897" "6066847" "6012019" "6014577" "6124134" "6137108" "6151517" "6157041" "6159255").PN. OR ("6161028" "6114699" "6115673" "6124134" "6137108" "6151517" "6124030").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 |

| S62 902 | ("10039080" "10055121" "10066970" "10076257" "10078052" "10258265" | US- OR PGPUB; | 55 33 | 2019/09/10 15:51 |
|---------|---|---|-------|---------------------|
| | "10076257" "10078052" "10258265" "10258266" "2002000270" | 31 131 | | 10:01 |
| | "10258266" "20020099279" | USPAT; | | |
| | "20060005944" "20060025659" "20060076473" "20070140864" | USOCR | | |
| | "20060076473" "20070149864" "20070238955" "20070293792" | | | |
| | 1 | | | |
| | "20080130232" "20080139908" | | | |
| | "20090030327" "20090043180" | | | |
| | "20090129102" "20090247984" | | | |
| | "20090259114" "20090275844" | | | |
| | "20090306487" "20100004518" | | | |
| | "20100030040" "20100217102" | | | |
| | "20110001605" "20110004082" | | | |
| | "20110082711" "20110105854" | | | |
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| | "20110213212" "20110230733" | | | |
| | "20110237911" "20120059267" | | | |
| | "20120179006" "20120209082" | | | |
| | "20120209084" "20120227739" | *************************************** | | |
| | "20120283524" "20120296178" | | | |
| | "20120319816" "20120330112" | | | |
| | "20130023775" "20130041591" | *************************************** | | |
| | "20130045685" "20130046204" | | | |
| | "20130060147" "20130096405" | *************************************** | | |
| | "20130096936" "20130190581" | | | |
| | "20130197328" "20130211214" | | | |
| | "20130243021" "20130253334" | | | |
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| | "20130324808" "20130331670" | | | |
| | "20130338461" "20140012100" | | | |
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| | "20140121483" "20140127137" | | | |
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| | "20140163344 20140163402 "20140166076" "20140171146" | | | |
| | "20140171763" "20140171146" | | | |
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| | "20140180154" "20140194709" "20140194711" "20140194766" | | | |
| | \$1 | | | |
| | | *************************************** | | |
| | "20140243627" "20140266790" | | | |
| | "20140275808").PN. OR ("20140275835" | | | |
| | "20140275871" "20140275872" "20140275881" "20140288400" | | | |
| | <u> </u> | | | |
| | "20140296664" "20140303520" | *************************************** | | |
| | "20140316228" "20140323825" "20140320208" "20140323825" | | | |
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| | "20150366472" "20150366507" | | | |
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| | "20160038045" "20160045118" | | | |
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| "20160051157" | "20160051158" | | *** |
|----------------------|-----------------------|--|---|
| "20160051205" | ! | | |
| ξ ! | "20160058302" | **** | |
| "20160058309" | "20160058312" | **** | |
| <u>"20160058338"</u> | "20160058347" | *************************************** | |
| "20160058356" | "20160058370" | *************************************** | |
| "20160066823" | "20160066824" | *************************************** | |
| "20160066879" | "20160071392" | *************************************** | |
| \{\} | | *************************************** | |
| "20160072429" | "20160073967" | *************************************** | |
| "20160081552" | "20160095543" | *************************************** | |
| ["20160095548" | "20160103598" | | |
| "20160113527" | "20160143548" | | |
| "20160154950" | "20160157780" | | |
| "20160166183" | "20160166210" | The state of the s | |
| "20160192869" | "20160196388" | *************************************** | |
| { | ' | *************************************** | |
| "20160197436" | "20160213281" | | |
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| ["20160256082" | "20160267238" | The state of the s | |
| "20160287181" | "20160296173" | *************************************** | |
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| "20160378069" | "20160378071" | | |
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| "20170086689" | "20170086742" | | |
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| ("20170354332" | | *************************************** | |
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| "20170358239" | "20170358240" | *************************************** | |
| "20170358242" | "20170360306" | | |
| "20170366657" | "20180014781" | | *************************************** |
| "20180025287" | "20180042556" | | |
| "20180049694" | "20180050235" | | *************************************** |
| "20180055375" | "20180055390" | The state of the s | **** |
| "20180055439" | "20180056129" | *************************************** | |
| "20180078151" | "20180078182" | *************************************** | *************************************** |
| "20180110469" | "20180153418" | | |
| 31 | ' | The state of the s | **** |
| "20180164853" | "20180196514" | | |
| "20180228414" | "20180238734" | | *************************************** |
| "20180279956" | "20190104973" | | |
| "20190110719" | "3910701" "4114604" | | |
| "4258719" "42 | 67844" "4438338" | | |
| "4444471" "46 | 53498" "4655225" | | |
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| 21 | 05623" "4880304" | | |
| 51 | 64408" "5028787" | | |
| 31 | 41187" "5043820" | | |
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| 11 | 69214" "5077476" | | |
| \$1 | 99842" "5122925" | | |
| \{\) | 37023" "5159929" | | |
| "5163438" "52 | 22295" "5222495" | | |
| "5222496" "524 | 49576" "5250342" | | |
| "5278627" "52 | 97548" "5319355" | | |
| 31 | 37745" "5341805" | | |
| 31 | 77676" "5427093" | | |
| 31 | 37275" "5441054" | | |
| \$1 · | · | | |
| 51 | 56252" "5479934" | | |
| 81 | 82036" "5490505" | | |
| \$1 | 94043" "5511546" | | |
| "5533511" "55 | 34851" "5551422" | | |
| "5553615" "55 | 53616" "5561275" | | |
| "5562002" "559 | 90649" "5601079" | | |
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| "5602924" | "5625458" | "5632272" | *************************************** | *************************************** | | |
|--------------------------|--------------|------------|---|---|--|--|
| '5638816" | "5638818" | "5645440" | | | | |
| "5676143" | "5685299" | "5743262" | | **** | | |
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| '5760910" İ | "5766131" | "5769785" | | **** | | |
| "5782757" İ | "5785659" | "5791347" | | | | |
| "5792052" İ | "5810734" | "5823950" | | | | |
| "5826885" | | "5833618") | PN | | | |
| | 78" "58609 | , | 88 | | | |
| | | | 23 | *** | | |
| "5902235" | "5903357" | "5904654" | | | | |
| "5919134" | "5934925" | "5940182" | | | | |
| '5957840" | "5995855" | "5997343" | | | | |
| "6002952" | "6011986" | "6027452" | | | | |
| "6036642" | "6045509" | "6049727" | | | | |
| "6067462" | "6081735" | "6088607" | | *** | | |
| "6110522" Ì | "6124597" | "6128521" | | | | |
| "6129675" İ | "6144866" | "6144868" | | | | |
| "6151516" | "6152754" | "6157850" | | | | |
| "6165005" | "6172743" | "6181958" | | | | |
| | | | | | | |
| "6184521" "COOOSEC" | "6206830" | "6223063" | | | | |
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| "6241683" | "6253097" | "6256523" | | **** | | |
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| "6317627" | "6321100" | "6325761" | | **** | | |
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| "6345194" İ | "6349228" | "6353750" | | | | |
| "6360113" | "6360114" | "6360115" | | *** | | |
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| "6388240" | "6397091" | "6430437" | | | | |
| | | | | | | |
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| "6643530" İ | "6650917" | "6654624" | | | | |
| "6658276" | "6661161" | "6668185" | | | | |
| "6671531" | "6678543" | "6681133" | | | | |
| "6684090" | "6684091" | "6697656" | | | | |
| | | | | **** | | |
| "6697657" "6714804" | "6697658" | "6699194" | | **** | | |
| "6714804" | | "6721585" | | | | |
| "6725075" | | "6735459" | | *** | | |
| '6745060" | "6748254" | "6760607" | | | | |
| '6770028" | | "6792300" | | | | |
| '6813511" | "6816010" | "6816241" | | **** | | |
| '6816741" | | "6826419" | | | | |
| "6830711" | | | | | | |
| ("6850788" | | | | **** | | |
| "6898452" | | "6920345" | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | |
| 6931268" | | "6939305" | | **** | | |
| | | | | | | |
| '6943348" '6070700" | "6950687" | "6961598" | | | | |
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| "9553625" "9591975" "9593969" "9651405" "9668676" "9668680" "9699546" "9716937" "9717425" "9723997" "9781984" "9838775" "9848823" "9866671" "9867575" "9898049" "9918646" "9952095" | "9386961" | "9392945" | "9397448" | 1 | | | |
| "9651405" "9668676" "9668680" "9699546" "9716937" "9717425" "9723997" "9781984" "9838775" "9848823" "9866671" "9867575" "9898049" "9918646" "9952095" | "9489081" | "9497534" | "9526430" | | | | |
| "9699546" "9716937" "9717425" "9723997" "9781984" "9838775" "9848823" "9866671" "9867575" "9898049" "9918646" "9952095" | "9553625" | "9591975" | "9593969" | | | | |
| "9723997" "9781984" "9838775" "9848823" "9866671" "9867575" "9898049" "9918646" "9952095" | "9651405" | "9668676" | "9668680" | | | | |
| "9848823" "9866671" "9867575" "9898049" "9918646" "9952095" "D326715" "D353195" "D353196" | | "9716937" | "9717425" | | | | |
| "9898049" "9918646" "9952095" "D326715" "D353195" "D353196" | "9723997" | "9781984" | "9838775" | | | | |
| "D326715" "D353105" "D353106" | "9848823" | "9866671" | "9867575" | | | | |
| "D326715" "D353195" "D353196" | "9898049" | "9918646" | "9952095" | | | | |
| | "D326715" | "D353195" | "D353196" | | | | |
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| | | "D356870" "D359546" "D361840" "D362063" "D363120" "D378414" "D390666" "D393830" "D403070" "D414870" "D452012" "D455834" "D463561" "D481459" "D502655" "D508862" "D510625" "D514461" "D535031" "D537164" "D547454" "D549830" "D550364" "D551350" "D553248" "D554263" "D562985" "D566282" "D567125" "D569001" "D569521" "D587657" "D603966" "D606659" "D609193" "D614305" "D621516" "D692145" "D755392" "RE37922" "RE38476" "RE38492" "RE39672" "RE41317" "RE41912" "RE42753" "RE43169" "RE43860" "RE44823" "RE44875").PN. OR | | | | |
|-----|-----|---|----------------------------------|----|-----|---------------------|
| S63 | 183 | reflectance with transmittance and winakur.xp. | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:00 |
| S64 | 14 | (energiz\$4 energis\$4 activat\$4) with (light LED diode) same (select\$4 choos\$4 switch\$4) with (reflectance transmittance reflect\$4 transmit\$4) and winakur.xp. | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:08 |
| S65 | 352 | (energiz\$4 energis\$4 activat\$4) with (light LED diode) same (select\$4 choos\$4 switch\$4) with (reflectance transmittance reflect\$4 transmit\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:12 |
| S66 | 34 | (energiz\$4 energis\$4 activat\$4) with (light LED diode) with set with plurality and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:33 |
| S67 | 34 | (energiz\$4 energis\$4 activat\$4) with (light LED diode) with first adj set and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:36 |
| S68 | 24 | S67 not S66 | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:37 |
| S69 | 2 | "13423705" | US- PGPUB; USPAT | OR | ON | 2019/09/10 16:40 |
| S70 | 5 | (("20060270920") or ("3638640") or ("8414499") or ("3638640") or ("8418499") or ("9597021")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/09/10 16:43 |

EAST Search History (Interference)

< This search history is empty>

9/11/2019 11:19:56 AM

 $\pmb{\text{C:}} \ \textbf{Users} \ \textbf{mfardanesh} \ \textbf{Documents} \ \textbf{EAST} \ \textbf{Workspaces} \ \textbf{16312080.wsp}$

Receipt date: 08/15/2019

PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 1 OF 1 | Attorney Docket No. | MAS.1007C1 |

| | U.S. PATENT DOCUMENTS | | | | | | | |
|----------------------|-----------------------|---|-----------------------------------|-------------------|--|--|--|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | | | |
| | 1 | 5,099,842 | 03-31-1992 | Mannheimer et al. | | | | |
| | 2 | 5,601,079 | 02-11-1997 | Wong et al. | | | | |
| | 3 | 6,223,063 | 04-24-2001 | Chaiken et al. | | | | |
| | 4 | 2002/0042558 | 04-11-2002 | Mendelson | | | | |

| | FOREIGN PATENT DOCUMENTS | | | | | | | | |
|----------------------|--------------------------|--|-----------------------------------|--------------------|---|----|--|--|--|
| Examiner Initials | Cite No. | Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T¹ | | | |
| | 5 | WO 02/028274 | 04-11-2002 | CYBRO MEDICAL LTD. | | | | | |

| | | NON PATENT LITERATURE DOCUMENTS | |
|----------------------|-------------|---|----|
| 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, page(s), volume-issue number(s), publisher, city and/or country where published. | T¹ |
| | 6 | Konig, V. et al., "REFLECTANCE PULSE OXIMETRY - PRINCIPLES AND OBSTETRIC APPLICATION IN THE ZURICH SYSTEM," J Clin Monit 1998; 14: 403-412. | |

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| Examiner Signature | /MARJAN FARD | ANESH/ | Date Considered | 09/06/2019 |
|--------------------|--------------|--------|-----------------|------------|
|--------------------|--------------|--------|-----------------|------------|

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

T1 - Place a check mark in this area when an English language Translation is attached.

Doc code: RCEX Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (02-18)
Request for Continued Examination (RCE)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

| REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL (Submitted Only via EFS-Web) | | | | | | | |
|---|--|---------------------------------|----------------------------|-------------------------------|---|-------------|--------------|
| Application Number | 16226249 | Filing Date | 2018-12-19 | Docket Number (if applicable) | MAS.1007C1 | Art Unit | 3791 |
| First Named Inventor | Al-Ali, Ammar | | • | Examiner Name | Fardanesh, Marjan | | |
| Request for Co | This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV | | | | | | |
| | | SU | JBMISSION REQ | UIRED UNDER 37 | CFR 1.114 | | |
| in which they w | ere filed unless a | applicant inst | | applicant does not wis | nents enclosed with the RCE will she to have any previously filed u | | |
| Previously submission | submitted. If a fir n even if this box | nal Office act is not checke | ion is outstanding, ed. | any amendments file | d after the final Office action ma | y be con | sidered as a |
| ☐ Cor | sider the argume | nts in the Ap | peal Brief or Reply | Brief previously filed | on | | |
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| Am | endment/Reply | | | | | | |
| ⊠ Info | rmation Disclosur | e Statement | (IDS) | | | | |
| Affic | davit(s)/ Declarati | on(s) | | | | | |
| ☐ Oth | er | | | | | | |
| MISCELLANEOUS | | | | | | | |
| Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required) | | | | | | | |
| Other | | | | | | | |
| FEES | | | | | | | |
| The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed. The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 111410 | | | | | | | |
| | 8 | SIGNATURI | E OF APPLICAN | T, ATTORNEY, OR | AGENT REQUIRED | | |
| 1 ' | Practitioner Signant nt Signature | ature | | | | | |
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Doc code: RCEX PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Doc description: Request for Continued Examination (RCE)

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.

| Signature of Registered U.S. Patent Practitioner | | | | | | |
|--|--------------------|---------------------|------------|--|--|--|
| Signature | 'Aaron S. Johnson/ | Date (YYYY-MM-DD) | 2019-08-15 | | | |
| Name | Aaron S. Johnson | Registration Number | 74164 | | | |

This collection of information is required by 37 CFR 1.114. 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 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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

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

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

Docket No.: MAS.1007C1 Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

First Inventor: Ammar Al-Ali

App. No. : 16/226249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791

Conf. No. : 1002

Mail Stop RCE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is believed to be required.

Application No.: 16/226249

Filing Date: December 19, 2018

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 15, 2019 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

IDS

31137842

PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 1 OF 1 | Attorney Docket No. | MAS.1007C1 |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|-------------|---|-----------------------------------|-------------------|--|--|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | | |
| | 1 | 5,099,842 | 03-31-1992 | Mannheimer et al. | | | |
| | 2 | 5,601,079 | 02-11-1997 | Wong et al. | | | |
| | 3 | 6,223,063 | 04-24-2001 | Chaiken et al. | | | |
| | 4 | 2002/0042558 | 04-11-2002 | Mendelson | | | |

| | FOREIGN PATENT DOCUMENTS | | | | | | | |
|----------------------|--------------------------|--|-----------------------------------|--------------------|---|----|--|--|
| Examiner Initials | Cite No. | Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T¹ | | |
| | 5 | WO 02/028274 | 04-11-2002 | CYBRO MEDICAL LTD. | | | | |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-------------|---|----------------|--|
| 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, page(s), volume-issue number(s), publisher, city and/or country where published. | T ¹ | |
| | 6 | Konig, V. et al., "REFLECTANCE PULSE OXIMETRY - PRINCIPLES AND OBSTETRIC APPLICATION IN THE ZURICH SYSTEM," J Clin Monit 1998; 14: 403-412. | | |

31137798

Examiner Signature Date Considered

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

T¹ - Place a check mark in this area when an English language Translation is attached.

(19) World Intellectual Property Organization International Bureau





(43) International Publication Date 11 April 2002 (11.04.2002)

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(10) International Publication Number WO 02/28274 A1

- (51) International Patent Classification⁷:
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- (22) International Filing Date: 27 August 2001 (27.08.2001)
- (25) Filing Language:

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English

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138884

5 October 2000 (05.10.2000)

- (71) Applicant (for all designated States except US): CYBRO MEDICAL LTD. [IL/IL]; Matam Building 30, 31905 Haifa (IL).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): MENDELSON, Yizhak [US/US]; 31 Whisper Drive, Worcester, MA 01609 (US).
- (74) Agents: YEE, James, R. et al.; Howard & Howard Attorneys, P.C., Suite 101, The Pinehurst Office Center, 39400 Woodward Avenue, Bloomfield Hills, MI 48304-5151 (US).

- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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

28274 A1

(54) Title: A PULSE OXIMETER AND A METHOD OF ITS OPERATION

(57) Abstract: A sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter. The sensor includes sensor housing, a source of radiation coupled to the housing, and a detector assembly coupled to the housing. The source of radiation is adapted to emit radiation at predetermined frequencies. The detector assembly is adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals. The signals are use to determine the parameter of the blood.

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A PULSE OXIMETER AND A METHOD OF ITS OPERATION

BACKGROUND OF THE INVENTION

Field of the Invention

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This invention is generally in the field of pulse oximetry, and relates to a sensor for use in a pulse oximeter, and a method for the pulse oximeter operation.

Background of the Invention

Oximetry is based on spectrophotometric measurements of changes in the color of blood, enabling the non-invasive determination of oxygen saturation in the patient's blood. Generally, oximetry is based on the fact that the optical property of blood in the visible (between 500 and 700nm) and near-infrared (between 700 and 1000nm) spectra depends strongly on the amount of oxygen in blood.

Referring to Fig. 1, there is illustrated a hemoglobin spectra measured by oximetry based techniques. Graphs G1 and G2 correspond, respectively, to reduced hemoglobin, or deoxyhemoglobin (Hb), and oxygenated hemoglobin, or oxyhemoglobin (HbO₂), spectra. As shown, deoxyhemoglobin (Hb) has a higher optical extinction (i.e., absorbs more light) in the red region of spectrum around 660nm, as compared to that of oxyhemoglobin (HbO₂). On the other hand, in the near-infrared region of the spectrum around 940nm, the optical absorption by deoxyhemoglobin (Hb) is lower than the optical absorption of oxyhemoglobin (HbO₂).

Prior art non-invasive optical sensors for measuring arterial oxyhemoglobin saturation (SaO₂) by a pulse oximeter (termed SpO₂) are typically comprised of a pair of small and inexpensive light emitting diodes (LEDs), and a single highly sensitive silicon photodetector. A red (R) LED centered on a peak emission wavelength around 660nm and an infrared (IR) LED centered on a peak emission wavelength around 940nm are used as light sources.

Pulse oximetry relies on the detection of a photoplethysmographic signal caused by variations in the quantity of arterial blood associated with periodic contraction and relaxation of a patient's heart. The magnitude of this signal depends on

the amount of blood ejected from the heart into the peripheral vascular bed with each systolic cycle, the optical absorption of the blood, absorption by skin and tissue components, and the specific wavelengths that are used to illuminate the tissue. SaO₂ is determined by computing the relative magnitudes of the R and IR photoplethysmograms. Electronic circuits inside the pulse oximeter separate the R and IR photoplethysmograms into their respective pulsatile (AC) and non-pulsatile (DC) signal components. An algorithm inside the pulse oximeter performs a mathematical normalization by which the time-varying AC signal at each wavelength is divided by the corresponding time-invariant DC component which results mainly from the light absorbed and scattered by the bloodless tissue, residual arterial blood when the heart is in diastole, venous blood and skin pigmentation.

Since it is assumed that the AC portion results only from the arterial blood component, this scaling process provides a normalized R/IR ratio (i.e., the ratio of AC/DC values corresponding to R- and IR-spectrum wavelengths, respectively), which is highly dependent on SaO₂, but is largely independent of the volume of arterial blood entering the tissue during systole, skin pigmentation, skin thickness and vascular structure. Hence, the instrument does not need to be re-calibrated for measurements on different patients. Typical calibration of a pulse oximeter is illustrated in Fig. 2 by presenting the empirical relationship between SaO₂ and the normalized R/IR ratio, which is programmed by the pulse oximeters' manufacturers.

Pulse oximeters are of two kinds operating, respectively, in transmission and reflection modes. In transmission-mode pulse oximetry, an optical sensor for measuring SaO_2 is usually attached across a fingertip, foot or earlobe, such that the tissue is sandwiched between the light source and the photodetector.

In reflection-mode or backscatter type pulse oximetry, as shown in Fig. 3, the LEDs and photodetector are both mounted side-by-side next to each other on the same planar substrate. This arrangement allows for measuring SaO₂ from multiple convenient locations on the body (e.g. the head, torso, or upper limbs), where conventional transmission-mode measurements are not feasible. For this reason, non-invasive reflectance pulse oximetry has recently become an important new clinical technique

with potential benefits in fetal and neonatal monitoring. Using reflectance oximetry to monitor SaO₂ in the fetus during labor, where the only accessible location is the fetal scalp or cheeks, or on the chest in infants with low peripheral perfusion, provides several more convenient locations for sensor attachment.

Reflection pulse oximetry, while being based on similar spectrophotometric principles as the transmission one, is more challenging to perform and has unique problems that can not always be solved by solutions suitable for solving the problems associated with the transmission-mode pulse oximetry. Generally, comparing transmission and reflection pulse oximetry, the problems associated with reflection pulse oximetry consist of the following:

In reflection pulse oximetry, the pulsatile AC signals are generally very small and, depending on sensor configuration and placement, have larger DC components as compared to those of transmission pulse oximetry. As illustrated in Fig. 4, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms in reflection pulse oximetry can be adversely affected by strong reflections from a bone. This problem becomes more apparent when applying measurements at such body locations as the forehead and the scalp, or when the sensor is mounted on the chest over the ribcage. Similarly, variations in contact pressure between the sensor and the skin can cause larger errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the sensor housing towards deeper subcutaneous structures. Consequently, the highly reflective bloodless tissue compartment near the surface of the skin can cause large errors even at body locations where the bone is located too far away to influence the incident light generated by the sensor.

Another problem with currently available reflectance sensors is the potential for specular reflection caused by the superficial layers of the skin, when an air gap exists between the sensor and the skin, or by direct shunting of light between the LEDs and the photodetector through a thin layer of fluid which may be due to excessive sweating or from amniotic fluid present during delivery.

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It is important to keep in mind the two fundamental assumptions underlying the conventional dual-wavelength pulse oximetry, which are as follows:

(1) the path of light rays with different illuminating wavelengths in tissue are substantially equal and, therefore, cancel each other; and (2) each light source illuminates the same pulsatile change in arterial blood volume.

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Furthermore, the correlation between optical measurements and tissue absorptions in pulse oximetry are based on the fundamental assumption that light propagation is determined primarily by absorbance due to Lambert-Beer's law neglecting multiple scattering effects in biological tissues. In practice, however, the optical paths of different wavelengths in biological tissues is known to vary more in reflectance oximetry compared to transmission oximetry, since it strongly depends on the light scattering properties of the illuminated tissue and sensor mounting.

Several human validation studies, backed by animal investigations, have suggested that uncontrollable physiological and physical parameters can cause large variations in the calibration curve of reflectance pulse oximeters primarily at low oxygen saturation values below 70%. It was observed that the accuracy of pulse oximeters in clinical use might be adversely affected by a number of physiological parameters when measurements are made from sensors attached to the forehead, chest, or the buttock area. While the exact sources of these variations are not fully understood, it is generally believed that there are a few physiological and anatomical factors that may be the major source of these errors. It is also well known for example that changes in the ratio of blood to bloodless tissue volumes may occur through venous congestion, vasoconstriction/vasodilatation, or through mechanical pressure exerted by the sensor on the skin.

Additionally, the empirically derived calibration curve of a pulse oximeter can be altered by the effects of contact pressure exerted by the probe on the skin. This is associated with the following. The light paths in reflectance oximetry are not well defined (as compared to transmission oximetry), and thus may differ between the red and infrared wavelengths. Furthermore, the forehead and scalp areas consist of a relatively thin subcutaneous layer with the cranium bone underneath, while the tissue

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of other anatomical structures, such as the buttock and limbs, consists of a much thicker layer of skin and subcutaneous tissues without a nearby bony support that acts as a strong light reflector.

Several in vivo and in vitro studies have confirmed that uncontrollable physiological and physical parameters (e.g., different amounts of contact pressure applied by the sensor on the skin, variation in the ratio of bloodless tissue-to-blood content, or site-to-site variations) can often cause large errors in the oxygen saturation readings of a pulse oximeter, which are normally derived based on a single internally-programmed calibration curve. The relevant in vivo studies are disclosed in the following publications:

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- 1. Dassel, et al., "Effect of location of the sensor on reflectance pulse oximetry", British Journal of Obstetrics and Gynecology, vol. 104, pp. 910-916, (1997);
- 2. Dassel, et al., "Reflectance pulse oximetry at the forehead of newborns: The influence of varying pressure on the probe", Journal of Clinical Monitoring, vol. 12, pp. 421-428, (1996).]

The relevant in vitro studies are disclosed, for example in the following publication:

3. Edrich et al., "Fetal pulse oximetry: influence of tissue blood content and hemoglobin concentration in a new in-vitro model", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S29-S34, (1997).

Improved sensors for application in dual-wavelength reflectance pulse oximetry have been developed. As disclosed in the following publication: Mendelson, et al., "Noninvasive pulse oximetry utilizing skin reflectance photoplethysmography", IEEE Transactions on Biomedical Engineering, vol. 35, no. 10, pp. 798-805 (1988), the total amount of backscattered light that can be detected by a reflectance sensor is directly proportional to the number of photodetectors placed around the LEDs. Additional improvements in signal-to-noise ratio were achieved by increasing the active area of the photodetector and optimizing the separation distance between the light sources and photodetectors.

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Another approach is based on the use of a sensor having six photodiodes arranged symmetrically around the LEDs that is disclosed in the following publications:

4. Mendelson, et al., "Design and evaluation of a new reflectance pulse oximeter sensor", Medical Instrumentation, vol. 22, no. 4, pp. 167-173 (1988); and

5. Mendelson, et al., "Skin reflectance pulse oximetry: in vivo measurements from the forearm and calf", Journal of Clinical Monitoring, vol. 7, pp. 7-12, (1991).

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According to this approach, in order to maximize the fraction of backscattered light collected by the sensor, the currents from all six photodiodes are summed electronically by internal circuitry in the pulse oximeter. This configuration essentially creates a large area photodetector made of six discrete photodiodes connected in parallel to produce a single current that is proportional to the amount of light backscattered from the skin. Several studies showed that this sensor configuration could be used successfully to accurately measure SaO₂ from the forehead, forearm and the calf on humans. However, this sensor requires a means for heating the skin in order to increase local blood flow, which has practical limitations since it could cause skin burns.

Yet another prototype reflectance sensor is based on eight dual-wavelength LEDs and a single photodiode, and is disclosed in the following publication: Takatani et al., "Experimental and clinical evaluation of a noninvasive reflectance pulse oximeter sensor", Journal of Clinical Monitoring, vol. 8, pp. 257-266 (1992). Here, four R and four IR LEDs are spaced at 90-degree intervals around the substrate and at an equal radial distance from the photodiode.

A similar sensor configuration based on six photodetectors mounted in the center of the sensor around the LEDs is disclosed in the following publication: Konig, et al., "Reflectance pulse oximetry – principles and obstetric application in the Zurich system", Journal of Clinical Monitoring, vol. 14, pp. 403-412 (1998).

According to the techniques disclosed in all of the above publications, only LEDs of two wavelengths, R and IR, are used as light sources, and the computation of SaO₂ is based on reflection photoplethysmograms measured by a single photodetector, regardless of whether one or multiple photodiodes chips are used to construct the sensor. This is because of the fact that the individual signals from the photodetector

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elements are all summed together electronically inside the pulse oximeter. Furthermore, while a radially-symmetric photodetector array can help to maximize the detection of backscattered light from the skin and minimize differences from local tissue inhomogeneity, human and animal studies confirmed that this configuration can not completely eliminate errors caused by pressure differences and site-to-site variations.

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The use of a nominal dual-wavelength pair of 735/890nm was suggested as providing the best choice for optimizing accuracy, as well as sensitivity in dual-wavelength reflectance pulse oximetry, in US 5,782,237 and 5,421,329. This approach minimizes the effects of tissue heterogeneity and enables to obtain a balance in path length changes arising from perturbations in tissue absorbance. This is disclosed in the following publications:

- 6. Mannheimer at al., "Physio-optical considerations in the design of fetal pulse oximetry sensors", European Journal of Obstetrics and Gynecology and Reproductive Biology, vol. 72, suppl. 1, pp. S9-S19, (1997); and
- 7. Mannheimer at al., "Wavelength selection for low-saturation pulse oximetry", IEEE Transactions on Biomedical Engineering, vol. 44, no. 3, pp. 48-158 (1997)].

However, replacing the conventional R wavelength at 660nm, which coincides with the region of the spectrum where the difference between the extinction coefficient of Hb and HbO₂ is maximal, with a wavelength emitting at 735nm, not only lowers considerably the overall sensitivity of a pulse oximeter, but does not completely eliminate errors due to sensor placement and varying contact pressures.

Pulse oximeter probes of a type comprising three or more LEDs for filtering noise and monitoring other functions, such as carboxyhemoglobin or various indicator dyes injected into the blood stream, have been developed and are disclosed, for example, in WO 00/32099 and US 5,842,981. The techniques disclosed in these publications are aimed at providing an improved method for direct digital signal formation from input signals produced by the sensor and for filtering noise.

None of the above prior art techniques provides a solution to overcome the most essential limitation in reflectance pulse oximetry, which requires the automatic

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correction of the internal calibration curve from which accurate and reproducible oxygen saturation values are derived, despite variations in contact pressure or site-to-site tissue heterogeneity.

In practice, most sensors used in reflection pulse oximetry rely on closely spaced LED wavelengths in order to minimize the differences in the optical path lengths of the different wavelengths. Nevertheless, within the wavelength range required for oximetry, even closely spaced LEDs with closely spaced wavelengths mounted on the same substrate can lead to large random error in the final determination of SaO₂.

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SUMMARY OF THE INVENTION AND ADVANTAGES

The object of the invention is to provide a novel sensor design and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in general. Another object of the invention is to provide a novel sensor and method that functions to correct the calibration relationship of a reflectance pulse oximeter, and reduce measurement inaccuracies in the lower range of oxygen saturation values (typically below 70%), which is the predominant range in neonatal and fetal applications.

Yet another object of the present invention is to provide automatic correction of the internal calibration curve from which oxygen saturation is derived inside the oximeter in situations where variations in contact pressure or site-to-site tissue heterogeneity may cause large measurement inaccuracies.

Another object of the invention is to eliminate or reduce the effect of variations in the calibration of a reflectance pulse oximeter between subjects, since perturbations caused by contact pressure remain one of the major sources of errors in reflectance pulse oximetry. In fetal pulse oximetry, there are additional factors, which must be properly compensated for in order to produce an accurate and reliable measurement of oxygen saturation. For example, the fetal head is usually the presenting part, and is a rather easily accessible location for application of reflectance pulse oximetry. However, uterine contractions can cause large and unpredictable variations in the pressure exerted on the head and by the sensor on the skin, which can lead to

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large errors in the measurement of oxygen saturation by a dual-wavelength reflectance pulse oximeter. Another object of the invention is to provide accurate measurement of oxygen saturation in the fetus during delivery.

The basis for the errors in the oxygen saturation readings of a dual-wavelength pulse oximeter is the fact that, in practical situations, the reflectance sensor applications affect the distribution of blood in the superficial layers of the skin. This is different from an ideal situation, when a reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Therefore, the R and IR DC signals practically measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. In these uncontrollable practical situations, the changes caused are normally not compensated for automatically by calculating the normalized R/IR ratio since the AC portions of each photoplethysmogram, and the corresponding DC components, are affected differently by pressure or site-to-site variations. Furthermore, these changes depend not only on wavelength, but depend also on the sensor geometry, and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters.

The inventor has found that the net result of this nonlinear effect is to cause large variations in the slope of the calibration curves. Consequently, if these variations are not compensated automatically, they will cause large errors in the final computation of SpO₂, particularly at low oxygen saturation levels normally found in fetal applications.

Another object of the present invention is to compensate for these variations and to provide accurate measurement of oxygen saturation. The invention consists of, in addition to two measurement sessions typically carried out in pulse oximetry based on measurements with two wavelengths centered around the peak emission values of 660nm (red spectrum) and 940nm ± 20 nm (IR spectrum), one additional measurement session is carried out with an additional wavelength. At least one additional wavelength is preferably chosen to be substantially in the IR region of the electromagnetic spectrum, i.e., in the NIR-IR spectrum (having the peak emission value above 700nm).

In a preferred embodiment the use of at least three wavelengths enables the calculation of an at least one additional ratio formed by the combination of the two IR wavelengths, which is mostly dependent on changes in contact pressure or site-to-site variations. In a preferred embodiment, slight dependence of the ratio on variations in arterial oxygen saturation that may occur, is easily minimized or eliminated completely, by the proper selection and matching of the peak emission wavelengths and spectral characteristics of the at least two IR-light sources.

Preferably, the selection of the IR wavelengths is based on certain criteria. The IR wavelengths are selected to coincide with the region of the optical absorption curve where HbO₂ absorbs slightly more light than Hb. The IR wavelengths are in the spectral regions where the extinction coefficients of both Hb and HbO₂ are nearly equal and remain relatively constant as a function of wavelength, respectively.

In a preferred embodiment, tracking changes in the ratio formed by the two IR wavelengths, in real-time, permits automatic correction of errors in the normalized ratio obtained from the R-wavelength and each of the IR-wavelengths. The term "ratio" signifies the ratio of two values of AC/DC corresponding to two different wavelengths. This is similar to adding another equation to solve a problem with at least three unknowns (i.e., the relative concentrations of HbO₂ and Hb, which are used to calculate SaO₂, and the unknown variable fraction of blood-to-tissue volumes that effects the accurate determination of SaO₂), which otherwise must rely on only two equations in the case of only two wavelengths used in conventional dual-wavelength pulse oximetry. In a preferred embodiment, a third wavelength provides the added ability to compute SaO₂ based on the ratio formed from the R-wavelength and either of the IR-wavelengths. In a preferred embodiment, changes in these ratios are tracked and compared in real-time to determine which ratio produces a more stable or less noisy signal. That ratio is used predominantly for calculating SaO₂.

The present invention utilizes collection of light reflected from the measurement location at different detection locations arranged along a closed path around light emitting elements, which can be LEDs or laser sources. Preferably, these detection locations are arranged in two concentric rings, the so-called "near" and "far"

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rings, around the light emitting elements. This arrangement enables optimal positioning of the detectors for high quality measurements, and enables discrimination between photodetectors receiving "good" information (i.e., AC and DC values which would result in accurate calculations of SpO₂) and "bad" information (i.e., AC and DC values which would result in inaccurate calculations of SpO₂).

There is thus provided according to one aspect of the present invention, a sensor for use in an optical measurement device for non-invasive measurements of blood parameters, the sensor comprising:

- (1) a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength lying in a red (R) spectrum, and the at least second and third wavelengths lying substantially in the infrared (IR) spectrum; and
- (2) a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along at least one closed path around the light source.

The term "closed path" used herein signifies a closed curve, like a ring, ellipse, or polygon, and the like.

The detector assembly is comprised of at least one array of discrete detectors (e.g., photodiodes) accommodated along at least one closed path, or at least one continuous photodetector defining the closed path.

The term "substantially IR spectrum" used herein signifies a spectrum range including near infrared and infrared regions.

According to another aspect of the present invention, there is provided a pulse oximeter utilizing a sensor constructed as defined above, and a control unit for operating the sensor and analyzing data generated thereby.

According to yet another aspect of the present invention, there is provided a method for non-invasive determination of a blood parameter, the method comprising the steps of:

illuminating a measurement location with at least three different wavelengths $\lambda 1$, $\lambda 2$ and $\lambda 3$, the first wavelength $\lambda 1$ lying in a red (R) spectrum, and the at least

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second and at least third wavelengths $\lambda 2$ and $\lambda 3$ lying substantially in the infrared (IR) spectrum;

detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and

analyzing the generated data and determining the blood parameter.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

- Fig. 1 illustrates hemoglobin spectra as measured by oximetry based techniques;
- Fig. 2 illustrates a calibration curve used in pulse oximetry as typically programmed by the pulse oximeters manufacturers;
 - Fig. 3 illustrates the relative disposition of light source and detector in reflection-mode or backscatter type pulse oximetry;
 - Fig. 4 illustrates light propagation in reflection pulse oximetry;
- Figs. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under ideal and practical conditions, respectively;
 - Fig. 6 illustrates variations of the slopes of calibration curves in reflectance pulse oximetry measurements;
 - Fig. 7 illustrates an optical sensor according to the invention;
- Fig. 8 is a block diagram of the main components of a pulse oximeter utilizing the sensor of Fig. 7;
 - Fig. 9 is a flow chart of a selection process used in the signal processing technique according to the invention; and
 - Figs. 10A to 10C are flow charts of three main steps, respectively, of the signal processing method according to the invention.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, Figs. 1 and 2 illustrate typical hemoglobin spectra and calibrations curve utilized in the pulse oximetry measurements.

The present invention provides a sensor for use in a reflection-mode or backscatter type pulse oximeter. The relative disposition of light source and detector in the reflection-mode pulse oximeter are illustrated in Fig. 3.

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Fig. 4 shows light propagation in the reflection-mode pulse oximeter where, in addition to the optical absorption and reflection due to blood, the DC signal of the R and IR photoplethysmograms can be adversely affected by strong reflections from the bone.

Figs. 5A and 5B illustrate a pulse oximeter reflectance sensor operating under, respectively, ideal and practical conditions. Referring now to Fig. 5A, it is shown that, under ideal conditions, reflectance sensor measures light backscattered from a homogenous mixture of blood and bloodless tissue components. Accordingly, the normalized R/IR ratio in dual-wavelength reflection type pulse oximeters, which relies on proportional changes in the AC and DC components in the photoplethysmograms, only reflect changes in arterial oxygen saturation.

Referring now to Fig. 5B, in practical situations, the sensor applications affect the distribution of blood in the superficial layers of the skin. Accordingly, the R and IR DC signals measured by photodetectors contain a relatively larger proportion of light absorbed by and reflected from the bloodless tissue compartments. As such, the changes in DC signals depend not only on wavelength but also sensor geometry and thus cannot be eliminated completely by computing the normalized R/IR ratio, as is typically the case in dual-wavelength pulse oximeters. The result is large variations in the slope of the calibration curves, as illustrated in Fig. 6. Referring now to Fig. 6, graphs C1, C2 and C3 show three calibration curves, presenting the variation of the slope for oxygen saturation values between 50% and 100%.

Referring to Fig. 7, there is illustrated an optical sensor 10 designed according to the invention aimed at minimizing some of the measurement inaccuracies in a

reflectance pulse oximeter. The sensor 10 comprises such main constructional parts as a light source 12 composed of three closely spaced light emitting elements (e.g., LEDs or laser sources) 12a, 12b and 12c generating light of three different wavelengths, respectively; an array of discrete detectors (e.g., photodiodes), a "far" detector 16 and a "near" detector 18, arranged in two concentric ring-like arrangements (constituting closed paths) surrounding the light emitting elements; and a light shield 14. In the present example, six photodiodes form each ring. All these elements are accommodated in a sensor housing 17. The light shield 14 is positioned between the photodiodes and the light emitting elements, and prevents direct optical coupling between them, thereby maximizing the fraction of backscattered light passing through the arterially perfused vascular tissue in the detected light.

It should be noted that more than three wavelengths can be utilized in the sensor. The actual numbers of wavelengths used as a light source and the number of photodetectors in each ring are not limited and depend only on the electronic circuitry inside the oximeter. The array of discrete photodiodes can be replaced by one or more continuous photodetector rings.

In addition to the R and IR light emitting elements 12a and 12b as used in the conventional pulse oximeter sensors, the sensor 10 incorporates the third, reference, light emitting element 12c, which emits light in the NIR-IR spectrum. Wavelength $\lambda 1$ and $\lambda 2$ of the R and IR light emitting elements 12a and 12b are centered, respectively, around the peak emission values of 660nm and 940nm, and wavelength $\lambda 3$ of the third light emitting element 12c has the peak emission value above 700nm (typically ranging between 800nm and 900nm). In the description below, the light emitting elements 12b and 12c are referred to as two IR light emitting elements, and wavelengths $\lambda 2$ and $\lambda 3$ are referred to as two IR wavelengths.

During the operation of the sensor 10, different light emitting elements are selectively operated for illuminating a measurement location (not shown) with different wavelengths. Each of the photodetectors detects reflected light of different wavelengths and generates data indicative of the intensity I of the detected light of different wavelengths.

It should be noted that the sensor can be of a compact design utilizing an integrated circuit manufactured by CMOS technology. This technique is disclosed in a co-pending application assigned to the assignee of the present application. According to this technique, the sensor comprises a package including the light source, a block of two tubular optical waveguides of different diameters concentrically dislocated one inside the other and surrounding the light source, and an integrated circuit plate comprising two ring-like areas of photodiodes positioned concentrically one inside the other. The integrated circuit is also provided with a plurality of printed contact areas and electric conductors intended for mounting the light source thereon, controlling the light source, and transmitting electric signals produced by the photodiodes areas for further processing.

Fig. 8 illustrates a block diagram of a pulse oximeter 20 utilizing the above-described sensor 10. The pulse oximeter typically includes a control unit 21, which is composed of an electronic block 22 including A/D and D/A converters connectable to the sensor 10, a microprocessor 24 for analyzing measured data, and a display 26 for presenting measurement results. The measured data (i.e., electrical output of the sensor 10 indicative of the detected light) is directly processed in the block 22, and the converted signal is further processed by the microprocessor 24. The microprocessor 24 is operated by a suitable software model for analyzing the measured data and utilizing reference data (i.e., calibration curve stored in a memory) to compute the oxygen saturation value, which is then presented on the display 26. The analysis of the measured data utilizes the determination of AC- and DC-components in the detected light for each wavelength, $\lambda 1$, $\lambda 2$, and $\lambda 3$, respectively, i.e., $I_1^{(AC)}$, $I_1^{(DC)}$, $I_2^{(AC)}$, $I_2^{(DC)}$, $I_3^{(AC)}$, and $I_3^{(DC)}$, and the calculation of AC/DC ratio for each wavelength, namely, $W_1=I_1^{(AC)}I_1^{(DC)}$, $W_2=I_2^{(AC)}/I_2^{(DC)}$, and $W_3=I_3^{(AC)}/I_3^{(DC)}$, as will be described more specifically further below with reference to Figs. 9 and 10A-10C.

The pulse oximeter 20 with the sensor arrangement shown in Fig. 7 provides the following three possible ratio values: W_1/W_2 , W_1/W_3 and W_2/W_3 . It should be noted that W_1/W_2 and W_1/W_3 are the ratios that typically have the highest sensitivity to oxygen saturation. This is due to the fact that $\lambda 1$ is chosen in the red region of the

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electromagnetic spectrum, where the changes in the absorption between Hb and HbO₂ are the largest, as described above with reference to Fig. 1. Therefore, in principle, the absorption ratios formed by either wavelength pair $\lambda 1$ and $\lambda 2$ or wavelength pair $\lambda 1$ and $\lambda 3$ can be used to compute the value of SaO₂.

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The inventor conducted extensive human and animal studies, and confirmed that either of the two ratios W_1/W_2 and W_1/W_3 can be affected not only by changes in arterial oxygen saturation, but also by sensor placement and by the amount of pressure applied by the sensor on the skin. Any calculation of SaO_2 based on either of the two ratios W_1/W_2 and W_1/W_3 alone (as normally done in commercially available dual-wavelength pulse oximeters) could result in significant errors. Furthermore, since at least two wavelengths are necessary for the calculation of arterial oxygen saturation, it is not feasible to self-correct the calibration curve for variations due to contact pressure or site-to-site variations utilizing the same two wavelengths used already to compute SaO_2 .

The inventor has found that the third ratio W_2/W_3 formed by the combination of the two IR wavelengths is mostly dependent on changes in contact pressure or site-to-site variations. Furthermore, this ratio can depend, but to a much lesser degree, on variations in arterial oxygen saturation. The dependency on arterial oxygen saturation, however, is easily minimized or eliminated completely, for example by selection and matching of the peak emission wavelengths and spectral characteristics of the two IR light emitting elements 12b and 12c.

Generally, the two IR wavelengths $\lambda 2$ and $\lambda 3$ are selected to coincide with the region of the optical absorption curve where HbO₂ absorbs slightly more light than Hb, but in the spectral region, respectively, where the extinction coefficients of both Hb and HbO₂ are nearly equal and remain relatively constant as a function of wavelength. For example, at 940nm and 880nm, the optical extinction coefficients of Hb and HbO₂ are approximately equal to 0.29 and 0.21, respectively. Therefore, ideally, the ratio of W2/W3 should be close to 1, except for situations when the AC/DC signals measured from $\lambda 2$ and $\lambda 3$ are affected unequally causing the ratio W2/W3 to deviate from 1.

Fortunately, variations in the ratio W2/W3 mimic changes in the ratios W_1/W_2 and W_1/W_3 since these ratios are all affected by similar variations in sensor positioning or other uncontrollable factors that normally can cause large errors in the calibration curve from which oxygen saturation is typically derived. Thus, by tracking in real-time changes in the ratio formed by wavelengths $\lambda 2$ and $\lambda 3$, it is possible to automatically correct for errors in the normalized ratios obtained from wavelengths $\lambda 1$ and $\lambda 2$, or from $\lambda 1$ and $\lambda 3$.

The use of an additional third wavelength in the sensor serves another important function (not available in conventional dual-wavelength pulse oximeters), which is associated with the following. Reflectance pulse oximeters have to be capable of detecting and relying on the processing of relatively low quality photoplethysmographic signals. Accordingly, electronic or optical noise can cause large inaccuracies in the final computation of SaO₂. Although the amount of electronic or optical noise pickup from the sensor can be minimized to some extent, it is impossible to render the signals measured by the pulse oximeter completely noise free. Therefore, pulse oximeters rely on the assumption that any noise picked up during the measurement would be cancelled by calculating the ratio between the R- and IR-light intensities measured by the photodetector. Practically, however, the amount of noise that is superimposed on the R- and IR-photoplethysmograms cannot be cancelled completely and, thus, can lead to significant errors in the final computation of SaO₂ which, in dual-wavelength pulse oximeters, is based only on the ratio between two wavelengths.

By utilizing a third wavelength, the invention has the added ability to compute SaO_2 based on the ratio formed from either W_1/W_2 or W_1/W_3 . An algorithm utilized in the pulse oximeter according to the invention has the ability to track and compare in real-time changes between W_1/W_2 and W_1/W_3 to determine which ratio produces a more stable or less noisy signal and selectively choose the best ratio for calculating SaO_2 .

The method according to the invention utilizes the so-called "selection process" as part of the signal processing technique based on the measured data obtained with the multiple photodetectors. The main steps of the selection process are shown in

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Fig. 9 in a self-explanatory manner. Here, the symbol i corresponds to a single photodetector element in the array of multiple discrete photodetector elements, the term "Ist" signifies the last photodetector element in the array, and the term "DATA" signify three ratios (AC/DC) computed separately for each of the three wavelengths, namely, W₁, W₂ and W₃.

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The selection process is associated with the following: Practically, each time one of the light emitting elements is in its operative position (i.e., switched on), all of the photodetectors in the sensor receiving backscattered light from the skin. However, the intensity of the backscattered light measured by each photodetector may be different from that measured by the other photodetectors, depending on the anatomical structures underneath the sensor and its orientation relative to these structures.

Thus, the selection process is used to discriminate between photodetectors receiving "good" signals (i.e., "good" signal meaning that the calculation of SpO_2 from the pulsating portion of the electro-optic signal (AC) and the constant portion (DC) would result in accurate value) and "bad" signals (i.e., having AC and DC values which would result in inaccurate calculations of SpO_2). Accordingly, each data point (i.e., ratio W_{1i} , W_{2i} or W_{3i} detected at the corresponding i^{th} detector) is either accepted, if it meets a certain criteria based for example on a certain ratio of AC to DC values (e.g., such that the intensity of AC signal is about 0.05-2.0% of the intensity of DC signal), or rejected. All of the accepted data points (data from accepted detection locations) are then used to calculate the ratios W_1/W_2 , W_1/W_3 and W_2/W_3 , and to calculate the SpO_2 value, in conjunction with the signal processing technique, as will be described further below with reference to Figs. 10A-10C.

Besides the use of the third IR-wavelength to compensate for changes in the internal calibration curve of the pulse oximeter, the pulse oximeter utilizing the sensor according to the invention provides a unique new method to compensate for errors due to sensor positioning and pressure variability. This method is based on multiple photodetector elements, instead of the conventional approach that relies on a single photodetector.

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While optical sensors with multiple photodetectors for application in reflectance pulse oximetry have been described before, their main limitation relates to the way the information derived from these photodetectors is processed. Although the primary purpose of utilizing multiple photodetectors is to collect a larger portion of the backscattered light from the skin, practically, summing the individual intensities of each photodetector and using the resulting value to compute SaO₂ can introduce large errors into the calculations. These errors can be caused, for example, by situations where the sensor is placed over inhomogeneous tissue structures such as when the sensor is mounted on the chest. The case may be such that, when using a continuous photodetector ring to collect the backscattered light, a portion of the photodetector ring lies over a rib, which acts as a strongly reflecting structure that contributes to a strong DC component, and the remaining part of the photodetector is positioned over the intercostals space, where the DC signal is much smaller. In this case, the final calculation of SaO₂ would be inaccurate, if the current produced by this photodetector is used indiscriminately to compute the DC value before the final computation of SaO₂ is performed. Therefore, in addition to automatically correcting errors in the calibration curve as outlined above using three different LEDs (one R and two different IR wavelengths), the sensor 10 has the optional ability to track automatically and compare changes in the R/IR ratios obtained from each of the discrete photodiodes individually. For example, if some of either the near or the far photodetectors in the two concentrically arranged arrays detect larger than normal DC signals during the operation of one of the photodiodes compared to the other photodiodes in the sensor, it could be indicative of one of the following situations: the sensor is positioned unevenly, the sensor is partially covering a bony structure, or uneven pressure is exerted by the sensor on the skin causing partial skin "blanching" and therefore the blood-to-bloodless tissue ratio might be too high to allow accurate determination of SaO₂. If such a situation is detected, the oximeter has the ability to selectively disregard the readings obtained from the corresponding photodetectors. Otherwise, if the DC and AC signals measured from each photodetector in the array are similar in magnitude, which is an indication that the

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sensor is positioned over a homogeneous area on the skin, the final computation of SaO₂ can be based on equal contributions from every photodetector in the array.

Turning now to Figs. 10A, 10B and 10C, there are illustrated three main steps of the signal processing technique utilized in the present invention. Here, TH_1 and TH_2 are two different threshold values (determined experimentally) related respectively to W_2/W_3 and $(W_1/W_2-W_1/W_3)$.

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During step 1 (Fig. 10A), measured data generated by the "near" and "far" photodetectors indicative of the detected (backscattered) light of wavelength $\lambda 2$ and $\lambda 3$ is analyzed to calculate the two ratios W_2/W_3 (far and near). If one of the calculated ratios (far or near) is not in the range of $1\pm TH_1$ (TH_1 is for example 0.1), then this data point is rejected from the SpO₂ calculation, but if both of them are not in the mentioned range, a corresponding alarm is generated indicative of that the sensor position should be adjusted. Only if there are calculated ratios which are in the range of $1\pm TH1$, they are accepted and the process (data analysis) proceeds by performing step 2.

Step 2 (Fig. 10B) consists of determining whether the quality of each photoplethysmogram is acceptable or not. The quality determination is based on the relative magnitude of each AC component compared to its corresponding DC component. If the quality is not acceptable (e.g., the signal shape detected by any detector varies within a time frame of the measurement session, which may for example be 3.5 sec), the data point is rejected and a corresponding alarm signal is generated. If the AC/DC ratio of W₁, W₂ and W₃ are within an acceptable range, the respective data point is accepted, and the process proceeds through performing step 3.

In step 3 (Fig. 10C), the measured data is analyzed to calculate ratios W_1/W_2 and W_1/W_3 from data generated by far and near photodetectors, and to calculate the differences (W_1/W_2 - W_1/W_3).

In a perfect situation, W_1/W_2 (far) is very close to W_1/W_3 (far), and W_1/W_2 (near) is very close to W_1/W_3 (near). In a practical situation, this condition is not precisely satisfied, but all the ratios are close to each other if the measurement situation is "good".

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Then, the calculated differences are analyzed to determine the values (corresponding to far and near photodetectors) that are accepted and to use them in the SpO_2 calculation. For each detector that satisfied the condition $ABS(W_1/W_2 - W_1/W_3) < TH_2$), where ABS signifies the absolute value, its respective data point is accepted and used to calculate the oxygen saturation value that will be displayed. If the condition is not satisfied, the data point is rejected. If all data points are rejected, another measurement session is carried out.

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It should be noted that, although the steps 1-3 above are exemplified with respect to signal detection by both near and far photodetectors, each of these steps can be implemented by utilizing only one array of detection locations along the closed path. The provision of two such arrays, however, provides higher accuracy of measurements.

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CLAIMS

What is claimed is:

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1. A sensor for use in an optical measurement device for non-invasive measurement of a blood parameter, the sensor comprising:

- (a) a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength $\lambda 1$ lying in a red (R) spectrum, and the at least second and third wavelengths $\lambda 2$ and $\lambda 3$ lying substantially in the infrared (IR) spectrum; and
- (b) a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along at least one closed path around the light source.
 - 2. A sensor as set forth in claim 1, for use in a pulse oximeter, the at least second and third wavelengths $\lambda 2$ and $\lambda 3$ being selected to coincide with a spectral region of the optical absorption curve, where HbO₂ absorbs slightly more light than Hb, and where the extinction coefficients of Hb and HbO₂ are nearly equal and remain relatively constant as a function of wavelength.
- A sensor, as set forth in claim 2, wherein the second wavelength λ2 is in the
 IR spectral region around 940nm+/-20nm, and the third wavelength λ3 is above 700nm.
 - 4. A sensor, as set forth in claim 1, wherein the detector assembly comprises at least one array of detector elements arranged in a spaced-apart relationship along the at least one closed path.

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- 5. A sensor, as set forth in claim 1, wherein the detector assembly comprises at least one ring-shaped detector element.
- 6. A sensor according to claim 1, wherein the plurality of the detection locations are arranged along two concentric closed paths around the light source.

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7. A sensor, as set forth in claim 6, wherein the detector assembly comprises two arrays of detector elements, the detector elements of each array being arranged in a spaced apart relationship along the corresponding one of the closed paths.

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- 8. A sensor, as set forth in claim 6, wherein the detector assembly comprises two concentric ring-shaped detector elements.
- 9. A sensor, as set forth in claim 1, manufactured by CMOS technology, the sensor comprising a package including said light source, and an integrated circuit plate, which comprises said at least one closed path of the detector assembly positioned around the light source, and a plurality of printed contact areas and electric conductors for mounting the light source thereon, controlling the light source, and transmitting electric signals produced by the detector assembly for further processing.

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- 10. A sensor for use in an optical measurement device for non-invasive measurement of a blood parameter, the sensor comprising:
- a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength $\lambda 1$ lying in a red (R) spectrum, and the at least second and third wavelengths $\lambda 2$ and $\lambda 3$ lying substantially in the infrared (IR) spectrum; and

a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along two concentric closed path around the light source.

- 11. A pulse oximeter comprising a sensor and a control unit for operating the sensor and analyzing data generated thereby, the sensor comprising:
- (a) a light source for illuminating a measurement location with incident light of at least three wavelengths, the first wavelength $\lambda 1$ lying in a red (R) spectrum,

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and the at least second and third wavelengths $\lambda 2$ and $\lambda 3$ lying substantially in the infrared (IR) spectrum; and

(b) a detector assembly for detecting light returned from the illuminated location, the detector assembly being arranged so as to define a plurality of detection locations along at least one closed path around the light source.

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- 12. A method for non-invasive determination of a blood parameter, the method comprising the steps of:
- (i) illuminating a measurement location with at least three different wavelengths, a first wavelength $\lambda 1$ lying in a red (R) spectrum, and at least second and third wavelengths $\lambda 2$ and $\lambda 3$ lying substantially in the infrared (IR) spectrum;
- (ii) detecting light returned from the measurement location at different detection locations and generating data indicative of the detected light, wherein said different detection locations are arranged so as to define at least one closed path around the measurement location; and
 - (iii) analyzing the generated data and determining the blood parameter.
- 13. The method according to claim 12, wherein the analysis of the generated data comprises the steps of:
- calculating data indicative of an AC/DC ratio in the light detected at each of the detection locations for the at least three wavelengths;

analyzing the calculated data and determining accepted detection locations to select corresponding AC/DC ratios for each of the at least three wavelengths, $\lambda 1$, $\lambda 2$ and $\lambda 3$; and

- utilizing the selected ratios for determining the blood parameter.
 - 14. The method according to claim 13, wherein the determination of the blood parameter comprises the steps of:

calculating values of the ratio W_2/W_3 for the accepted detection locations in at 30 least one closed path;

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analyzing each of the calculated values to determine whether it satisfies a first predetermined condition, so as to generate a signal indicative of that a sensor position is to be adjusted, if the condition is not satisfied;

if the condition is satisfied, determining whether the quality of a photoplethysmogram is acceptable;

if the quality is acceptable, analyzing the selected ratios for calculating ratios W_1/W_2 and W_1/W_3 from the data detected in at least one closed path, and calculating the differences ABS (W_1/W_2 - W_1/W_3); and,

analyzing the calculated differences for determining whether each of the differences satisfies a second predetermined condition for determining the blood parameter if the condition is satisfied.

15. The method according to claim 14, wherein said first predetermined condition consists of that the calculated value of W_2/W_3 is inside a predetermined range around the value one, said predetermined range being defined by the first threshold value, and the second predetermined condition consists of that the calculated difference ABS $(W_1/W_2 - W_1/W_3)$ is less than certain, second threshold value.

16. A pulse oximeter for detecting a value of a parameter of blood, comprising:a sensor housing;

a source of radiation coupled to the housing and being adapted to emit radiation at predetermined frequencies;

a detector assembly coupled to the housing and being adapted to detect reflected radiation at first, second, and third frequencies and to generate respective first, second, and third signals, wherein the first, second, and third signals are indicative of a value of the reflected radiation at the respective first, second, and third frequencies; and,

a control unit coupled to the detector assembly and adapted to receive the first, second, and third signals, to calculate first, second and third ratios of the first, second, and third signals and to responsively determine the parameter of the blood as a function of the first, second and third ratios.

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17. A pulse oximeter, as set forth in claim 16, wherein the control unit is adapted to determine the parameter of the blood as a function of the first and second ratios and a calibration curve.

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- 18. A pulse oximeter, as set forth in claim 17, wherein the calibration curve is adjusted as a function of the third ratio.
- 19. A pulse oximeter, as set forth in claim 16, wherein the first ratio is defined by the first signal divided by the second signal.
 - 20. A pulse oximeter, as set forth in claim 16, wherein the second ratio is defined by the first signal divided by the third signal.
- 15 21. A pulse oximeter, as set forth in claim 16, wherein the third ratio is defined by the second signal divided by the third signal.
 - 22. A pulse oximeter, as set forth in claim 16, wherein the first frequency is in a red frequency range, the second frequency is in a near-infrared frequency range, and the third frequency is in an infrared frequency range.
 - 23. A pulse oximeter, as set forth in claim 22, wherein the first ratio is defined by the first signal divided by the second signal, the second ratio is defined by the first signal divided by the third signal, and the third ratio is defined by the second signal divided by the third signal.
 - 24. A pulse oximeter, as set forth in claim 16, wherein the control unit is adapted to determine the parameter of the blood as a function of a more stable one of the first and second ratios.

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25. A pulse oximeter for detecting a value of a parameter of blood, comprising: a sensor housing;

a source of radiation coupled to the housing and being adapted to emit radiation at predetermined frequencies;

a detector assembly coupled to the housing and being adapted to detect reflected radiation at first, second, and third frequencies and to generate respective first, second, and third signals, wherein the first, second, and third signals are indicative of a value of the reflected radiation at the respective first, second, and third frequencies; and,

a control unit coupled to the detector assembly and being adapted to calculate first and second ratios of the first, second, and third signals, wherein the first ratio is defined by the first signal divided by the second signal and the second ratio is defined by the first signal divided by the third signal, and wherein the control unit is adapted to determine the parameter of the blood as a function of a more stable one of the first and second ratios.

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- 26. A pulse oximeter, as set forth in claim 25, wherein the control unit is adapted to determine the parameter of the blood as a function of the more stable one of the first and second ratios and a calibration curve.
- 20 27. A pulse oximeter, as set forth in claim 26, wherein the calibration curve is adjusted as a function of a third ratio.
 - 28. A pulse oximeter, as set forth in claim 27, wherein the third ratio is defined by the second signal divided by the third signal.

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29. A pulse oximeter, as set forth in claim 25, wherein the first frequency is in a red frequency range, the second frequency is in a near-infrared frequency range, and the third frequency is in an infrared frequency range.

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30. A pulse oximeter, as set forth in claim 25, wherein the control unit is adapted to track the first and second ratios and determine which one of the first and second ratios is more stable in real-time.

31. A pulse oximeter for detecting a value of a parameter of blood, comprising:

a sensor housing;

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a source of radiation coupled to the housing and being adapted to emit radiation at predetermined frequencies; and,

a plurality of detectors coupled to the housing and being adapted to detect reflected radiation at first, second, and third frequencies and to responsively generate a plurality of first sensor signals indicative of the reflected radiation at the first frequency, a plurality of second sensor signals indicative of the reflected radiation at the second frequency, and a plurality of third sensor signals indicative of the reflected radiation at the third frequency;

a control unit being coupled to the plurality of detectors and adapted to receive the plurality of first, second and third sensor signals, to analyze the first, second and third sensor signals and determine which of the first, second and third sensor signals are valid and to generate first, second, and third frequency signals as a function of valid first sensor signals, valid second sensor signals, and valid third sensor signals, respectively and to determine the parameter of the blood as a function of the valid first, second, and third sensor signals.

- 32. A pulse oximeter, as set forth in claim 31, wherein the control unit is adapted to calculate first, second and third ratios of the valid first, second, and third signals and to responsively determine the parameter of the blood as a function of the first, second and third ratios.
- 33. A pulse oximeter, as set forth in claim 32, wherein the control unit is adapted to determine the parameter of the blood as a function of the first and second ratios and a calibration curve.

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- 34. A pulse oximeter, as set forth in claim 33, wherein the calibration curve is adjusted as a function of the third ratio.
- 5 35. A pulse oximeter, as set forth in claim 32, wherein the first ratio is defined by the valid first signals divided by the valid second signals.
 - 36. A pulse oximeter, as set forth in claim 32, wherein the second ratio is defined by the valid first signals divided by the valid third signals.

37. A pulse oximeter, as set forth in claim 32, wherein the third ratio is defined by the valid second signals divided by the valid third signals.

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- 38. A pulse oximeter, as set forth in claim 31, wherein the first frequency is in a red frequency range, the second frequency is in a near-infrared frequency range, and the third frequency is in an infrared frequency range.
 - 39. A pulse oximeter, as set forth in claim 32, wherein the first ratio is defined by the valid first signals divided by the valid second signals, the second ratio is defined by the valid first signals divided by the valid third signals, and the third ratio is defined by the valid second signals divided by the valid third signals.
 - 40. A pulse oximeter, as set forth in claim 32, wherein the control unit is adapted to determine the parameter of the blood as a function of a more stable one of the first and second ratios.

41. A pulse oximeter, as set forth in claim 31, wherein the plurality of first, second, and third sensor signals having an AC portion and a DC portion.

42. A pulse oximeter, as set forth in claim 41, wherein a sensor signal is valid if it a ratio of the AC portion to the DC portion is within a predetermined range.

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- 43. A pulse oximeter, as set forth in claim 42, wherein the predetermined range is 0.05 to 2.0 percent.
- 5 44. A sensor for use in an optical measurement device for non-invasive measurement of a blood parameter, comprising:

a sensor housing;

- a source of radiation coupled to the housing and being adapted to emit radiation at predetermined frequencies;
- a detector assembly coupled to the housing and being adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals, wherein the detector assembly is ring shaped.
- 45. A sensor, as set forth in claim 44, wherein the detector assembly includes a plurality of detectors arranged along a closed loop path.
 - 46. A sensor, as set forth in claim 45, wherein the closed loop path has a circular shape.
- A sensor, as set forth in claim 45, wherein the closed loop path has an elliptical shape.
 - 48. A sensor, as set forth in claim 45, wherein the closed loop path has a polygonal shape.
- 25 49. A sensor, as set forth in claim 44, wherein the detector assembly includes a continuous photodetector ring.
 - 50. A sensor, as set forth in claim 49, wherein the continuous photodetector ring has a circular shape.

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- 51. A sensor, as set forth in claim 49, wherein the continuous photo detector ring has an elliptical shape.
- 52. A sensor, as set forth in claim 49, wherein the continuous photo detector 5 ring has a polygonal shape.
 - 53. A sensor, as set forth in claim 44, wherein the detector assembly includes a first plurality of detectors arranged along an inner closed loop path and a second plurality of detectors arranged along an outer closed loop path.

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- 54. A sensor, as set forth in claim 53, wherein the inner and outer closed loop paths have a circular shape.
- 55. A sensor, as set forth in claim 49, wherein the inner and outer closedloop paths have an elliptical shape.
 - 56. A sensor, as set forth in claim 49, wherein the inner and outer closed loop paths have a polygonal shape.
- 57. A sensor for use in an optical measurement device for non-invasive measurement of a blood parameter, comprising:

a sensor housing;

a source of radiation coupled to the housing and being adapted to emit radiation at predetermined frequencies;

a detector assembly coupled to the housing and being adapted to detect reflected radiation at least one predetermined frequency and to generate respective signals, wherein the detector assembly includes a plurality of pairs of detectors, each pair of detectors including a near detector and a far detector.

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- 58. A sensor, as set forth in claim 57, wherein the near detectors are arranged along an inner closed loop path and the far detectors are arranged along an outer closed loop paths.
- 5 59. A sensor, as set forth in claim 58, wherein the inner and outer closed loop paths have a circular shape.
 - 60. A sensor, as set forth in claim 58, wherein the inner and outer closed loop paths have an elliptical shape.

61. A sensor, as set forth in claim 58, wherein the inner and outer closed loop paths have a polygonal shape.

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- 62. A method for detecting a value of a parameter of blood using a sensor adapted to emit radiation at predetermined frequencies, to detect reflected radiation at first, second, and third frequencies and to generate respective first, second, and third signals, wherein the first, second, and third signals are indicative of a value of the reflected radiation at the respective first, second, and third frequencies, the method including the steps of:
- 20 receiving the first, second, and third signals;
 calculating first, second and third ratios of the first, second, and third signals;
 and,

responsively determining the parameter of the blood as a function of the first, second and third ratios.

- 63. A method, as set forth in claim 62, wherein the parameter of the blood is determined as a function of the first and second ratios and a calibration curve.
- 64. A method, as set forth in claim 63, including the step of adjusting the calibration curve as a function of the third ratio.

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- 65. A method, as set forth in claim 62, wherein the first ratio is defined by the first signal divided by the second signal.
- 5 66. A method, as set forth in claim 62, wherein the second ratio is defined by the first signal divided by the third signal.
 - 67. A method, as set forth in claim 62, wherein the third ratio is defined by the second signal divided by the third signal.

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- 68. A method, as set forth in claim 62, wherein the first frequency is in a red frequency range, the second frequency is in a near-infrared frequency range, and the third frequency is in an infrared frequency range.
- 15 69. A method, as set forth in claim 62, wherein the first ratio is defined by the first signal divided by the second signal, the second ratio is defined by the first signal divided by the third signal, and the third ratio is defined by the second signal divided by the third signal.
 - 70. A method, as set forth in claim 62, including the step of determining a more stable of the first and second ratios, wherein the parameter of the blood is determined using the more stable one of the first and second ratios.
- 71. A method for detecting a value of a parameter of blood using a sensor adapted to emit radiation at predetermined frequencies, to detect reflected radiation at first, second, and third frequencies and to generate respective first, second, and third signals, wherein the first, second, and third signals are indicative of a value of the reflected radiation at the respective first, second, and third frequencies, the method including the steps of:
- 30 receiving the first, second and third signals;

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calculate first and second ratios of the first, second and third signals, wherein the first ratio is defined by the first signal divided by the second signal and the second ratio is defined by the first signal divided by the third signal; and,

determining the parameter of the blood as a function of a more stable one of the first and second ratios.

72. A method, as set forth in claim 71, wherein the parameter of the blood as a function of the more stable one of the first and second ratios and a calibration curve.

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- 73. A method, as set forth in claim 72, including the step of adjusted the calibration curve as a function of a third ratio.
- 74. A method, as set forth in claim 73, wherein the third ratio is defined by the second signal divided by the third signal.
 - 75. A method, as set forth in claim 71, wherein the first frequency is in a red frequency range, the second frequency is in an infrared frequency range, and the third frequency is in a near-infrared frequency range.

- 76. A method, as set forth in claim 71, including the step of tracking the first and second ratios and determining which one of the first and second ratios is more stable in real-time.
- 25 77. A method for detecting a value of a parameter of blood using a sensor adapted to emit radiation at predetermined frequencies, to detect reflected radiation at first, second, and third frequencies and to responsively generate a plurality of first sensor signals indicative of the reflected radiation at the first frequency, a plurality of second sensor signals indicative of the reflected radiation at the second frequency, and

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a plurality of third sensor signals indicative of the reflected radiation at the third frequency, the method comprising:

receiving the plurality of first, second and third sensor signals;

analyzing the first, second and third sensor signals and determining which of the first, second and third sensor signals are valid;

generating first, second, and third frequency signals as a function of valid first sensor signals, valid second sensor signals, and valid third sensor signals, respectively; and,

determining the parameter of the blood as a function of the valid first, second, and third sensor signals.

78. A method, as set forth in claim 77, including the step of calculating first, second and third ratios of the first, second, and third valid signals and responsively determining the parameter of the blood as a function of the first, second and third ratios.

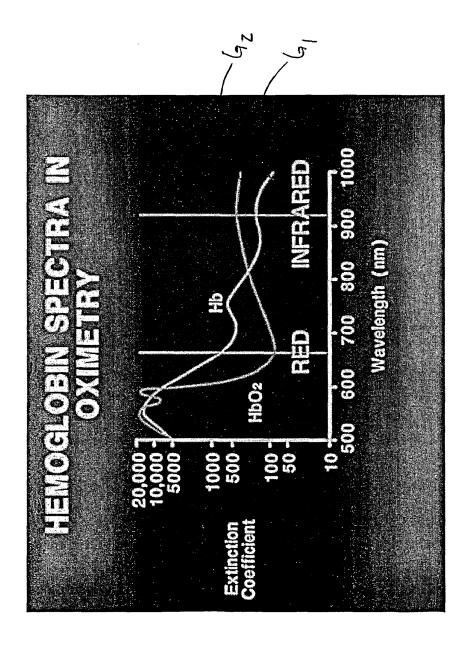
79. A method, as set forth in claim 78, wherein the parameter of the blood is determined as a function of the first and second ratios and a calibration curve.

- 80. A method, as set forth in claim 79, including the step of adjusting the 20 calibration curve as a function of the third ratio.
 - 81. A method, as set forth in claim 78, wherein the first ratio is defined by the valid first signals divided by the valid second signals.
- 82. A method, as set forth in claim 78, wherein the second ratio is defined by the valid first signals divided by the valid third signals.
 - 83. A method, as set forth in claim 78, wherein the third ratio is defined by the valid second signals divided by the valid third signals.

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- 84. A method, as set forth in claim 78, wherein the first frequency is in a red frequency range, the second frequency is in an infrared frequency range, and the third frequency is in a near-infrared frequency range.
- 5 85. A method, as set forth in claim 78, wherein the first ratio is defined by the valid first signals divided by the valid second signals, the second ratio is defined by the valid first signals divided by the valid third signals, and the third ratio is defined by the valid second signals divided by the valid third signals.
- 10 86. A method, as set forth in claim 78, including the step of determining the parameter of the blood as a function of a more stable one of the first and second ratios.
 - 87. A method, as set forth in claim 77, wherein the plurality of first, second, and third sensor signals have an AC portion and a DC portion.
- 15 88. A method, as set forth in claim 87, wherein a sensor signal is valid if a ratio of the AC portion to the DC portion is within a predetermined range.
 - 89. A method, as set forth in claim 88, wherein the predetermined range is 0.05 to 2.0 percent.



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CALIBRATION OF A PULSE OXIMETER

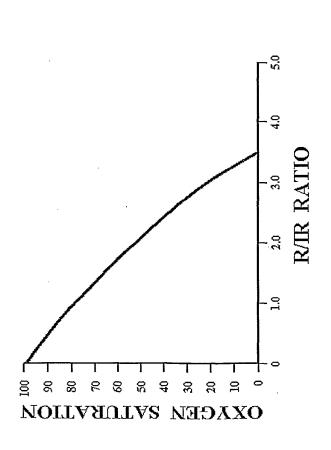
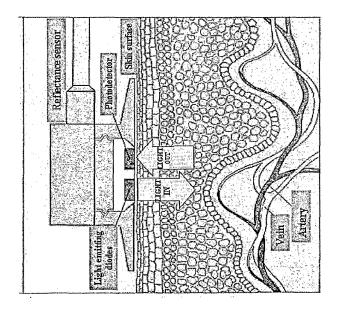
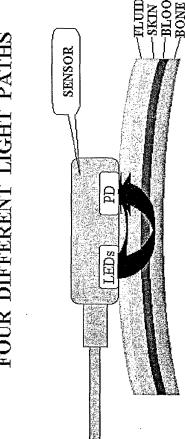


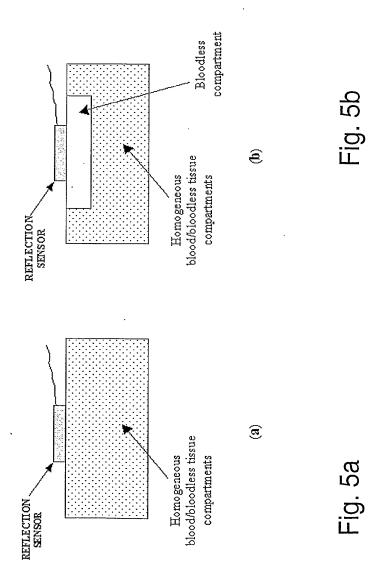
Fig. 2



-<u>ig</u>. 3

FOUR DIFFERENT LIGHT PATHS





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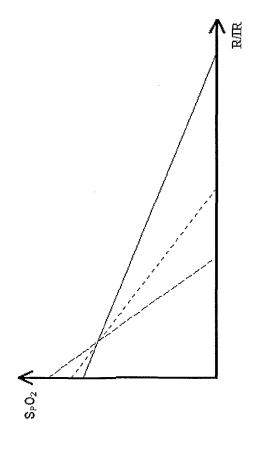


Fig. 6

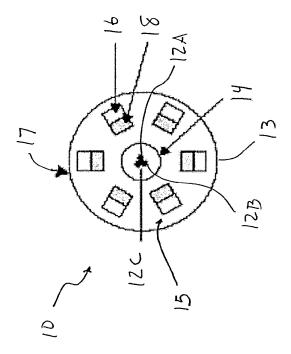
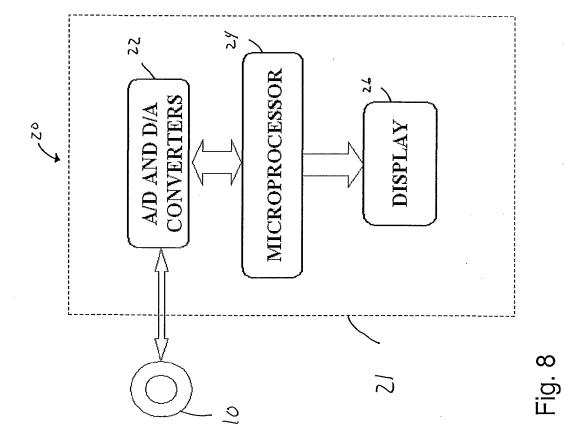
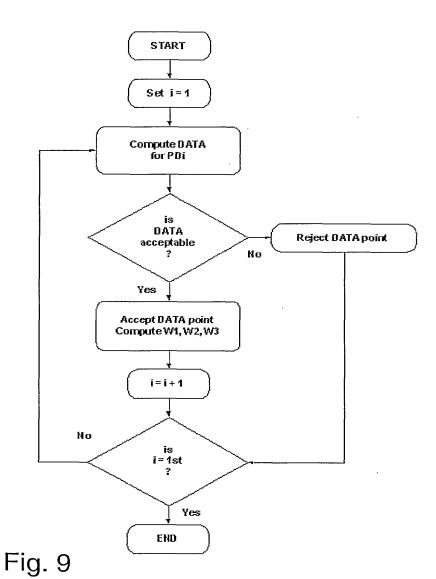


Fig. 7





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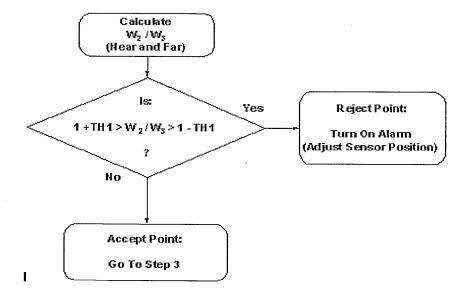


Fig. 10A

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Step 2

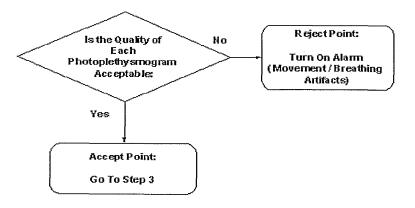


Fig. 10B

Step 3

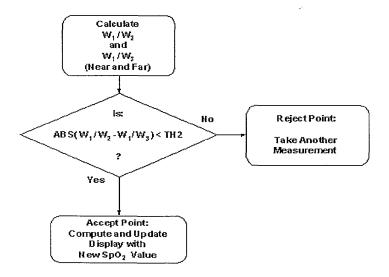


Fig. 10C

INTERNATIONAL SEARCH REPORT

In al Application No PCT/US 01/26642

| | | | PCT/US 01/26642 | | |
|--|---|---|---|--|--|
| A. CLASSII IPC 7 | FICATION OF SUBJECT MATTER A61B5/00 | | | | |
| According to | o International Patent Classification (IPC) or to both national classif | fication and IPC | | | |
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| Electronic d | lata base consulted during the international search (name of data | base and, where practical | al, search terms used) | | |
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| citation or other special reason (as specified) "()" the unreal referring to an oral disclosure, use, exhibition or other means | | involve an invent "Y" document of partic cannot be consic document is com | 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. | | |
| later | nent published prior to the international filing date but than the priority date claimed | "&" document membe | er of the same patent family | | |
| | e actual completion of the international search | Date of mailing o | of the international search report | | |
| | d mailing address of the ISA | Authorized office | эг | | |
| | 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 | Lemerc | cier, D | | |

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nal Application No
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| Doc Code: PET.AUTO Document Description: Petition au | tomatically granted by EFS-Web | PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce | | | |
|---|--|--|--|--|--|
| Electronic Petition Request | PETITION TO WITHDRAW AN APP THE ISSUE FEE UNDER 37 CFR 1.3 | LICATION FROM ISSUE AFTER PAYMENT OF | | | |
| Application Number | 16226249 | | | | |
| Filing Date | 19-Dec-2018 | 19-Dec-2018 | | | |
| First Named Inventor | or Ammar Al-Ali | | | | |
| Art Unit | Art Unit 3791 | | | | |
| Examiner Name | MARJAN FARDANESH | | | | |
| Attorney Docket Number | Attorney Docket Number MAS.1007C1 | | | | |
| Title | ADVANCED PULSE OXIMETRY SENSOR | R | | | |
| withdraw an application from issishowing of good and sufficient reshowing of good and sufficient reshowing of good and sufficient reshowing of good and sufficient reshowing reasons. A grantable petition requires the (1) Petition fee; and (2) One of the following reasons: (a) Unpatentability of one or more are unpatentable, an amendment claims to be patentable; (b) Consideration of a request for (c) Express abandonment of the a CPA under 37 CFR 1.53(d). | ue, applicant must file a petition under this seasons why withdrawal of the application from WITHDRAW THIS APPLICATION FROM ISSU following items: e claims, which must be accompanied by and to such claim or claims, and an explanation continued examination in compliance with | | | | |
| Petition Fee | | | | | |
| Small Entity | | | | | |
| | | | | | |
| Regular Undiscounted | | | | | |
| Reason for withdrawal from issue | | | | | |

| One or more claims are unpatentable | | | | | |
|---|--|--|--|--|--|
| Consideration of a request for continued examination (RCE) (List of Required Documents and Fees) | | | | | |
| Applicant hereby expressly abandons the instant application (any attorney/agent signing for this reason must have power of attorney pursuant to 37 CFR 1.32(b)). | | | | | |
| RCE request, submission, and fee. | | | | | |
| I certify, in accordance with 37 CFR 1.4(d)(4) that: The RCE request ,submission, and fee have already been filed in the above-identified application on | | | | | |
| Are attached. | | | | | |
| THIS PORTION MUST BE COMPLETE | ED BY THE SIGNATORY OR SIGNATORIES | | | | |
| I certify, in accordance with 37 CFR | l certify, in accordance with 37 CFR 1.4(d)(4) that I am: | | | | |
| An attorney or agent registered in this application. | An attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application. | | | | |
| An attorney or agent registered to practice before the Patent and Trademark Office, acting in a representative capacity. | | | | | |
| ○ A sole inventor | | | | | |
| A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application | | | | | |
| A joint inventor; all of whom are signing this e-petition | | | | | |
| Signature | /Aaron S. Johnson/ | | | | |
| Name | Aaron S. Johnson | | | | |
| Registration Number | Registration Number 74164 | | | | |

| Electronic Patent Application Fee Transmittal | | | | | | |
|--|------------|--------------------------------------|----------|--------|-------------------------|--|
| Application Number: | | 16226249 | | | | |
| Filing Date: | | 19-Dec-2018 | | | | |
| Title of Invention: | | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | | ımar Al-Ali | | | | |
| Filer: | | Aaron Samuel Johnson/Melissa Ramirez | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | | |
| Filed as Large Entity | | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) | |
| Basic Filing: | | | | | | |
| PETITION FEE- 37 CFR 1.17(H) (GROUP III) | | 1464 | 1 | 140 | 140 | |
| RCE- 1ST REQUEST | | 1801 | 1 | 1300 | 1300 | |
| Pages: | | | | | | |
| Claims: | | | | | | |
| Miscellaneous-Filing: | | | | | | |
| Petition: | | | | | | |
| Patent-Appeals-and-Interference: | | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|-----------------------------------|----------|-----------|--------|-------------------------|
| Post-Allowance-and-Post-Issuance: | | | | |
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| | Tot | al in USD | (\$) | 1440 |
| | | | | |



UNITED STATES PATENT AND TRADEMARK OFFICE

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

Decision Date: August 15, 2019

In re Application of:

DECISION ON PETITION

Ammar Al-Ali

UNDER CFR 1.313(c)(2)

Application No: 16226249

Filed: 19-Dec-2018

Attorney Docket No: MAS.1007C1

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed August 15, 2019 , to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

This application file is being referred to Technology Center AU 3791 for processing of the request for continuing examination under 37 CFR 1.114.

Office of Petitions

| Electronic Acknowledgement Receipt | | | | |
|--------------------------------------|--------------------------------------|--|--|--|
| EFS ID: | 36887098 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Aaron Samuel Johnson/Melissa Ramirez | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 15-AUG-2019 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 16:06:54 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | yes |
|--|------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$1440 |
| RAM confirmation Number | E20198EG06308859 |
| Deposit Account | 111410 |
| Authorized User | Melissa Ramirez |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

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| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Receipt date: 07/19/2019 16/226,249 - GAU: 3791

PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT DI AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 11 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature /MARJAN | FARDANESH/ | Date Considered | 07/19/2019 |
|----------------------------|------------|-----------------|------------|

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

T1 - Place a check mark in this area when an English language Translation is attached.

Receipt date: 12/19/2018 16/226,249 - GAU: 3791

PTO/SB/08 Equivalent

| | Application No. | Unassigned |
|---------------------------------------|----------------------|----------------|
| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT DI AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 27 OF 28 | Attorney Docket No. | MAS.1007C1 |

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Examiner Signature /MARJAN FARDANESH/ Date Considered 02/06/2019

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

T1 - Place a check mark in this area when an English language Translation is attached.

Receipt date: 12/19/2018 16/226,249 - GAU: 3791

PTO/SB/08 Equivalent

| | Application No. | Unassigned |
|---------------------------------------|----------------------|----------------|
| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT DI AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 12 OF 28 | Attorney Docket No. | MAS.1007C1 |

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8/9/2<u>019</u>

Examiner Signature /MARJAN FARDANESH/ Date Considered 02/06/2019

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

T1 - Place a check mark in this area when an English language Translation is attached.

Docket No.: MAS.1007C1 August 5, 2019
Page 1 of 1

Please Direct All Correspondence to Customer Number 64735

TRANSMITTAL OF DECLARATION

First Inventor : Ammar Al-Ali

App. No. : 16/226249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Art Unit : 3791

Conf No. : 1002

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

Dear Sir:

The above-captioned application was filed without a Declaration and/or Substitute Statement. Enclosed in compliance with 37 CFR 1.53(f) are the following.

(X) Declaration(s) for:

Ammar Al-Ali

The Commissioner is hereby authorized to charge any additional fees which may be required, now or in the future, or credit any overpayment, to Account No. 11-1410.

/Aaron S. Johnson/ Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

Approved for use through 11/30/2020. OME 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OME control number.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

| Title of Invention | ADVANCED PULSE OXIMETRY SENSOR |
|--|---|
| As the belo | w named inventor, I hereby declare that: |
| This declar is directed t |) |
| The above-i | dentified application was made or authorized to be made by me. |
| I believe tha | t I am the original inventor or an original joint inventor of a claimed invention in the application. |
| | nowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 prisonment of not more than five (5) years, or both. |
| | WARNING: |
| contribute to (other than a to support a petitioners/a USPTO. Pe application (patent. Furt referenced is | policant is cautioned to avoid submitting personal information in documents filed in a patent application that may identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers is check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO petition or an application. If this type of personal information is included in documents submitted to the USPTO, pplicants should consider redacting such personal information from the documents before submitting them to the tilioner/applicant is advised that the record of a patent application is available to the public after publication of the unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a hermore, the record from an abandoned application may also be available to the public if the application is a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms ubmitted for payment purposes are not retained in the application file and therefore are not publicly available. |
| LEGAL N | AME OF INVENTOR |
| Inventor: | Ammar Al-Ali Date (Optional): 8/2/19 |
| Note: An appi been previous | ication data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have sly filed. Use an additional PTO/AIA/01 form for each additional inventor. |

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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. 8cx 1459, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

| Electronic Acknowledgement Receipt | | | | | |
|--------------------------------------|--------------------------------------|--|--|--|--|
| EFS ID: | 36784542 | | | | |
| Application Number: | 16226249 | | | | |
| International Application Number: | | | | | |
| Confirmation Number: | 1002 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | |
| Customer Number: | 64735 | | | | |
| Filer: | Aaron Samuel Johnson/Melissa Ramirez | | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | |
| Receipt Date: | 05-AUG-2019 | | | | |
| Filing Date: | 19-DEC-2018 | | | | |
| Time Stamp: | 16:14:38 | | | | |
| 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.) |
|--------------------|----------------------|---------------------------|--|---------------------|---------------------|
| | | | 15485 | | |
| 1 | Transmittal Letter | TRANSMITTAL_MAS1007C1.pdf | 23207c27c8253ba8d514d93212aa19ead65 b9628 | no | 1 |
| Warnings: | | | | | |

| Information: | | | | | |
|--------------|---------------------------|-----------------------------|--|-------|---|
| | | | 1166962 | | |
| 2 | Oath or Declaration filed | Declaration_MAS1007.PDF | 5427ae2c0bbbb118e58a49ee3844b8b6d5 102148 | no | 1 |
| Warnings: | | | | | |
| Information: | | | | | |
| | | Total Files Size (in bytes) | 11 | 82447 | |

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.

PART B - FEE(S) TRANSMITTAL

| Complete and send | this form, together | with applicable fee(s |), by mail or fax, or v | ia EFS-Web. | | |
|---|--|--|--|--|---|---|
| By mail, send to: | Mail Stop ISSUE Commissioner for P.O. Box 1450 Alexandria, Virgii | Patents | | | By fax, send to | o: (571)-273-2885 |
| further correspondence is | form should be used for tr ncluding the Patent, adva | ransmitting the ISSUE FE | E and PUBLICATION FER n of maintenance fees will dence address; and/or (b) in | be mailed to the current o | orrespondence address as | indicated unless corrected |
| CURRENT CORRESPOND 64735 KNOBBE, MA | 7590 07/30 ARTENS, OLSON PORATION (MAS) REET FLOOR | lock 1 for any change of address) 1/2019 1 & BEAR, LLP | Not Fee pap hav I he Stat add: | e: A certificate of maili (s) Transmittal. This cer ers. Each additional pap e its own certificate of m Certificate reby certify that this Ferese Postal Service with services to the Mail Stop | ng can only be used for tificate cannot be used fo er, such as an assignmen ailing or transmission. te of Mailing or Transm (s) Transmittal is being ufficient postage for first ISSUE FEE address abov | domestic mailings of the r any other accompanying t or formal drawing, must |
| ikviivė, ca 72 | .U14 | | | | | (Date) |
| | _ | | | | | |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATI | ORNEY DOCKET NO. | CONFIRMATION NO. |
| 16/226,249 TITLE OF INVENTION | 12/19/2018 I: ADVANCED PULSE | OXIMETRY SENSOR | Ammar Al-Ali | | MAS.1007C1 | 1002 |
| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
| nonprovisional | UNDISCOUNTED | \$1000 | \$0.00 | \$0.00 | \$1000 | 10/30/2019 |
| | | | | | | |
| EXAM | MINER | ART UNIT | CLASS-SUBCLASS |] | | |
| FARDANES | H, MARJAN | 3791 | 600-323000 | | | |
| ☐ "Fee Address" ind | ondence address (or Cha B/122) attached. lication (or "Fee Address more recent) attached. U | unge of Correspondence | or agents OR, alternati (2) The name of a sing registered attorney or a | o 3 registered patent atto vely, le firm (having as a men agent) and the names of rneys or agents. If no na | ther a up to 2 Olson & | , Martens, Bear, LLP |
| 3. ASSIGNEE NAME A | ND RESIDENCE DATA | | THE PATENT (print or typ | | | |
| PLEASE NOTE: Unle recorded, or filed for (A) NAME OF ASSI | recordation, as set forth | ied below, no assignee dat in 37 CFR 3.11 and 37 CF | a will appear on the patent FR 3.81(a). Completion of (B) RESIDENCE: (CITY | this form is NOT a subs | titute for filing an assignr | nust have been previously nent. |
| MASIMO C | ORPORATION | | Irvine, CA | | | |
| Please check the appropr | riate assignee category or | categories (will not be pr | rinted on the patent) : \Box In | ndividual 🔼 Corporation | or other private group en | ntity 🗖 Government |
| 4a. Fees submitted: 4b. Method of Payment: Zi Electronic Payment | (Please first reapply any | plication Fee (if required) previously paid fee show Enclosed check | Advance Order - ‡ on above) Non-electronic payment by | - | pTO-2038) | |
| _ | | | deficiency, or credit any o | | | |
| Applicant assertin Applicant changin | ng micro entity status. See g small entity status. See ng to regular undiscounte | ee 37 CFR 1.29 237 CFR 1.27 d fee status. | NOTE: If the application to be a notification of los NOTE: Checking this bo entity status, as applicable | entity amount will not b was previously under m s of entitlement to micro x will be taken to be a not e. | e accepted at the risk of a icro entity status, checkin entity status. otification of loss of entitl | application abandonment. In this box will be taken |
| | | | 3. See 37 CFR 1.4 for sign | - | ertifications. | |
| Authorized Signature | /Aaron S. Johns | on/ | | Date 8/5/2019 | | |
| Typed or printed nam | e <u>Aaron S. John</u> | son | | Registration No. | 74,164 | |

Page 2 of 3 OMB 0651-0033

| Electronic Patent Application Fee Transmittal | | | | | |
|---|--------------------------------------|-------------|----------|--------|-------------------------|
| Application Number: | 16 | 226249 | | | |
| Filing Date: | 19 | -Dec-2018 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | An | nmar Al-Ali | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | |
| Filed as Large Entity | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
| Basic Filing: | | | | | |
| Pages: | | | | | |
| Claims: | | | | | |
| Miscellaneous-Filing: | | | | | |
| Petition: | | | | | |
| Patent-Appeals-and-Interference: | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | |
| UTILITY APPL ISSUE FEE | | 1501 | 1 | 1000 | 1000 |
| | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------|----------|-----------|--------|-------------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| | Tot | al in USD | (\$) | 1000 |
| | | | | |

| Electronic Ack | Electronic Acknowledgement Receipt | | | |
|--------------------------------------|------------------------------------|--|--|--|
| EFS ID: | 36786505 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Aaron Samuel Johnson/Jennifer Neat | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 05-AUG-2019 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 19:03:14 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | yes |
|--|------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$1000 |
| RAM confirmation Number | E201985J03365661 |
| Deposit Account | 111410 |
| Authorized User | Jennifer Neat |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing: | _ | | | | |
|--------------------|---|-----------------------------|--|---------------------|--------------------|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl. |
| | | | 216473 | | |
| 1 | I Issue Fee Payment (PTO-85B) ISSUE-FEE_MAS1007C1.PDF | | b635829f9adcf94920da07ab5bba0794bf3a 0d99 | no | 1 |
| Warnings: | | | | | |
| Information: | | | | | |
| | | | 30292 | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 8ec6fc7439f3425d5da30960b347eeb2270 91eb3 | no | 2 |
| Warnings: | - | <u> </u> | <u> </u> | | |
| Information: | | | | | |
| | | Total Files Size (in bytes) |): 24 | 16765 | |

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

64735 7590 07/30/2019
KNOBBE, MARTENS, OLSON & BEAR, LLP
MASIMO CORPORATION (MASIMO)
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
FARDANESH, MARJAN

ART UNIT PAPER NUMBER

3791

DATE MAILED: 07/30/2019

| ı | APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|-------------|----------------------|---------------------|------------------|
| | 16/226 249 | 12/19/2018 | Ammar Al-Ali | MAS 1007C1 | 1002 |

TITLE OF INVENTION: ADVANCED PULSE OXIMETRY SENSOR

| APPLN. TYPE | ENTITY STATUS | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|---------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | UNDISCOUNTED | \$1000 | \$0.00 | \$0.00 | \$1000 | 10/30/2019 |

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

Page 1 of 3

PART B - FEE(S) TRANSMITTAL Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web. Mail Stop ISSUE FEE By mail, send to: By fax, send to: (571)-273-2885 Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. Certificate of Mailing or Transmission 64735 7590 07/30/2019 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below. 2040 MAIN STREET (Typed or printed name FOURTEENTH FLOOR (Signatur IRVINE, CA 92614 APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 16/226.249 12/19/2018 MAS.1007C1 Ammar Al-Ali 1002 TITLE OF INVENTION: ADVANCED PULSE OXIMETRY SENSOR APPLN TYPE ENTITY STATUS ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE nonprovisional UNDISCOUNTED \$1000 \$0.00 \$0.00 \$1000 10/30/2019 EXAMINER ART UNIT CLASS-SUBCLASS FARDANESH, MARJAN 3791 600-323000 1. Change of correspondence address or indication of "Fee Address" (37 2. For printing on the patent front page, list (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is "Fee Address" indication (or "Fee Address" Indication form PTO/ listed, no name will be printed. SB/47; Rev 03-09 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) Please check the appropriate assignee category or categories (will not be printed on the patent) : 🗖 Individual 🗖 Corporation or other private group entity 🗖 Government 4a. Fees submitted: ☐Issue Fee ■Publication Fee (if required) Advance Order - # of Copies 4b. Method of Payment: (Please first reapply any previously paid fee shown above) 🗖 Electronic Payment via EFS-Web Enclosed check Non-electronic payment by credit card (Attach form PTO-2038) The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 5. Change in Entity Status (from status indicated above)

Authorized Signature _____ Date ___

Page 2 of 3

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue

fee payment in the micro entity amount will not be accepted at the risk of application abandonment. NOTE: If the application was previously under micro entity status, checking this box will be taken

to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro

Registration No.

Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

Applicant changing to regular undiscounted fee status.

Typed or printed name

OMB 0651-0033

entity status, as applicable

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. |
|---------------------------------|-----------------|----------------------|-------------------------|------------------|
| 16/226,249 | 12/19/2018 | Ammar Al-Ali | MAS.1007C1 | 1002 |
| 64735 75 | 90 07/30/2019 | | EXAM | IINER |
| KNOBBE, MAR | TENS, OLSON & B | FARDANESH, MARJAN | | |
| | RATION (MASIMO) | | ART UNIT | PAPER NUMBER |
| 2040 MAIN STRE FOURTEENTH FI | | 3791 | THERTOMBER | |
| IRVINE, CA 9261 | | | DATE MAILED: 07/30/2019 | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

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

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

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

Notice Requiring Inventor's Oath or Declaration

| | Applicant(s) Ammar Al-Ali |
|-------------------|------------------------------|
| Examiner | Art Unit |
| FARDANESH, MARJAN | 3791 |

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

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 inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) MUST be filed <u>no later than the date on which the issue fee is paid.</u> See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

 A properly executed inventor's oath or declaration has not been received for the following inventor(s): Ammar Al-Ali.

Applicant may submit the inventor's oath or declaration at any time before the Notice of Allowance and Fee(s) Due, PTOL-85, is mailed.

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

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

| | Application No. 16/226,249 | Applicant(s | 5) |
|---|--|---|--|
| Notice of Allowability | Examiner MARJAN FARDANESH | Art Unit 3791 | AIA (FITF) Status Yes |
| The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS (herewith (or previously mailed), a Notice of Allowance (PTOL-85) of NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIC of the Office or upon petition by the applicant. See 37 CFR 1.313 and the office of the Office of | OR REMAINS) CLOSED in this a or other appropriate communicat GHTS. This application is subject | application. If not ion will be mailed | t included d in due course. THIS |
| 1. ☐ This communication is responsive to amendments filed on 0 ☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) was/ | | | |
| 2. An election was made by the applicant in response to a rest restriction requirement and election have been incorporated | | ng the interview o | on; the |
| 3. The allowed claim(s) is/are See Continuation Sheet. As a repart Prosecution Highway program at a participating int information, please see http://www.uspto.gov/patents/init_PPHfeedback@uspto.gov. | ellectual property office for the co | orresponding app | |
| 4. Acknowledgment is made of a claim for foreign priority unde | r 35 U.S.C. § 119(a)-(d) or (f). | | |
| Certified copies: | | | |
| a) □All b) □ Some *c) □ None of the: | | | |
| Certified copies of the priority documents have Certified copies of the priority documents have | | | |
| 3. Copies of the certified copies of the priority documents have | | | e application from the |
| International Bureau (PCT Rule 17.2(a)). | damente nave been rederved in t | mo national stag | e application from the |
| * Certified copies not received: | | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | ply complying wi | th the requirements |
| 5. CORRECTED DRAWINGS (as "replacement sheets") must | be submitted. | | |
| including changes required by the attached Examiner's Paper No./Mail Date | Amendment / Comment or in the | Office action of | |
| Identifying indicia such as the application number (see 37 CFR 1. sheet. Replacement sheet(s) should be labeled as such in the hea | | | t (not the back) of each |
| 6. DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT F | | | |
| Attachment(s) | | | |
| 1. Notice of References Cited (PTO-892) | 5. 🗹 Examiner's Ame | | |
| 2. ✓ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 07/01/2019, 07/19/2019. | 6. Examiner's Stat | ement of Reaso | ns for Allowance |
| 3. Examiner's Comment Regarding Requirement for Deposit | 7. 🗌 Other | | |
| of Biological Material 4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 07/18/2019. | | | |
| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | /ERIC F WINAKUR Primary Examiner, | | |
| ., | , | | |
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U.S. Patent and Trademark Office PTOL-37 (Rev. 08-13)

Notice of Allowability

Part of Paper No./Mail Date 20190718

Continuation of 3. The allowed claim(s) is/are: 57-64,67-70,72-74,77-78,81-83,85 and 87-95

1. The present application, filed on or after March 16, 2013, is being examined

under the first inventor to file provisions of the AIA.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes

and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be

submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an interview with Mr.

Jarom Kesler on 07/18/2019. Applicant agreed to amend the claims, as set forth below,

to clarify the relationship between the irradiated tissue portion, detected tissue portion,

and the light block.

The application has been amended as follows:

Claim 57 was amended as follows:

57. A wrist-worn physiological monitoring device configured for placement on a

user at a tissue measurement site, the device comprising:

a light emission source comprising a plurality of emitters configured to irradiate a

circular portion of the tissue measurement site by emitting light towards the

tissue measurement site, the tissue measurement site being located on a wrist of the

user, the plurality of emitters configured to emit one or more wavelengths;

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a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by a circular portion of tissue of the user at the tissue measurement site, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user; and

a light block forming an enclosing wall between the light emission source and the plurality of detectors, the light block defining the irradiated circular portion of the tissue measurement site, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side,

wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site.

Claim 67 was amended as follows:

67. A method of measuring a physiological parameter in a user's blood, the method comprising:

irradiating a circular portion of a tissue measurement site by emitting, from a plurality of emitters of a light emission source of a physiological monitoring device, light of one or more wavelengths toward the tissue measurement site, the tissue measurement site located on a wrist of the user;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters of the light emission source after attenuation through a circular portion of tissue of the user at the tissue measurement site; and

providing a cylindrical light block forming an enclosing wall between the light emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue measurement site, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light;

outputting, from the plurality of detectors, at least one signal responsive to the detected light;

receiving, by a processor, the outputted at least one signal responsive to the detected light; and processing, by the processor, the received at least one signal responsive to the detected light to determine a physiological parameter.

Claim 77 was amended as follows:

77. A wrist-worn physiological monitoring sensor comprising:

a light emission source comprising a plurality of optical sources configured to irradiate a circular portion of a tissue measurement site by emitting light towards the tissue measurement site on a user, the tissue measurement site located on a wrist of the user, the plurality of optical sources configured to emit one or more wavelengths;

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by a circular portion of tissue of the user at the tissue measurement site, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the outputted at least one signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user; and

a light block forming an enclosing wall between the light emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, the light block forming a light isolation chamber defined by the enclosing wall, wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

Art Unit: 3791

interview, applicant is encouraged to use the USPTO Automated Interview Request

(AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Patricia Mallari can be reached on (571)272-4729. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC F WINAKUR/

Primary Examiner, Art Unit 3791

/MARJAN FARDANESH/

Examiner, Art Unit 3791

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| | Application No. 16/226,249 | Applicar Al-Ali et a | ` ' | |
|---------------------------------------|----------------------------------|-------------------------|---|-------------|
| Applicant-Initiated Interview Summary | Examiner MARJAN FARDANESH | Art Unit 3791 | AIA (First Inventor to File) Status Yes | Page 1 of 2 |

All participants (applicant, applicants representative, PTO personnel):

1. MARJAN FARDANESH (Examiner); Telephonic

2. Jarom Kesler (Attorney of Record); Telephonic

3. Aaron Johnson (Attorney of Record); Telephonic

Date of Interview: 07 May 2019

Claims Discussed: claim 57 was discussed.

Prior Art Discussed: Hannula and Cui were discussed.

Amendment proposed: Applicant proposed amendments to capture the subject matter of figure 7 in order to overcome the prior art.

Issues Discussed:

Item(s) under 35 U.S.C. 102:

Prior art rejection were discussed and compared to figure 7 of the current application. Applicant will take the discussions into consideration while filing a formal response.

Item(s) under 35 U.S.C. 103:

Prior art rejection were discussed and compared to figure 7 of the current application. Applicant will take the discussions into consideration while filing a formal response.

Attachment(s): Proposed Amendments,

| /MARJAN FARDANESH/ | /ERIC F WINAKUR/ |
|-------------------------|---------------------------------|
| Examiner, Art Unit 3791 | Primary Examiner, Art Unit 3791 |
| | |

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04

Please further see: MPEP 713.04

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)

37 CFR § 1.2 Business to be transacted in writing

U.S. Patent and Trademark Office PTOL-413/413b (Rev. 01/01/2015)

Interview Summary

Paper No. 20190718

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|--------------|-------------------------|---|
| Search Notes | 16/226,249 | Al-Ali et al. |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| CPC - Searched* | | |
|----------------------------------|------------|----------|
| Symbol | Date | Examiner |
| EAST-See search history printout | 03/04/2019 | /mf/ |
| EAST-See search history printout | 07/19/2019 | /mf/ |

| CPC Combination Sets - Searched* | | |
|----------------------------------|------|----------|
| Symbol | Date | Examiner |
| | | |

| US Classificat | US Classification - Searched* | | |
|------------------------------|-------------------------------|--|--|
| Class Subclass Date Examiner | | | |
| | | | |

 $^{^{\}star}$ See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

| Search Notes | | |
|---------------------------|------------|----------|
| Search Notes | Date | Examiner |
| PALM-inventor name search | 03/04/2019 | /mf/ |

| Interference Search | | | |
|--|-----------------------------|------------|----------|
| US Class/CPC Symbol US Subclass/CPC Group Date Examine | | | Examiner |
| EAST- | See search history printout | 07/19/2019 | /mf/ |
| | | | |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | |
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| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali et al. |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| CPC | | | | |
|--------|--------|---------|---------|------------|
| Symbol | | Туре | Version | |
| A61B | / 5 | 14552 | F | 2013-01-01 |
| A61B | / 5 | 6826 | 1 | 2013-01-01 |
| A61B | / 5 | / 0002 | 1 | 2013-01-01 |
| A61B | / 5 | 02416 | 1 | 2013-01-01 |
| A61B | / 5 | 14532 | 1 | 2013-01-01 |
| A61B | / 5 | / 14546 | 1 | 2013-01-01 |
| A61B | / 5 | 4875 | I | 2013-01-01 |
| A61B | / 5 | 7278 | I | 2013-01-01 |
| A61B | / 5 | 742 | I | 2013-01-01 |
| A61B | / 2562 | / 04 | А | 2013-01-01 |

| CPC Combination Sets | | | | |
|----------------------|------|-----|---------|---------|
| Symbol | Туре | Set | Ranking | Version |
| | | | | |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 19 July 2019 | Total Claims Allowed: | | |
|---|--------------|-----------------------|-------------------|--|
| (Assistant Examiner) | (Date) | 30 | | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 19 July 2019 | O.G. Print Claim(s) | O.G. Print Figure | |
| (Primary Examiner) | (Date) | 1 | 7 | |

U.S. Patent and Trademark Office

Part of Paper No.: 20190718

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali et al. |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| | MARJAN FARDANESH | 3791 |
|------------------------------|------------------|-------------------------|
| | | |
| INTERNATIONAL CLASSIFICATION | l | |
| CLAIMED | | |
| A61B | <i>f</i> 5 | 1455 |
| NON-CLAIMED | | |
| | | |
| | | |
| US ORIGINAL CLASSIFICATION | | |
| CLASS | | SUBCLASS |
| 600 | 310 | |
| CROSS REFERENCES(S) | | |
| CLASS | SUBCLASS (C | ONE SUBCLASS PER BLOCK) |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 19 July 2019 | Total Claims Allowed: | | | |
|---|--------------|-----------------------|-------------------|--|--|
| (Assistant Examiner) | (Date) | 30 | | | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 19 July 2019 | O.G. Print Claim(s) | O.G. Print Figure | | |
| (Primary Examiner) | (Date) | 1 | 7 | | |

U.S. Patent and Trademark Office

Part of Paper No.: 20190718

| | Application/Control No. | Applicant(s)/Patent Under Reexamination |
|----------------------|-------------------------|---|
| Issue Classification | 16/226,249 | Al-Ali et al. |
| | Examiner | Art Unit |
| | MARJAN FARDANESH | 3791 |

| | Claims re | enumbe | ered in th | ie sam | e order a | as pres | ented by | applic | ant [|] CPA | <i>Y</i> | T.D. | R.1 | 1.47 | |
|-------|-----------|--------|------------|--------|-----------|---------|----------|--------|----------|-------|----------|-------|----------|-------|----------|
| CLAIM | CLAIMS | | | | | | | | | | | | | | |
| Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original | Final | Original |
| 1 | 57 | | 66 | | 75 | | 84 | 28 | 93 | | | | | | |
| 2 | 58 | 9 | 67 | | 76 | 24 | 85 | 29 | 94 | | | | | | |
| 3 | 59 | 10 | 68 | 19 | 77 | | 86 | 30 | 95 | | | | | | |
| 4 | 60 | 11 | 69 | 20 | 78 | 25 | 87 | | | | | | | | |
| 5 | 61 | 12 | 70 | | 79 | 26 | 88 | | | | | | | | |
| 6 | 62 | | 71 | | 80 | 27 | 89 | | | | | | | | |
| 7 | 63 | 13 | 72 | 21 | 81 | 16 | 90 | | | | | | | | |
| 8 | 64 | 14 | 73 | 22 | 82 | 17 | 91 | | | | | | | | |
| | 65 | 15 | 74 | 23 | 83 | 18 | 92 | | | | | | | | |

| /MARJAN FARDANESH/ Examiner, Art Unit 3791 | 19 July 2019 | Total Claims Allowed: | | | |
|---|--------------|-----------------------|-------------------|--|--|
| (Assistant Examiner) | (Date) | 30 | | | |
| /ERIC F WINAKUR/ Primary Examiner, Art Unit 3791 | 19 July 2019 | O.G. Print Claim(s) | O.G. Print Figure | | |
| (Primary Examiner) | (Date) | 1 | 7 | | |

U.S. Patent and Trademark Office

Part of Paper No.: 20190718

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First : Ammar Al-Ali

Inventor

App. Nos. : 16/226249; 15/195199

Filed : December 19, 2018; June 28, 2016

For : ADVANCED PULSE OXIMETRY SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791; 3791 Conf. No. : 1002; 3453

Docket : MAS.1007C1; MAS.1007A

Nos.

INTERVIEW AGENDA

Type: Telephone

Date and Time: May 7, 2019, 2:00PM EST, 11:00AM PST

Participants: Examiner Fardanesh and Applicant's representatives Jarom Kesler (Reg. No.

57,046) and Aaron Johnson (Reg. No. 74,164)

- A. Discuss disclosed embodiments and claimed invention
- B. Review references cited in Office Action
- C. Discuss differences between references and claimed invention

PROPOSED CLAIM AMENDMENTS FOR APP. NO. 16/226249

- 1-56. (Cancelled)
- 57. (**Currently Amended**) A wrist-worn physiological monitoring device configured for placement on a user at a tissue measurement site, the device comprising:

a light emission source comprising a plurality of emitters configured to <u>irradiate a circular portion of the tissue measurement site by emitting light towards the tissue measurement site, the tissue measurement site being located on a wrist of the user, the plurality of emitters comprising one or more light emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength;</u>

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user; and

a light block forming an enclosing wall between the <u>light emission source</u> and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, <u>light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the <u>enclosing</u> wall prevents at least a portion of light emitted from the <u>light emission sourceplurality of emitters</u> from being detected by the plurality of detectors without attenuation by the tissue, <u>and wherein the plurality of detectors</u> are arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site.</u>

- 58. (**Previously Presented**) The physiological monitoring device of Claim 57, further comprising a display configured to present information related to the determined physiological parameter to the user.
- 59. **(Previously Presented)** The physiological monitoring device of Claim 58, wherein the display is a touch-screen display.

- 60. (**Previously Presented**) The physiological monitoring device of Claim 57, wherein the enclosing wall of the light block is a circular wall.
- 61. (**Previously Presented**) The physiological monitoring device of Claim 57, wherein, when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.
- 62. (**Previously Presented**) The physiological monitoring device of Claim 57, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 63. (Currently Amended) The physiological monitoring device of Claim 57, wherein the <u>light emission source isplurality of emitters are</u> positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.
- 64. **(Previously Presented)** The physiological monitoring device of Claim 57, wherein the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate.
 - 65. (Cancelled)
 - 66. (Cancelled)
- 67. (**Currently Amended**) A method of measuring a physiological parameter in a user's blood, the method comprising:

irradiating a circular portion of a tissue measurement site by emitting, from a plurality of emitters of a light emission source of a physiological monitoring device, light of one or more wavelengths toward [[a]]the tissue measurement site, the tissue measurement site located on a wrist of the userthe plurality of emitters comprise one or more light emitting diodes (LEDs) and the one or more wavelengths comprises at least an infrared wavelength;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters of the light emission source after attenuation through tissue of the user at the

tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes; and

providing a cylindrical light block forming an enclosing wall between the <u>light</u> emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the enclosing wall prevents at least a portion of light emitted from the <u>light</u> emission source plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light;

outputting, from the plurality of detectors, at least one signal responsive to the detected light;

receiving, by a processor, the outputted at least one signal responsive to the detected light; and

processing, by the processor, the received at least one signal responsive to the detected light to determine a physiological parameter.

- 68. (Currently Amended) The method of Claim 67, wherein the <u>light emission</u> source isphurality of emitters are positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.
- 69. (**Previously Presented**) The method of Claim 67, further comprising presenting, with a display of the physiological monitoring device, information related to the determined physiological parameter to the user.
- 70. (**Previously Presented**) The method of Claim 69, wherein the display is a touch-screen display.

71. (Cancelled)

FOR DISCUSSION PURPOSES ONLY - NOT FOR ENTRY

- 72. (**Previously Presented**) The method of Claim 67, wherein when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.
- 73. (**Previously Presented**) The method of Claim 67, further comprising spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to the tissue measurement site.
- 74. (**Previously Presented**) The method of Claim 67, wherein the physiological parameter is indicative of at least one of pulse rate, perfusion index, oxygen content, and total hemoglobin.
 - 75. (Cancelled)
 - 76. (Cancelled)
- 77. (**Currently Amended**) A wrist-worn physiological monitoring sensor comprising:
 - <u>a light emission source comprising</u> a plurality of optical sources configured to <u>irradiate a circular portion of a tissue measurement site by emitting</u> light towards [[a]]the tissue measurement site on a user, the tissue measurement site located on a wrist of the user, the plurality of optical sources comprising one or more light emitting diodes (LEDs)—configured to emit one or more wavelengths; the one or more wavelengths comprising at least an infrared wavelength;
 - a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;
 - a processor configured to receive the outputted at least one signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user; and
 - a light block forming an enclosing wall between the <u>light emission source</u> and the plurality of detectors, the light emission source arranged proximate a first side of the

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enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring sensor is worn by the user, the light block forming a light isolation chamber defined by the enclosing wall, wherein the enclosing wall prevents at least a portion of light emitted from the light emission sourceplurality of emitters from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light.

- 78. (Currently Amended) The physiological monitoring sensor of Claim 77, wherein the <u>light emission source isplurality of optical sources are</u> located outside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site, and wherein the plurality of detectors are arranged inside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site.
 - 79. (Cancelled)
 - 80. (Cancelled)
- 81. (**Previously Presented**) The physiological monitoring sensor of Claim 77, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 82. (**Previously Presented**) The physiological monitoring sensor of Claim 77, further comprising a display configured to present information related to the determined physiological parameter to the user.
- 83. **(Previously Presented)** The physiological monitoring sensor of Claim 82, wherein the display is a touch-screen display.
 - 84. (Cancelled)
- 85. (Currently Amended) The physiological monitoring sensor of Claim 77, wherein when the physiological monitoring sensor is worn by the user at the tissue measurement site, the plurality of <u>optical sourcesemitters</u> are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring sensor is worn by the user.

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86. (Cancelled)

- 87. (New) The physiological monitoring device of Claim 57, wherein the plurality of emitters comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 88. (New) The physiological monitoring device of Claim 57, wherein the plurality of detectors comprise a plurality of photodiodes.
- 89. (New) The physiological monitoring device of Claim 57, further comprising a light concentrator configured to direct the attenuated, reflected light to the plurality of detectors.
- 90. (New) The method of Claim 67, wherein the plurality of emitters comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 91. **(New)** The method of Claim 67, wherein the plurality of detectors comprise a plurality of photodiodes.
- 92. (New) The method of Claim 67, further comprising, directing, with a light concentrator, the light emitted by the light emission source after attenuation through tissue of the user at the tissue measurement site to the plurality of detectors.
- 93. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of optical sources comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 94. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of detectors comprise a plurality of photodiodes.
- 95. (New) The physiological monitoring sensor of Claim 77, further comprising a light concentrator configured to direct the attenuated, reflected light to the plurality of detectors.

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| STATEMENT DI AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
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| Examiner Signature /MARJAN FARDANESH/ | Date Considered 07/19/2019 |
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| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
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| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
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| SHEET 11 OF 12 | Attorney Docket No. | MAS.1007C1 |

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16/226,249 - GAU: 3791 Receipt date: 07/19/2019

PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
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| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 12 OF 12 | Attorney Docket No. | MAS.1007C1 |

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EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
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| L20 | 239 | (fiber conduit guide pipe) and (clock | US- | OR | OFF | 2019/07/19 |
| | 200 | watch wristwatch wrist adj watch) and | PGPUB; | i | OFF | 11:05 |
| | | winakur.xp. | USPAT; | | | 11.03 |
| | | willardi.xp. | USOCR | | | |
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| | | "5833602" "5848030" "RE24502").PN. | | | | |
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| S4 | 44 | palti.in. and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/12 13:37 |
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| S13 | 69 | threshold with (hyperglycemia hypoglycemia) with compar\$5 and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/06/13 14:29 |
| S14 | 16 | scalar with (activity acceleration) with threshold and A61B5/\$.cpc. | US- PGPUB; | OR | ON | 2019/06/14 11:53 |

| | *************************************** | | USPAT | | | |
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| S15 | 2 | "15697311" | US- PGPUB; USPAT | OR | ON | 2019/06/17 12:06 |
| S16 | 16 | ((("VERIFOOD") near3 ("LTD"))).AS,AANM. | USPAT | OR | OFF | 2019/06/17 14:15 |
| S17 | 42 | ((("GOLDRING") near3 ("Damian"))).INV. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:15 |
| S18 | 49 | ((("VERIFOOD") near3 ("LTD"))).AS,AANM. | US- PGPUB; USPAT | OR | OFF | 2019/06/17 14:15 |
| S19 | 1 | ((("VERIFOOD") near3 ("LTD"))).AS,AANM. and catheter | US- PGPUB; USPAT | OR | OFF | 2019/06/17 14:20 |
| S20 | 42 | ((("VERIFOOD") near3 ("LTD"))).AS,AANM. and block\$4 | US- PGPUB; USPAT | OR | OFF | 2019/06/17 14:23 |
| S21 | 81 | ("0679577" "20020039186" "20020131047" "20020163641" "20020191127" "20040019462" "20040136577" "20050151975" "20050196046" "20060086901" "20060124656" "20060146315" "20070230932" "20080061236" "20080073510" "20080137328" "20080204578" "20080277625" "20100110442" "20100128370" "20100134794" "20100128370" "2010021979" "20100271352" "20100284005" "20100309454" "20110255745" "20110261252" "20120019819" "20120053426" "20120019819" "20120053426" "20140293091" "20140052555" "20140293091" "20140320858" "20150306138" "20150055132" "2015030879" "20150369725" "20160033328" "5469252" "6031233" "7236243" "7262839" "7286233" "7414724" "7420663" "7433042" "7528957" "7535617" "7667740" "7805319" "7897923" "7986193" "8060383" "8149415" "8269174" "8274739" "8284401" "8330945" "8462420" "8542359" "8665440" "9060113" "9291504" "9383258").PN. OR ("9562848").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:24 |
| S22 | 1485 | (tube catheter) same (block\$4 actuator) and (spectroscopy spectrometer) and A61B5/\$.cpc. | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:27 |
| S23 | 89 | (tube catheter) same (block\$4 actuator) same (spectroscopy spectrometer) and A61B5/\$.cpc. | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:27 |

| Toc : | 15. | | 11.15 | (| (C): | |
|------------|------|---|----------------------------------|----|------|---------------------|
| | 61 | (tube catheter) same (block\$4 actuator) same (spectroscopy spectrometer) and A61B5/\$.cpc. and (fluid urine) | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:28 |
| S25 | 1225 | (tube catheter) same (block\$4 actuator) and (spectroscopy spectrometer) and A61B5/\$.cpc. and (fluid urine) | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:29 |
| S26 | 637 | (tube catheter) with (block\$4 actuator) and (spectroscopy spectrometer) and A61B5/\$.cpc. and (fluid urine) | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:29 |
| S27 | 158 | (tube catheter) with (block\$4 actuator) and (spectroscopy spectrometer) and A61B5/\$.cpc. and (urine) | US- PGPUB; USPAT; USOCR | OR | ON | 2019/06/17 14:33 |
| S28 | 18 | (("6069696") or ("6072576") or ("6333501") or ("6441375") or ("6456373") or ("6615142") or ("6639666") or ("6700661") or ("6717669") or ("6836325") or ("6864978") or ("7009702") or ("7038774") or ("7068366") or ("7075643") or ("7084974") or ("7145650") or ("7151600")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:39 |
| S29 | 2 | (("7158225") or ("7235766")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:41 |
| S30 | 21 | (("7245372") or ("7248370") or ("7251037") or ("7339665") or ("7426446") or ("7436511") or ("7489396") or ("7528957") or ("7649627") or ("767969") or ("7817273") or ("7868296") or ("7876435") or ("7881892") or ("7907282") or ("7929130") or ("7999933") or ("8125633") or ("8144322") or ("8169607")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:43 |
| S31 | 21 | (("8169608") or ("8247774") or ("8477305") or ("8526002") or ("8593628") or ("8604412") or ("8654327") or ("8675188") or ("8711360") or ("8711362") or ("8735820") or ("8742320") or ("8760645") or ("8773659") or ("8786854") or ("8848187") or ("8862445") or ("8867033") or ("8868387") or ("8873046") or ("8937717")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:46 |
| S32 | 21 | (("8976357") or ("9030662") or ("9063011") or ("9074933") or ("9128055") or ("9163986") or ("9173508") or ("9182280") or ("9234800") or ("9239264") or ("9297821") or ("9301626") or ("9310564") or ("9383308") or ("9395244") or ("9417180") or ("9464934") or ("9464934") or | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:48 |

| | 1 | ("9488468") or ("9488523")).PN. | 1 | | | |
|------------|----|---|----------------------------------|----|-----|---------------------|
| S33 | 19 | (("9508765") or ("9518917") or ("9546902") or ("9546904") or ("9557220") or ("9568363") or ("20050117151") or ("20050128477") or ("20060132760") or ("20080265146") or ("20080297791") or ("20100165337") or ("20110037975") or ("20130107260") or ("20130182250") or ("20140046630") or ("20140168636") or ("20140333932")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:51 |
| S34 | 22 | (("20150062577") or ("20160103354") or ("20150108333") or ("20150116707") or ("20150119661") or ("20150153225") or ("20150323383") or ("20160018260") or ("20160091369") or ("20160223400") or ("20160231171") or ("20160245700") or ("20160282182") or ("20160299004") or ("20160305820") or ("20160313184") or ("20160334274") or ("20160356646") or ("20160356647")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 14:53 |
| S35 | 2 | S33 and (tube catheter) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 14:55 |
| S36 | 0 | S28 and S29 and S30 and S31 and S32 and S33 and S34 | US- PGPUB; USPAT | OR | OFF | 2019/06/17 14:56 |
| S37 | 3 | S28 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:03 |
| S38 | 0 | S29 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S39 | 6 | S30 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S40 | 7 | S31 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S41 | 3 | S32 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S42 | 2 | S33 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S43 | 5 | S34 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:04 |
| S44 | 2 | S28 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) and (block\$4 actuat\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:08 |
| S45 | 0 | S29 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) and (block\$4 actuat\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:13 |
| S46 | 6 | S30 and (tube catheter) and (spectroscopy spectrometer | US- PGPUB; | OR | OFF | 2019/06/17 15:13 |

| | | spectrograph\$4) and (block\$4 actuat\$4) | USPAT | | | |
|-----|-----|---|----------------------------------|----|-----|---------------------|
| S47 | 6 | S31 and (tube catheter) and (spectroscopy spectrometer spectrograph\$4) and (block\$4 actuat\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:14 |
| S48 | 1 | "15660573" and (block\$4 actuat\$4) | US- PGPUB; USPAT | OR | OFF | 2019/06/17 15:16 |
| S49 | 0 | S31 and (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:18 |
| S50 | 0 | S32 and (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:18 |
| S51 | 0 | S33 and (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:18 |
| S52 | 0 | S34 and (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:18 |
| S53 | 791 | (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:18 |
| S54 | 179 | (tube catheter) with (blocker block\$2 actuator actuat\$2) with (urine drain fluid) and (spectroscopy spectrometer spectrograph\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:19 |
| S55 | 95 | fardanesh.xa. and (tube catheter) | US- PGPUB; USPAT | OR | ON | 2019/06/17 15:31 |
| S56 | 28 | ("20020016536" "20020080368" "20030084906" "20040186468" "20060281992" "3814081" "4223680" "4281645" "4510938" "4782819" "4907876" "5221255" "5433216" "5476434" "5728092" "5769791" "5788647" "5807261" "5853005" "5916153" "6010453" "6334064" "6406431" "6447462" "6505074" "6519487" "6690958" "6699175").PN. OR ("8412294").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 15:41 |
| S57 | 114 | ("20010016699" "20010021817" "20010037079" "20010041892" "20020103453" "20020147423" "20030009123" "20030045784" "20030070969" "20030097087" "20030143116" "20030196949" "20030210390" "20030212316" "20040087845" "20050094127" "20060036185" "20060144776" "20060026079" "20060290625" "20070015963" "20070100219" "200700149871" "20070179433" "20080081970" "20080129047" "20080080300570" "20090054751" "200900247850" "20090322861" | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/17 15:47 |

| S58 | 13 | "20100004518" "20100072280" "20100110416" "20100113891" "20100168531" "20100298677" "20110004082" "20110022077" "20110160679" "20120120384" "20120154789" "20160296687" "2357238" "3507951" "3580683" "3728032" "3740156" "4243883" "4444498" "4759369" "4784768" "4936993" "5073171" "5126686" "5171456" "5222948" "5231464" "5247434" "5312535" "5351686" "5366630" "5372136" "5456253" "5458566" "5476764" "5670050" "5674390" "5676644" "5729333" "5779529" "5792052" "6018673" "6069687" "6090061" "6284131" "6284142" "6510330" "6554788" "6654621" "6746415" "6784820" "7018353" "7241825" "7247143" "7671974" "8133194" "8287739" "8315682" "8328748" "8333724" "8517968" "8518247" "9002655" "9212988" "D206714" "D212218" "D270281" "D335096" "D409750" "D518573" "D623302" "D625824" "D630536" "D654999" "D684695" "D684697" "D698440").PN. OR ("9801993").URPN. | US- | OR | OFF | 2019/06/17 |
|-----|-----|---|----------------------------------|----|-----|---------------------|
| | | "20080097288" "4215940" "4830013" "4989606" "5249584" "5453248" "5462052" "5871627" "5944660" "6144444" "7018353").PN. OR ("9091660").URPN. | PGPUB; USPAT; USOCR | | | 15:50 |
| S59 | 153 | (urine urinary) with infection and (spectrometer spectroscopy spectrograph\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/17 16:15 |
| S60 | 77 | (compress\$4) with (tube catheter) with (stop\$4 prevent\$4) with flow\$4 and (spectroscopy and spectrometer spectrograph\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/17 16:34 |
| S61 | 2 | (compress\$4) with (tube catheter) with (stop\$4 prevent\$4) with flow\$4 same (urine urinary) with infection | US- PGPUB; USPAT | OR | ON | 2019/06/17 16:42 |
| S62 | 11 | (compress\$4) with (tube catheter) with (stop\$4 prevent\$4) with flow\$4 and (urine urinary) with infection | US- PGPUB; USPAT | OR | ON | 2019/06/17 16:43 |
| S67 | 0 | (("2013021153") or ("2014165697") or ("2013035602") or ("2009182216") or ("2009182216") or ("2010251804") or ("2014365142") or ("2014081106")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/18 15:53 |
| S68 | 7 | (("20130021153") or ("20140165697") or ("20130035602") or ("20090182216") or ("20090182216") or ("20100251804") or ("20140365142") or ("20140081106")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/18 15:53 |
| S69 | 1 | "15557319" | US- PGPUB; USPAT | OR | OFF | 2019/06/18 16:03 |

| S70 | 370 2 "14745180" and determin\$4 adj dT | | US- PGPUB; USPAT | OR | OFF | 2019/06/18 17:29 |
|-----|---|--|----------------------------------|----|-----|---------------------|
| S71 | 2 | "14745180" and determin\$4 with dT | US- PGPUB; USPAT | OR | OFF | 2019/06/18 17:29 |
| S72 | 3 | (("5439002") or ("5033471") or ("20150105676")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/19 11:25 |
| S73 | 6962 | A61B5/02\$.cpc. and wrist and (screen display) and pressure | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:30 |
| S74 | 6962 | A61B5/02\$.cpc. and wrist and (screen display) and pressure and (cuff press\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:31 |
| S75 | 2559 | A61B5/02\$.cpc. and wrist same (screen display) and pressure and (cuff press\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:31 |
| S76 | display) same pressure and (cuff | | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:32 |
| S77 | 867 | A61B5/02\$.cpc. and wrist same (screen display) same pressure same (cuff press\$4) | | OR | ON | 2019/06/19 11:32 |
| S78 | 57 | A61B5/02\$.cpc. and wrist same (first and second) with (screen display) same pressure same (cuff press\$4) | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:32 |
| S79 | 2 | A61B5/02\$.cpc. and (wrist wristwatch wrist adj watch) adj (second two) adj display | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:39 |
| S80 | 783 | A61B5/02\$.cpc. and (second two) adj display | US- PGPUB; USPAT | OR | ON | 2019/06/19 11:42 |
| S81 | 3 | (("20150378312") or ("20160267310") or ("20150186092")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/19 11:47 |
| S82 | 1 | ("20110213212").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/19 12:02 |
| S83 | 1 | "14947688" | US- PGPUB; USPAT | OR | OFF | 2019/06/19 12:07 |
| S84 | 2 | (("20100137695") or ("20080114280")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/19 13:36 |
| S85 | 1 | "15592451" and processor | US- PGPUB; USPAT | OR | OFF | 2019/06/19 14:03 |
| S86 | 120 | (handheld mobile) with alcohol and strap and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/19 20:29 |
| S87 | 0 | (handheld mobile) with alcohol and strap and G01N33/49.cpc. | US- PGPUB; USPAT | | OFF | 2019/06/19 20:29 |

| S88 | 17 | (handheld mobile) with alcohol and strap | US- | OR | OFF | 2019/06/19 |
|------|-----|--|----------------------------------|-----|-----|---------------------|
| | | and A61B5/\$.cpc. and breath | PGPUB; USPAT | 011 | | 20:34 |
| S89 | 1 | ("6853304").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/19 20:42 |
| S90 | 10 | alcohol and breath and (inside with mouth) with camera | US- PGPUB; USPAT | OR | OFF | 2019/06/19 21:30 |
| S91 | 10 | (identification biometric) with (inside with mouth) with camera | US- PGPUB; USPAT | OR | OFF | 2019/06/19 21:34 |
| S92 | 1 | breath and alcohol and (micro adj camera) | US- PGPUB; USPAT | OR | OFF | 2019/06/19 21:39 |
| S93 | 216 | breath and alcohol and (camera) with Umouth U | | OR | OFF | 2019/06/19 21:40 |
| S94 | 216 | breath and alcohol and (identification biometric) and (second two) adj camera | | OR | ON | 2019/06/19 22:00 |
| S95 | 232 | breath and alcohol and (identification identif\$4 biometric) and (second two) adj camera | US- PGPUB; USPAT | OR | ON | 2019/06/19 22:00 |
| S96 | 1 | "15674434" and center | US- PGPUB; USPAT | OR | OFF | 2019/06/20 16:59 |
| S97 | 2 | "20130222271" | US- PGPUB; USPAT | OR | OFF | 2019/06/20 17:39 |
| S98 | 4 | (("20130271350") or ("20070158376") or ("20130222270") or ("20130222271")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/20 17:41 |
| S99 | 5 | (("20160267310") or ("20150186092") or ("4896676") or ("20150213580") or ("20150182147")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/20 17:45 |
| S100 | 1 | "15674434" | US- PGPUB; USPAT | OR | OFF | 2019/06/20 18:19 |
| S101 | 864 | (blood) adj pressure and (cuff) same press\$4 same (artery pulse) same wrist and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/20 21:09 |
| S102 | 8 | (("6216490") or ("4896676") or ("20170367649") or ("20150186092") or ("20150213580") or ("20150182147") or ("20130245391") or ("20070208258")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/20 21:11 |
| S103 | 3 | (("20140371552") or ("20090259407") or ("20110098542")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/21 10:24 |
| S104 | 5 | "14745180" | US- PGPUB; USPAT | OR | OFF | 2019/06/21 10:27 |
| | | | | | 1 | |

| S105 | 78 | "5900632" | US- PGPUB; USPAT | OR | OFF | 2019/06/21 11:18 |
|------|------|--|----------------------------------|----|-----|---------------------|
| S106 | 85 | ("4429999" "5040539" "5070242" "5075552" "5191215" "5313941" "5360004" "5361758" "5370114" "5372135" "5372136" "5383452" "5451787" "5461229" "5471056" "5473162" "5515847" "5666956").PN. OR ("5900632").URPN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/21 11:19 |
| S107 | 1 | "15388672" and hemoglobin and diuretic | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/21 13:13 |
| S108 | 1 | ("5335659").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/21 17:58 |
| S109 | 1 | ("20150182147").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/22 11:30 |
| S110 | 19 | alcohol same temperature with exhaled with breath and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:34 |
| S111 | 94 | alcohol same temperature with breath and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:37 |
| S112 | 75 | S111 not S110 | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:38 |
| S113 | 1 | "15557319" and temperature | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:45 |
| S114 | 15 | breath with temperature same compar\$4 same threshold and alcohol | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:47 |
| S115 | 0 | "4809810".pn. and refrence and temperature and alcohol | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:57 |
| S116 | 1 | "4809810".pn. and temperature and alcohol | US- PGPUB; USPAT | OR | OFF | 2019/06/22 12:57 |
| S117 | 1 | "15557319" | US- PGPUB; USPAT | OR | OFF | 2019/06/22 14:08 |
| S118 | 1 | ("20120276549").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/23 14:21 |
| S119 | 1 | ("20020026108").PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/06/24 14:09 |
| S120 | 3268 | implant\$4 and substrate with semiconductor with ceramic | US- PGPUB; USPAT | OR | ON | 2019/06/24 14:11 |
| S121 | 122 | implant\$4 and substrate with | US- | OR | ON | 2019/06/24 |

| | | semiconductor with ceramic and A61B5/\$.cpc. | PGPUB; USPAT | | *************************************** | 14:11 |
|------|---------|--|----------------------------------|----|---|---------------------|
| S122 | 98 | implant\$4 and substrate with semiconductor with ceramic and A61B5/\$.cpc. and glucose | US- PGPUB; USPAT | OR | ON | 2019/06/24 14:15 |
| S123 | 2069 | EMR and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/26 15:28 |
| S124 | 1059832 | blood aj pressure same (ppg photopleth\$7) same (ECG electrocardio\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/27 13:41 |
| S125 | 988 | blood adj pressure same (ppg photopleth\$7) same (ECG electrocardio\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/27 13:41 |
| S126 | 676 | blood adj pressure with (ppg photopleth\$7) same (ECG electrocardio\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/27 13:41 |
| S127 | 611 | blood adj pressure with (ppg photopleth\$7) with (ECG electrocardio\$4) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/06/27 13:42 |
| S128 | 1 | ("20120162438").PN. F I I | | OR | OFF | 2019/06/28 13:35 |
| S129 | 1 | "16195624" | US- PGPUB; USPAT | OR | OFF | 2019/07/16 14:35 |
| | 39 | (("3649964") or ("3721233") or ("3736927") or ("3822698") or ("3998213") or ("4019508") or ("4037595") or ("4297999") or ("4233972") or ("425501") or ("4430995") or ("4588425") or ("4590951") or ("4588425") or ("4590951") or ("4782832") or ("4802485") or ("4829998") or ("4802485") or ("4829998") or ("5035239") or ("5046492") or ("5035239") or ("504484") or ("5104430") or ("5113853") or ("5154168") or ("5273036") or ("5284160") or ("53372130") or ("5318020") or ("5372130") or ("20150021535") or ("20160015916") or ("20150367092")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/07/16 14:49 |
| S131 | 9 | ((("HANCOCK") near3 ("MEDICAL") near3 ("INC"))).AS,AANM. | USPAT | OR | OFF | 2019/07/16 14:50 |
| S132 | 57 | ((("GOFF") near3 ("Thomas") near3 ("G"))).INV. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/07/16 14:51 |
| S133 | 9 | ((("CHIANG") near3 ("Kirby"))).INV. | | OR | OFF | 2019/07/16 14:51 |
| S134 | 230 | ("20020078958" "20020104541" "20030062045" "20030079749" | US- PGPUB; | OR | OFF | 2019/07/16 14:52 |

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| "6772762" "6793629" "6854465" | :1 | | | | | | |
| | "6772762" | "6793629" | "6854465" | | | ***** | |
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| | | "6881192" "6889691" "6895959" | | | | |
| | | "6895962" "6920877" "6932084" | | | | |
| | | "6973929" "6990980" "7019652" | | | | |
| | | "7069932" "7089941" "7096864" | | | | |
| | | "7118608" "7156090" "7178525" | | | | |
| | | "7195014" "7200873" "7204250" | | | | |
| | | "7255103" "7297119" "7357136" "7398347" "7406066" "7406066" | | | | |
| | | "7382247" "7406966" "740696" "7471290" "7478635" "7487778" | | | | |
| | | "7471290 7476633 7467776 "7516743" "7575005" "7588033" | | | | |
| | | "7664546" "7681575" "7766841" | | | | |
| | | "7887492" "7913692" "7934500" | | | | |
| | | "7942824" "7975687" "8020557" | | | | |
| | | "8061354" "8172766" "8316848" | | | | |
| | | "8327846" "8336546" "8353290" | | | | |
| | | "8453640" "8475370" "8517017" | | | | |
| | | "8688187" "8720439" "8903467" | | | | |
| | | "8919344" "8925546" "D421298" | | | | |
| | | "D570473" "D643929" "D659235" | | | | |
| | | "D683444" "D683445" "D696393" | | | | |
| | | "D696394" "D710989" "D732158" | | | | |
| | | "D734446" "D740929").PN. OR | | | | |
| | | ("D740930" "RE35339").PN. OR | | | | |
| | | ("D776802").URPN. | <u> </u> | | <u> </u> | <u></u> |
| S135 | 30 | ("20050197550" "20050228299" | US- | OR | OFF | 2019/07/16 |
| | | "20070142715" "20070244378" | PGPUB; | | | 14:53 |
| | | "5099842" "5999834" "6006120" | USPAT; | | | |
| | | "6377829" "6725075" "6839585" | USOCR | | | |
| | | "6920345" "7225007" "7486977" | | | | |
| | | "7736310" "D452318" "D463561" | | | | |
| | | "D492783" "D557423" "D603966").PN. | | | | |
| | 1.70 | OR ("D643929").URPN. | | | | 0010107110 |
| S136 | 178 | ("3505993" "4537197" "4859057" "4880304").PN. OR ("5099842").URPN. | US- PGPUB: | OR | OFF | 2019/07/16 14:56 |
| | | 4000304).FN. On (3099042).Unriv. | USPAT: | | | 14.56 |
| | | | USOCR | | | |
| C127 | 20 | //"20050107550" "20050222200" | direction of the second | OP. | OEE | 2010/07/10 |
| S137 | 30 | ("20050197550" "20050228299" "20070142715" "20070244378" | US- PGPUB: | OR | OFF | 2019/07/16 14:58 |
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| | | 5099842 5999834 6006120 "6377829" "6725075" "6839585" | USOCR | | | |
| | | 6377629 | Joseph | | | |
| | | "7736310" "D452318" "D463561" | | | | |
| | | "D492783" "D557423" "D603966").PN. | | | | |
| | | OR ("D643929").URPN. | | | | |
| S138 | 147 | fardanesh.xa. and glucose | US- | OR | OFF | 2019/07/16 |
| | | 5 | PGPUB; | | | 15:00 |
| | | | USPAT; | | | |
| | | | USOCR | | | |
| S139 | 17 | ("20020072681" "20020173709" | US- | OR | OFF | 2019/07/16 |
| | , | "4017756" "4859057" "5224478" | PGPUB; | J | · · | 15:03 |
| | | "5345935" "6461305").PN. OR | USPAT: | | | 1.0.00 |
| | | ("6839585").URPN. | USOCR | | | |
| S140 | 6 | <u> </u> | i haranananananananananananananananananana | OP | OEE | 2010/07/10 |
| S14U | 6 | "15404117" and vasodilator | US- PGPUB: | OR | OFF | 2019/07/16 19:15 |
| | | | USPAT | | | 13.10 |
| | :1 | | hamman | 0.0 | il | 0010/07/ |
| | - | 3) | US- | OR | OFF | 2019/07/16 |
| S141 | 541 | vasodilat\$5 with (measur\$5 calculat\$5) | | 0 | 0 | 51 |
| S141 | 541 | vasodilat\$5 with (measur\$5 calculat\$5) and A61B5/\$.cpc. | PGPUB; | | 0.1 | 19:24 |
| S141 | 541 | and A61B5/\$.cpc. | | | | 51 |
| | 541 209 | and A61B5/\$.cpc. vasodilat\$5 with (measur\$5 calculat\$5) | PGPUB; USPAT US- | OR | OFF | 19:24 2019/07/16 |
| | | and A61B5/\$.cpc. | PGPUB; USPAT | | | 19:24 |

| S143 | 92 | vasodilat\$5 with (measur\$5 calculat\$5) and (ppg photoplethysm\$6) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/07/16 19:28 |
|------|------|---|----------------------------------|----|-----|---------------------|
| S144 | 5 | (("5830137") or ("5584296") or ("8452364") or ("20030036690") or ("5497771")).PN. | US- PGPUB; USPAT; USOCR | OR | OFF | 2019/07/17 13:37 |
| S145 | 1 | "16195624" and instruction\$4 US-PGPUB; USPAT | | OR | OFF | 2019/07/17 15:14 |
| S146 | 1 | "16226249" | US- PGPUB; USPAT | OR | OFF | 2019/07/17 16:22 |
| S147 | 2 | (("5833603") or ("20020026108")).PN. US- PGPUB; USPAT; USOCR | | OR | OFF | 2019/07/17 17:41 |
| S148 | 2794 | apnea and accelerometer and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/07/18 07:48 |
| S149 | 1543 | apnea and (sleep position\$1) same accelerometer and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/07/18 07:49 |
| S150 | 481 | apnea and (sleep and position\$1) same accelerometer and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/07/18 07:49 |
| S151 | 191 | apnea and accelerometer and (position\$4 same (PPG photoplethysm\$6)) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | OFF | 2019/07/18 07:51 |
| S152 | 406 | apnea and accelerometer and (position same (PPG photoplethysm\$6 saturation)) and A61B5/\$.cpc. | | OR | ON | 2019/07/18 07:54 |
| S153 | 128 | accelerometer and (position same (PPG photoplethysm\$6 saturation)) and A61B5/4818.cpc. | US- PGPUB; USPAT | OR | ON | 2019/07/18 08:04 |
| S154 | 14 | correlat\$4 with (oxygen saturation) with position and A61B5/4818.cpc. | US- PGPUB; USPAT | OR | ON | 2019/07/18 08:38 |

EAST Search History (Interference)

| Ref # | Hits | Search Query | 1 | Default Operator | Plurals | Time Stamp |
|----------|-------|---|------------------------|---------------------|---------|---------------------|
| S63 | 607 | hemoglobin and IVI | US- PGPUB; USPAT | OR | ON | 2019/06/17 18:47 |
| S64 | 582 | hemoglobin and IVI and (light intensity) | US- PGPUB; USPAT | OR | ON | 2019/06/17 18:47 |
| S65 | ; | hemoglobin and IVI and (light intensity) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/06/17 18:48 |
| S66 | I - } | temperature and (heat\$4 cool\$4) and glucose and oscilat\$4 and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/06/18 10:59 |

7/19/2019 1:24:37 PM

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EAST Search History

Bibliographic Data

| Application No: $16/226,24$ | 19 | | | |
|----------------------------------|--------------|-----------------|-----|-----------------------|
| Foreign Priority claimed: | O Yes | ● No | | |
| 35 USC 119 (a-d) conditions met: | Yes | ∠ No | | ☐ Met After Allowance |
| Verified and Acknowledged: | /MARJAN | FARDANESH/ | | |
| | Examiner's | Signature | | Initials |
| Title: | ADVANC | CED PULSE OXIME | ΓRΥ | SENSOR |
| | | | | |

| FILING or 371(c) DATE | CLASS | GROUP ART UNIT | ATTORNEY DOCKET NO. |
|-----------------------|-------|----------------|---------------------|
| 12/19/2018 | 600 | 3791 | MAS.1007C1 |
| RULE | | | |

APPLICANTS

MASIMO CORPORATION, Irvine, CA,

INVENTORS

Ammar Al-Ali San Juan Capistrano, CA, UNITED STATES

Stephen Scruggs Newport Beach, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15195199 06/28/2016

15195199 has PRO of 62188430 07/02/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

01/15/2019

STATE OR COUNTRY

UNITED STATES

ADDRESS

KNOBBE, MARTENS, OLSON & BEAR, LLP

MASIMO CORPORATION (MASIMO)

2040 MAIN STREET

FOURTEENTH FLOOR

IRVINE, CA 92614

UNITED STATES

FILING FEE RECEIVED

\$5,860

Receipt date: 07/01/2019

PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 1 OF 1 | Attorney Docket No. | MAS.1007C1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-------------|---|-----------------------------------|--------|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
| | 1 | 5,830,137 | 11-03-1998 | Scharf | |

| | FOREIGN PATENT DOCUMENTS | | | | | |
|----------------------|--------------------------|--|-----------------------------------|------|---|----|
| Examiner Initials | Cite No. | Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | Τ¹ |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-------------|---|----|
| 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, page(s), volume-issue number(s), publisher, city and/or country where published. | T¹ |

30349862

| Examiner Signature | /MARJAN FARDANESH/ | Date Considered | 07/18/2019 |
|--------------------|--------------------|-----------------|------------|
|--------------------|--------------------|-----------------|------------|

T1 - Place a check mark in this area when an English language Translation is attached. /M.F/



United States Patent and Trademark Office

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FILING or GRP ART 371(c) DATE FIL FEE REC'D ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS UNIT 16/226,249 12/19/2018 3791 2880 MAS.1007C1

64735 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR **IRVINE, CA 92614**

CONFIRMATION NO. 1002 UPDATED FILING RECEIPT



Date Mailed: 07/25/2019

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Ammar Al-Ali, San Juan Capistrano, CA;

Applicant(s)

MASIMO CORPORATION, Irvine, CA;

Power of Attorney: The patent practitioners associated with Customer Number 64735

Domestic Priority data as claimed by applicant

This application is a CON of 15/195.199 06/28/2016 which claims benefit of 62/188,430 07/02/2015

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

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

page 1 of 3

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

Title

ADVANCED PULSE OXIMETRY SENSOR

Preliminary Class

600

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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NOT GRANTED

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

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page 3 of 3



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE UNITED STATES DEPARTMENT OF A COMMUNICATION OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF THE ADDRESS OF A COMMUNICATION OF THE ADDRESS OF THE ADDRES

ATTY. DOCKET NO./TITLE APPLICATION NUMBER FILING OR 371(C) DATE FIRST NAMED APPLICANT 16/226,249 12/19/2018 MAS.1007C1 Ammar Al-Ali

64735 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR **IRVINE, CA 92614**

CONFIRMATION NO. 1002 37 CFR 1.48 ACKNOWLEDGEMENT **LETTER**



Date Mailed: 07/25/2019

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(a)

This is in response to the applicant's request under 37 CFR 1.48(a) submitted on 07/19/2019.

The request under 37 CFR 1.48(a) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

> 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.

| /mmasfaw/ | |
|-----------|--|
| | |

Docket No.: MAS.1007C1 July 25, 2019
Page 1 of 2

Please Direct All Correspondence to Customer Number 64735

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Ammar Al-Ali

App. No : 16/226,249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791

Conf No. : 1002

SUMMARY OF INTERVIEW

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

Dear Commissioner:

A telephonic interview was conducted and attended by Examiner Fardanesh and Applicant's representatives Jarom D. Kesler (Reg. No. 57,046) and Aaron S. Johnson (Reg. No. 74,164) on July 18, 2019. During the interview, proposed claim amendments were discussed to place the application in condition for allowance. Examiner Fardanesh and Applicant's representatives reached an agreement that the pending claims were supported by the written description of the application and that the pending claims were patentably distinct over the prior art of record.

Examiner Fardanesh requested the filing of a Terminal Disclaimer with reference to copending Application Serial No. 15/195199. Without commenting on the appropriateness of a Terminal Disclaimer, and solely in the interest of advancing prosecution, Applicant submitted a Terminal Disclaimer on July 18, 2019. Applicant notes that according to M.P.E.P § 804.02, the filing of a terminal disclaimer to obviate a rejection based on nonstatutory obviousness-type double patenting is not an admission regarding the propriety of the rejection. Applicant thanks Examiner Fardanesh for her time and consideration.

Application No.: 16/226,249

Filing Date: December 19, 2018

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 25, 2019 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

30945431

| Electronic Acknowledgement Receipt | | | |
|--------------------------------------|-------------------------------------|--|--|
| EFS ID: | 36691207 | | |
| Application Number: | 16226249 | | |
| International Application Number: | | | |
| Confirmation Number: | 1002 | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | |
| Customer Number: | 64735 | | |
| Filer: | Aaron Samuel Johnson/Evelyn Salcido | | |
| Filer Authorized By: | Aaron Samuel Johnson | | |
| Attorney Docket Number: | MAS.1007C1 | | |
| Receipt Date: | 25-JUL-2019 | | |
| Filing Date: | 19-DEC-2018 | | |
| Time Stamp: | 18:17:20 | | |
| Application Type: | Utility under 35 USC 111(a) | | |

Payment information:

| Submitted with Payment | no | | | |
|------------------------|----|-------------------|--------|----------|
| File Listing: | | | | |
| B | | ETI. C1 . /D 4 \/ | 84 141 | D |

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|--------------------|--|-----------------------|---|---------------------|---------------------|
| 1 | Applicant summary of interview with examiner | Summary_MAS1007C1.pdf | 19639 9c20c54ef5c9f5c01a508a807ba65afc47248 ec5 | no | 2 |
| Warnings: | • | • | | | |

| Information: | |
|------------------------------|-------|
| Total Files Size (in bytes): | 19639 |

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.

505587679 07/24/2019

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1 Stylesheet Version v1.2 EPAS ID: PAT5634478

| SUBMISSION TYPE: | NEW ASSIGNMENT |
|-----------------------|----------------|
| NATURE OF CONVEYANCE: | ASSIGNMENT |
| | |

CONVEYING PARTY DATA

| Name | Execution Date |
|--------------|----------------|
| AMMAR AL-ALI | 07/19/2019 |

RECEIVING PARTY DATA

| Name: MASIMO CORPORATION | |
|------------------------------|------------|
| Street Address: 52 DISCOVERY | |
| City: | IRVINE |
| State/Country: | CALIFORNIA |
| Postal Code: | 92618 |

PROPERTY NUMBERS Total: 2

| Property Type | Number | |
|---------------------|----------|--|
| Application Number: | 15195199 | |
| Application Number: | 16226249 | |

CORRESPONDENCE DATA

Fax Number: (949)760-9502

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 9497600404

Email: efiling@knobbe.com

Correspondent Name: KNOBBE, MARTENS, OLSON & BEAR, LLP

Address Line 1: 2040 MAIN STREET

Address Line 2: 14TH FLOOR

Address Line 4: IRVINE, CALIFORNIA 92614

| ATTORNEY DOCKET NUMBER: | MAS.1007A/ MAS.1007C1 |
|-------------------------|--|
| NAME OF SUBMITTER: | AARON S. JOHNSON |
| SIGNATURE: | /Aaron S. Johnson/ |
| DATE SIGNED: | 07/24/2019 |
| | This document serves as an Oath/Declaration (37 CFR 1.63). |

Total Attachments: 3

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COMBINED DECLARATION & ASSIGNMENT (37 CFR 1.63(e))

Application Data Sheet filed previously or concurrently

Docket Nos.: MAS.1007A; MAS.1007C1

Page 1 of 3

Title: ADVANCED PULSE OXIMETRY SENSOR

Inventors: Ammar Al-Ali

Declaration

This Declaration is directed to U.S. Application Nos. **15/195199** and **16/226249**, filed June 28, 2016 and December 19, 2018, respectively, and incorporating any amendments made thereto prior to the signature date of this Declaration.

As a named inventor, I declare that:

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 USC 1001 by fine or imprisonment of not more than five (5) years, or both.

I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

Assignment from Inventors

WHEREAS, above-identified inventors (individual(s) hereinafter "ASSIGNOR") invented certain new and useful improvements, technology, inventions, developments, ideas, ornamental designs, or discoveries related to ADVANCED PULSE OXIMETRY SENSOR (collectively hereinafter referred to as the "Work") for which an application for Letters Patent in the United States (identified above) has been filed or prepared for filing with the United States Patent and Trademark Office (hereinafter the "Application"), and ASSIGNOR desires to assign or confirm assignment of the Work and the Application to the below identified Assignee.

AND WHEREAS, Masimo Corporation, with its principal place of business at 52 Discovery, Irvine, California 92618 (hereinafter the "ASSIGNEE"), desires to acquire or confirm ownership of the entire right, title, and interest in and to the Application and the Work.

NOW, THEREFORE, for good and valuable consideration of which receipt is hereby acknowledged, ASSIGNOR hereby acknowledges that ASSIGNOR has sold, assigned, transferred, and set over, and by these presents does hereby sell, assign, transfer, and set over, unto said ASSIGNEE, **its** successors, legal representatives, and assigns, the entire right, title, and interest throughout the world in and to the Application and the Work, including:

all provisional applications relating to the Work and the Application (including but not limited to U.S. Provisional Application No(s). 62/188430, filed July 2, 2015 (respectively if plural applications));

all nonprovisional applications claiming priority to aforementioned provisional(s) and/or the Application, including, all divisions, continuations, continuations-in-part, and reissues, and all Letters Patent of the United States which may be granted thereon and all reissues and extensions thereof; and

all rights of priority under International Conventions and any related Letters Patent which may hereafter be granted or filed in any country or countries foreign to the United States, all extensions, renewals, and reissues thereof.

COMBINED DECLARATION & ASSIGNMENT (37 CFR 1.63(e))

Application Data Sheet filed previously or concurrently

Docket Nos.: MAS.1007A; MAS.1007C1

Page 2 of 3

Title: ADVANCED PULSE OXIMETRY SENSOR

Inventors: Ammar Al-Ali

ASSIGNOR hereby authorizes and requests the Commissioner of Patents of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents on applications as aforesaid, to issue all related Letters Patent to the ASSIGNEE, its successors, legal representatives, and assigns.

AND ASSIGNOR DOES HEREBY sell, assign, transfer, and convey to ASSIGNEE, **its** successors, legal representatives, and assigns all claims for damages and all remedies arising out of any violation of the rights assigned hereby that may have accrued prior to the date of assignment to ASSIGNEE, or may accrue hereafter, including, but not limited to, the right to sue for, collect, and retain damages for past infringements of said Letters Patent before or after issuance.

AND ASSIGNOR DOES HEREBY covenant and agree that ASSIGNOR will: communicate to said ASSIGNEE, its successors, legal representatives, and assigns any facts known to ASSIGNOR respecting the Work; testify in any legal proceeding; assist in the preparation of any other Patent Property relating to the Application and the Work or any improvements made thereto; sign/execute all lawful papers; authorize the filing of, execute, and make all rightful oaths and/or declarations in connection with the Application and the Work including any improvements made thereto, any patent applications filed therefrom, and any continuing application filed from any of the aforementioned applications; and generally do everything possible to aid the ASSIGNEE, its successors, legal representatives, and assigns, to obtain and enforce proper patent protection for the Work in all countries.

COMBINED DECLARATION & ASSIGNMENT (37 CFR 1.63(e)) Application Data Sheet filed previously or concurrently

| Application Data Sheet filed previously or concurrently |
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| Docket Nos.: MAS.1007A; MAS.1007C1 Page 3 of 3 |
| Title: ADVANCED PULSE OXIMETRY SENSOR |
| Inventors: Ammar Al-Ali |
| |
| Legal Name of Inventor: Ammar Al-Ali |
| IN TESTIMONY WHEREOF, I hereunto set my hand and seal this 14 day of 14 day of 15 day of 15 day of 16 day of 16 day of 16 day of 16 day of 16 day of 17 day of 18 day |
| Signature: |
| Cigration of the control of the cont |
| A NOTARY PUBLIC OR OTHER OFFICER COMPLETING THIS CERTIFICATE VERIFIES ONLY THE IDENTITY OF THE INDIVIDUAL WHO SIGNED THE DOCUMENT TO WHICH THIS CERTIFICATE IS ATTACHED, AND NOT THE TRUTHFULNESS, ACCURACY, OR VALIDITY OF THAT DOCUMENT. |
| STATE OF CALIFORNIA COUNTY OF CRANGE ss. On 1954249, before me, EUSAM MULET, notary public, personally |
| appeared Ammar Al-Ali who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument, and acknowledged to me that he/skie/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument. |
| I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct. |
| WITNESS my hand and official seal. Notary Signature |
| [SEAL] |
| EUSA M. MULET Notary Public - California Orange County Commission # 2173718 My Comm. Expires Dat 23, 2020 |

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 1 OF 12 | Attorney Docket No. | MAS.1007C1 |

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|----------------------|-----------------------|---|-----------------------------------|---------------------|--|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | |
| | 1 | 5,497,771 | 3/12/1996 | Rosenheimer | | |
| | 2 | 6,343,223 | 1/29/2002 | Chin et al. | | |
| | 3 | 5,987,343 | 11/16/1999 | Kinast | | |
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| | 20 | 9,466,919 | 10/11/2016 | Kiani et al. | | |
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| | 29 | 9,538,980 | 1/10/2017 | Telfort et al. | | |

| Examiner Signature | Date Considered |
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T¹ - Place a check mark in this area when an English language Translation is attached.

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| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY ALL LIDANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 2 OF 12 | Attorney Docket No. | MAS.1007C1 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-------------|---|-----------------------------------|-----------------|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
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| | 31 | 9,554,737 | 1/31/2017 | Schurman et al. | |
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| | 57 | 9,743,887 | 8/29/2017 | Al-Ali et al. | |
| | 58 | 9,749,232 | 8/29/2017 | Sampath et al. | |

| Examiner Signature | Date Considered |
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T¹ - Place a check mark in this area when an English language Translation is attached.

| | Application No. | 16/226249 |
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| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY ALL FLOANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 3 OF 12 | Attorney Docket No. | MAS.1007C1 |

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|----------------------|-----------------------|---|-----------------------------------|--------------------|--|--|
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| Examiner Signature | Date Considered |
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| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 4 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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| STATEMENT BY ALL EIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 5 OF 12 | Attorney Docket No. | MAS.1007C1 |

| | U.S. PATENT DOCUMENTS | | | | |
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| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
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| Examiner Signature | Date Considered |
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| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 6 OF 12 | Attorney Docket No. | MAS.1007C1 |

| | U.S. PATENT DOCUMENTS | | | | |
|----------------------|-----------------------|---|-----------------------------------|--------------------|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
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| | 169 | D833,624 | 11/13/2018 | DeJong et al. | |
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| | 172 | D835,284 | 12/4/2018 | Barker et al. | |
| | 173 | D835,285 | 12/4/2018 | Barker et al. | |
| | 174 | RE47,218 | 2/5/2019 | Ali-Ali | |

| Examiner Signature | Date Considered |
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| | Application No. | 16/226249 |
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| SHEET 7 OF 12 | Attorney Docket No. | MAS.1007C1 |

| U.S. PATENT DOCUMENTS | | | | | |
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| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
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| Examiner Signature | Date Considered |
|--------------------|-----------------|
|--------------------|-----------------|

T¹ - Place a check mark in this area when an English language Translation is attached.

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 8 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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| STATEMENT BY ALL LIDANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 9 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
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| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 10 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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| | Application No. | 16/226249 |
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| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 11 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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 $[\]mathsf{T}^1$ - Place a check mark in this area when an English language Translation is attached.

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|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
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| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 12 OF 12 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature | Date Considered |
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T¹ - Place a check mark in this area when an English language Translation is attached.

Docket No.: MAS.1007C1 Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

First Inventor: Ammar Al-Ali

App. No. : 16/226249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791 Conf. No. : 1002

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

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance.

This Statement is accompanied by the fees set forth in 37 CFR 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 19, 2019 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

30951026

| Electronic Patent Application Fee Transmittal | | | | | |
|---|--------------------------------------|----------|----------|--------|-------------------------|
| Application Number: | 16226249 | | | | |
| Filing Date: | 19-Dec-2018 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | | |
| Attorney Docket Number: | MA | S.1007C1 | | | |
| Filed as Large Entity | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
| Basic Filing: | | | | | |
| Pages: | | | | | |
| Claims: | | | | | |
| Miscellaneous-Filing: | | | | | |
| Petition: | | | | | |
| Patent-Appeals-and-Interference: | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | |
| Extension-of-Time: | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
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| Miscellaneous: | | | | |
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| | Tot | al in USD | (\$) | 240 |
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| Electronic Acknowledgement Receipt | | | | |
|--------------------------------------|--------------------------------------|--|--|--|
| EFS ID: | 36636368 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 19-JUL-2019 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 13:23:52 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$240 |
| RAM confirmation Number | 071919INTEFSW13250800 |
| Deposit Account | |
| Authorized User | |

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

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| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
| | | | 157671 | | |
| 1 | | IDS_MAS1007C1.pdf | 3a3162a75370e7d4ecbf40a717d6fee4d0b 2eb97 | yes | 13 |
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| 2 | Fee Worksheet (SB06) | fee-info.pdf | 6ab1762475a3900bb6fe5f09c8b26b73092 14039 | no | 2 |
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

Doc Code: R48.REQ

Document Description: Request under Rule 48 correcting inventorship

PTO/AIA/40 (04-18)

Approved for use through 11/30/2020. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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REQUEST FOR CORRECTION IN A
PATENT APPLICATION RELATING TO
INVENTORSHIP OR AN INVENTOR
NAME, OR ORDER OF NAMES, OTHER
THAN IN A REISSUE APPLICATION (37
CFR 1.48)

| 1, | | | | | |
|-------------------------------|-------------------|--|--|--|--|
| Application Number | 16/226249 | | | | |
| Filing Date | December 19, 2018 | | | | |
| First Named Inventor | Ammar Al-Ali | | | | |
| Art Unit | 3791 | | | | |
| Examiner Name | Fardanesh, Marjan | | | | |
| Practitioner Docket Number | MAS.1007C1 | | | | |

To: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Applicant hereby requests that the inventorship be corrected or changed, or that the name of the inventor or a joint inventor, or the order of the names of joint inventors, be changed, in the above-identified application. Note: 37 CFR 1.48 applies to any request to correct inventorship filed on or after September 16, 2012, regardless of the application filing date. Do not submit this form after payment of the issue fee or if the application has been patented. See 37 CFR 1.324 for correction of inventorship in a patent. Please check the applicable box(es) below. For a nonprovisional application: 1. This request is to correct or change the inventorship in a nonprovisional application (under 37 CFR 1.48(a)) and includes: An application data sheet (ADS) in accordance with 37 CFR 1.76(c) with the corrected or updated information shown with markings (e.g., underlining for insertions, strikethrough for deletions). See the Manual of Patent Examining Procedure (MPEP) section 601.05(a) for information about filing an ADS in an application filed on/after September 16, 2012. For information about filing a Supplemental ADS in an application filed before September 16, 2012, see MPEP 601.05(b). _s 140 The processing fee set forth in 37 CFR 1.17(i). An inventor is being added. An inventor's oath or declaration by any actual inventor who has not yet executed an oath or declaration is required (see 37 CFR 1.48(b)). See MPEP 602.01(a) for information about an inventor's oath or declaration for an application filed on/after September 16, 2012 (e.g., form PTO/AIA/01). For information about an inventor's oath or declaration for an application filed before September 16, 2012 (e.g., form PTO/SB/01), see MPEP 602.01(b). This request is being filed after the first Office action on the merits has been given or mailed (see 37 CFR 1.48(c) and 1.17(d)). Check one of the following: This request to correct or change the inventorship is due solely to the cancellation of claims in the application. _s 600 OR The fee set forth in 37 CFR 1.17(d) is due (in addition to the fee set forth in 37 CFR 1.17(i)).

[Page 1 of 2]

This collection of information is required by 37 CFR 1.48. 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 1.11 and 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.

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

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

REQUEST FOR CORRECTION IN A PATENT APPLICATION RELATING TO INVENTORSHIP OR AN INVENTOR NAME, OR ORDER OF NAMES, OTHER THAN IN A REISSUE APPLICATION (37 CFR 1.48)

| 2. This request is to correct or update the name of t nonprovisional application (under 37 CFR 1.48(f)) are | • | nventor, or the order of names of joint inventors, in a |
|--|--|---|
| updated name of the inventor, or the new ordedeletions). See the MPEP 601.05(a) for informations | er of names shown with ation about filing an AD | ng the complete inventive entity, including the corrected or h markings (e.g., underlining for insertions, strikethrough for its in an application filed on/after September 16, 2012. For after September 16, 2012, see MPEP 601.05(b). |
| The processing fee set forth in 37 CFR 1.17(i). | | \$ |
| For a provisional application: This request is to change or correct the inventorship application (under 37 CFR 1.48(d)) and includes: | , or correct or update t | the name of the inventor or a joint inventor, in a provisional |
| | ent may be an applicat | 7 CFR 1.33(b) and identifies each inventor by his or her legal ion data sheet in accordance with 37 CFR 1.76(c) that through for deletions). |
| The processing fee set forth in 37 CFR 1.17(q). | | \$ |
| Fee Payment Information: Applicant asserts small entity status. See 37 CFR 1.2 | 7. | |
| Applicant certifies micro entity status. See 37 CFR 1. Form PTO/SB/15A or B or equivalent must either be enclose | | previously |
| A check in the amount of the fee is enclosed. | | |
| Payment by credit card. Form PTO-2038 is attached. | | |
| The Director is hereby authorized to charge any fees to Deposit Account No. 11-1410 . | which may be required | d, or credit any overpayment |
| Payment made via EFS-Web. | | |
| WARNING: Information on this form may become on this form. Provide credit card information and a | • | |
| I am the | | |
| Applicant* attorney or agen Registration number | | attorney or agent acting under 37 CFR 1.34 Registration number |
| _{Signature} /Aaron S. Johnson/ | | |
| Typed or printed name Aaron S. Johnson | | |
| Date July 19, 2019 NOTE: This form must be signed in accordance with 37 Cl | R 1 33 See 37 CFR 1 4 | for signature requirements and certifications. *Juristic entities |
| must be represented by a patent practitioner (See 37 CFR | 1.31, applicable to any | paper filed on or after September 16, 2012 that is presented e forms if more than one signature is required, see below**. |
| ** Total of 1 forms are submitted. | | |

[Page 2 of 2]

Privacy Act Statement

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

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

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

| Electronic Patent Application Fee Transmittal | | | | | |
|---|--------------------------------------|-----------------|--------------|--------|-------------------------|
| Application Number: | 16 | 226249 | | | |
| Filing Date: | 19- | -Dec-2018 | | | |
| Title of Invention: | AD | VANCED PULSE OX | IMETRY SENSO | R | |
| First Named Inventor/Applicant Name: | Am | nmar Al-Ali | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | | |
| Attorney Docket Number: | MA | AS.1007C1 | | | |
| Filed as Large Entity | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
| Basic Filing: | | | , | | |
| Pages: | | | | | |
| Claims: | | | | | |
| Miscellaneous-Filing: | | | | | |
| PROCESSING FEE, EXCEPT PROV. APPLS. | | 1830 | 1 | 140 | 140 |
| Petition: | | | | | |
| Patent-Appeals-and-Interference: | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------------------------|----------|-----------|--------|-------------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| CORRECTION OF INVENTORSHIP ON MERITS | 1819 | 1 | 600 | 600 |
| | Tot | al in USD | (\$) | 740 |
| | | | | |

| Electronic Acknowledgement Receipt | | |
|--------------------------------------|------------------------------------|--|
| EFS ID: | 36637867 | |
| Application Number: | 16226249 | |
| International Application Number: | | |
| Confirmation Number: | 1002 | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | |
| Customer Number: | 64735 | |
| Filer: | Aaron Samuel Johnson/Jennifer Neat | |
| Filer Authorized By: | Aaron Samuel Johnson | |
| Attorney Docket Number: | MAS.1007C1 | |
| Receipt Date: | 19-JUL-2019 | |
| Filing Date: | 19-DEC-2018 | |
| Time Stamp: | 15:12:04 | |
| Application Type: | Utility under 35 USC 111(a) | |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$740 |
| RAM confirmation Number | 072219INTEFSW15124000 |
| Deposit Account | 111410 |
| Authorized User | Jennifer Neat |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| Document | | | | | |
|---|-------------------------------|------------------------|--|---------------------|--------------------|
| Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl. |
| | | | 35697 | | |
| 1 | Application Data Sheet | CORR-ADS_MAS1007C1.pdf | 02f64c428806c04b79ca5d289177fceaa6c1 6403 | no | 2 |
| Warnings: | | | | | |
| Information: | | | | | |
| This is not an USP | TO supplied ADS fillable form | | | | |
| | | | 167460 | | |
| 2 Request under Rule 48 correcting inventorship | | REQUEST_MAS1007C1.pdf | 987024ad2bb2fdd65ed67df6cd920ff30889 4516 | no | 3 |
| Warnings: | | | | | |
| Information: | | | | | |
| | | | 32197 | | |
| 3 | Fee Worksheet (SB06) | fee-info.pdf | e64f3fba10d3c9aa0c319d78deb9b83b539 31cb2 | no | 2 |
| Warnings: | | | | | |
| Information: | | | | | |

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.

Docket Number: MAS.1007C1

APPLICATION DATA SHEET

Application Information

Application Number: 16/226249

Filing Date: December 19, 2018

Title: ADVANCED PULSE OXIMETRY SENSOR

Attorney Docket Number: MAS.1007C1

Inventor Information 1

Given Name: Ammar Family Name: Al-Ali

City of Residence: San Juan Capistrano

State or Prov. of Residence: CA Country of Residence: US

Street: 30312 Via Bella

City: San Juan Capistrano

State or Province: CA
Country: US

Postal or Zip Code: 92675

Inventor Information 2

Given Name: Stephen
Family Name: Scruggs

City of Residence: Newport Beach

State or Prov. of Residence: CA
Country of Residence: US

Street: 307 Snug Harbor Road

City: Newport Beach

State or Province: CA

1 16/226249 Filed: December 19, 2018

Docket Number: MAS.1007C1

Country: US

Postal or Zip Code: 92663

Correspondence Information

Correspondence Customer Number: 64735

Phone Number: (949) 760-0404

Fax Number: (949) 760-9502

efiling@knobbe.com E-Mail Address:

Representative Information

Representative Customer Number: 64735

By:/Aaron S. Johnson/ Dated: July 19, 2019

Aaron S. Johnson

Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

30951164

| Doc Code: DIST.E.FILE Document Description: Electronic | Terminal Disclaimer - Filed | PTO/SB/25 U.S. Patent and Trademark Office Department of Commerce | | | | |
|---|--------------------------------------|---|--|--|--|--|
| Electronic Petition Request | TERMINAL DISCLAIMER TO OF | BVIATE A PROVISIONAL DOUBLE PATENTING "REFERENCE" APPLICATION | | | | |
| Application Number | 16226249 | | | | | |
| Filing Date | 19-Dec-2018 | | | | | |
| First Named Inventor | Ammar Al-Ali | Ammar Al-Ali | | | | |
| Attorney Docket Number | MAS.1007C1 | | | | | |
| Title of Invention | ADVANCED PULSE OXIMETRY | SENSOR | | | | |
| Filing of terminal disclaimer do | pes not obviate requirement for res | ponse under 37 CFR 1.111 to outstanding | | | | |
| ☐ This electronic Terminal Discla | imer is not being used for a Joint R | esearch Agreement. | | | | |
| Owner | F | Percent Interest | | | | |
| Masimo Corporation | | 100% | | | | |

The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)

15195199 filed on 06/28/2016

as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

| 0 | | CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) aimer has already been paid in the above-identified application. | | | | | | |
|-----------------|---|--|--|--|--|--|--|--|
| Appl | icant claims the following fee st | atus: | | | | | | |
| 0 | Small Entity | | | | | | | |
| 0 | Micro Entity | | | | | | | |
| • | Regular Undiscounted | | | | | | | |
| belie the li | f are believed to be true; and fu ke so made are punishable by fi | nade herein of my own knowledge are true and that all statements made on information and rther that these statements were made with the knowledge that willful false statements and ne or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and y jeopardize the validity of the application or any patent issued thereon. | | | | | | |
| THI | S PORTION MUST BE COMPLETE | D BY THE SIGNATORY OR SIGNATORIES | | | | | | |
| l ce | rtify, in accordance with 37 CFR | 1.4(d)(4) that I am: | | | | | | |
| • | An attorney or agent registered this application | to practice before the Patent and Trademark Office who is of record in | | | | | | |
| | Registration Number 7416 | 4 | | | | | | |
| 0 | A sole inventor | | | | | | | |
| 0 | A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application | | | | | | | |
| 0 | A joint inventor; all of whom ar | e signing this request | | | | | | |
| Sig | nature | /Aaron S. Johnson/ | | | | | | |
| Nar | ne | Aaron S. Johnson | | | | | | |

^{*}Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

| Electronic Patent A | \p p | lication Fee | Transmit | ttal | | |
|---|-------------------------------------|--------------|----------|--------|-------------------------|--|
| Application Number: | 162 | 226249 | | | | |
| Filing Date: | 19-Dec-2018 | | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | |
| Filer: | Aaron Samuel Johnson/Evelyn Salcido | | | | | |
| Attorney Docket Number: MAS.1007C1 | | | | | | |
| Filed as Large Entity | | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) | |
| Basic Filing: | | | | | | |
| STATUTORY OR TERMINAL DISCLAIMER | | 1814 | 1 | 160 | 160 | |
| Pages: | | | | | | |
| Claims: | | | | | | |
| Miscellaneous-Filing: | | | | | | |
| Petition: | | | | | | |
| Patent-Appeals-and-Interference: | | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------|----------|-----------|--------|-------------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| | Tot | al in USD | (\$) | 160 |
| | | | | |

| Doc Code: DISQ.E.FILE Document Description: Electronic Terminal Disclaimer – Approved |
|---|
| Application No.: 16226249 |
| Filing Date: 19-Dec-2018 |
| Applicant/Patent under Reexamination: Al-Ali |
| Electronic Terminal Disclaimer filed on Uuly 18, 2019 |
| |
| This patent is subject to a terminal disclaimer |
| DISAPPROVED |
| Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web |
| U.S. Patent and Trademark Office |

| Electronic Acknowledgement Receipt | | | | | |
|--------------------------------------|-------------------------------------|--|--|--|--|
| EFS ID: | 36626760 | | | | |
| Application Number: | 16226249 | | | | |
| International Application Number: | | | | | |
| Confirmation Number: | 1002 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | |
| Customer Number: | 64735 | | | | |
| Filer: | Aaron Samuel Johnson/Evelyn Salcido | | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | |
| Receipt Date: | 18-JUL-2019 | | | | |
| Filing Date: | 19-DEC-2018 | | | | |
| Time Stamp: | 15:56:05 | | | | |
| Application Type: | Utility under 35 USC 111(a) | | | | |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$160 |
| RAM confirmation Number | 071919INTEFSW15555800 |
| Deposit Account | 111410 |
| Authorized User | Evelyn Salcido |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing | j: | | | | |
|--------------------|--|----------------------------|--|---------------------|---------------------|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
| | | | 34022 | | |
| 1 | Terminal Disclaimer-Filed (Electronic) | e Terminal-Disclaimer.pdf | c7bd665ae2e3d36a449278736bd85784cb 4e886b | no | 2 |
| Warnings: | <u> </u> | | | l | |
| Information: | | | | | |
| | | | 30305 | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 3042f13ff3047cbe12f8fb019cf1d5d17eed2 ce3 | no | 2 |
| Warnings: | <u> </u> | | | | |
| Information: | | | | | |
| | | Total Files Size (in bytes |): 64 | 4327 | |

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.

MAS.1007C1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor: Ammar Al-Ali

App. No. : 16/226,249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791 Conf. No. : 1002

RESPONSE TO OFFICE ACTION DATED MARCH 29, 2019

Mail Stop Amendment

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

Dear Commissioner:

In response to the Non-final Office Action dated March 29, 2019, please consider the following.

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

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Amendments to the Drawings begin on page 10. A "Replacement Sheet" for each sheet of drawings being amended can be found in the Appendix.

Summary of Interview begins on page 11 of this paper.

Remarks begin on page 12 of this paper.

Filing Date: December 19, 2018

AMENDMENTS TO THE SPECIFICATION

Please amend the originally-filed specification as set forth below.

[0053] Referring now to FIG. 7B, a top view of the 3D sensor 700 is illustrated with both the emitter 702 and the light blocker cover 707 removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser 704. As light is emitted from the emitter 702 (not shown in FIG. 7B), it is diffused homogenously and directed to the tissue measurement site 102. The light blocker 706 forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector 710. The light blocker cover 707 blocks incidental light from entering the light isolation chamber from above. The light concentrator 710708 collects the reflected light from the tissue measurement site 102 and funnels it upward toward the detector 710 at the center of the 3D sensor 700.

Filing Date: December 19, 2018

AMENDMENTS TO THE CLAIMS

A complete listing of all claims is presented below with insertions underlined (e.g., <u>insertion</u>), and deletions struck through or in double brackets (e.g., <u>deletion</u> or [[deletion]]).

1-56. (Cancelled)

57. (**Currently Amended**) A wrist-worn physiological monitoring device configured for placement on a user at a tissue measurement site, the device comprising:

a light emission source comprising a plurality of emitters configured to <u>irradiate a circular portion of the tissue measurement site by emitting light towards the tissue measurement site, the tissue measurement site being located on a wrist of the user, the plurality of emitters comprising one or more light emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength;</u>

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site,—wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user; and

a light block forming an enclosing wall between the <u>light emission source and the</u> plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the enclosing wall prevents at least a portion of light emitted from the <u>light emission sourceplurality of emitters</u> from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site.

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- 58. (**Previously Presented**) The physiological monitoring device of Claim 57, further comprising a display configured to present information related to the determined physiological parameter to the user.
- 59. **(Previously Presented)** The physiological monitoring device of Claim 58, wherein the display is a touch-screen display.
- 60. (**Previously Presented**) The physiological monitoring device of Claim 57, wherein the enclosing wall of the light block is a circular wall.
- 61. (**Previously Presented**) The physiological monitoring device of Claim 57, wherein, when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.
- 62. (**Previously Presented**) The physiological monitoring device of Claim 57, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 63. (Currently Amended) The physiological monitoring device of Claim 57, wherein the <u>light emission source isplurality of emitters are</u> positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.
- 64. (**Previously Presented**) The physiological monitoring device of Claim 57, wherein the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate.
 - 65. (Cancelled)
 - 66. (Cancelled)
- 67. (**Currently Amended**) A method of measuring a physiological parameter in a user's blood, the method comprising:

<u>irradiating a circular portion of a tissue measurement site by emitting, from a</u> plurality of emitters of a light emission source of a physiological monitoring device, light

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of one or more wavelengths toward [[a]]the tissue measurement site, the tissue measurement site located on a wrist of the userthe plurality of emitters comprise one or more light emitting diodes (LEDs) and the one or more wavelengths comprises at least an infrared wavelength;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters of the light emission source after attenuation through tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes; and

providing a cylindrical light block forming an enclosing wall between the light emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the enclosing wall prevents at least a portion of light emitted from the light emission sourceplurality of emitters from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light;

outputting, from the plurality of detectors, at least one signal responsive to the detected light;

receiving, by a processor, the outputted at least one signal responsive to the detected light; and

processing, by the processor, the received at least one signal responsive to the detected light to determine a physiological parameter.

68. (Currently Amended) The method of Claim 67, wherein the <u>light emission</u> source isplurality of emitters are positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.

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69. (**Previously Presented**) The method of Claim 67, further comprising presenting, with a display of the physiological monitoring device, information related to the determined physiological parameter to the user.

70. (**Previously Presented**) The method of Claim 69, wherein the display is a touch-screen display.

71. (Cancelled)

72. (**Previously Presented**) The method of Claim 67, wherein when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.

73. (**Previously Presented**) The method of Claim 67, further comprising spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to the tissue measurement site.

74. (**Previously Presented**) The method of Claim 67, wherein the physiological parameter is indicative of at least one of pulse rate, perfusion index, oxygen content, and total hemoglobin.

75. (Cancelled)

76. (Cancelled)

77. (Currently Amended) A wrist-worn physiological monitoring sensor comprising:

a light emission source comprising a plurality of optical sources configured to irradiate a circular portion of a tissue measurement site by emitting light towards [[a]]the tissue measurement site on a user, the tissue measurement site located on a wrist of the user, the plurality of optical sources comprising one or more light emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength;

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the

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plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the outputted at least one signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user; and

a light block forming an enclosing wall between the <u>light emission source and the</u> plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, <u>light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring sensor is worn by the user, the light block forming a light isolation chamber defined by the enclosing wall, wherein the <u>enclosing</u> wall prevents at least a portion of light emitted from the <u>light emission sourceplurality of emitters</u> from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light.</u>

- 78. (Currently Amended) The physiological monitoring sensor of Claim 77, wherein the <u>light emission source isplurality of optical sources are</u> located outside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site, and wherein the plurality of detectors are arranged inside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site.
 - 79. (Cancelled)
 - 80. (Cancelled)
- 81. **(Previously Presented)** The physiological monitoring sensor of Claim 77, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 82. (**Previously Presented**) The physiological monitoring sensor of Claim 77, further comprising a display configured to present information related to the determined physiological parameter to the user.

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83. **(Previously Presented)** The physiological monitoring sensor of Claim 82, wherein the display is a touch-screen display.

84. (Cancelled)

85. (Currently Amended) The physiological monitoring sensor of Claim 77, wherein when the physiological monitoring sensor is worn by the user at the tissue measurement site, the plurality of optical sourcesemitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring sensor is worn by the user.

86. (Cancelled)

- 87. (New) The physiological monitoring device of Claim 57, wherein the plurality of emitters comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 88. (New) The physiological monitoring device of Claim 57, wherein the plurality of detectors comprise a plurality of photodiodes.
- 89. (New) The physiological monitoring device of Claim 57, further comprising a light concentrator configured to direct the attenuated, reflected light to the plurality of detectors.
- 90. (New) The method of Claim 67, wherein the plurality of emitters comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 91. **(New)** The method of Claim 67, wherein the plurality of detectors comprise a plurality of photodiodes.
- 92. (New) The method of Claim 67, further comprising, directing, with a light concentrator, the light emitted by the light emission source after attenuation through tissue of the user at the tissue measurement site to the plurality of detectors.
- 93. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of optical sources comprise one or more light emitting diodes (LEDs), and wherein the one or more wavelengths comprises at least an infrared wavelength.
- 94. **(New)** The physiological monitoring sensor of Claim 77, wherein the plurality of detectors comprise a plurality of photodiodes.

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95. (**New**) The physiological monitoring sensor of Claim 77, further comprising a light concentrator configured to direct the attenuated, reflected light to the plurality of detectors.

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AMENDMENTS TO THE DRAWINGS

Please replace Figure 7A with the enclosed Replacement Sheet.

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SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The interview was conducted on May 7, 2019 and attended by Examiner Fardanesh and Applicant's representatives Jarom D. Kesler (Reg. No. 57,046) and Aaron S. Johnson (Reg. No. 74,164).

Exhibits and/or Demonstrations

N/A.

Identification of Claims Discussed

Claims 57, 67, and 77.

Identification of Cited/Disclosed Art

- U.S. Patent No. 5,830,137 to Scharf.
- U.S. Patent No. 5,584,296 to Cui et al.
- U.S. Patent No. 8,452,364 to Hannula et al.
- U.S. Patent Pub. No. 2003/0036690 to Geddes et al.
- U.S. Patent No. 5,497,771 to Rosenheimer.

Proposed Amendments

Amendments as appearing herein.

<u>Issues Discussed and Results of Interview</u>

Applicant thanks Examiner Fardanesh for taking the time to conduct the Interview. During the interview, the claims were discussed in view of the cited prior art. Examiner Fardanesh acknowledged that the prior art did not teach three or more detectors arranged in a spatial configuration as recited in the claims.

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REMARKS

This paper is filed in response to the Office Action mailed March 29, 2019 ("Office Action"), in connection with the above-referenced patent application. Claims 57-86 were pending prior to the submission of this paper. Claims 57, 63, 67, 68, 77-78, and 85 have been amended and Claims 65-66, 71, 75-76, 79-80, 84, and 86 have been cancelled without prejudice or disclaimer. Claims 87-95 have been added as new. Thus, Claims 57-64, 67-70, 72-74, 77-78, 81-83, 85, and 87-95 are pending. Applicant respectfully requests allowance of the pending claims in light of the present response.

A. Information Disclosure Statement

As discussed during the interview on May 7, 2019 ("Interview"), Applicant is submitting an Information Disclosure Statement (IDS) herewith. The IDS contains a reference that was discussed during the Interview.

B. Claim Amendment Support

Claim 57 recites, among other things, a "plurality of detectors" "arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site." Claims 67 and 77 recite, among other things, a "plurality of detectors" "arranged in an array having a circular spatial configuration." Support for these claim amendments can be found throughout the present disclosure. For example, in multiple locations, the originally-filed application discusses providing "a plurality of detectors" in an arrangement "corresponding" to an "irradiated surface area" so as to appropriately capture light attenuated from a tissue measurement site. For example, paragraph [0042] of the originally-filed application states:

The detector 310 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 310 can be arranged in an array with a spatial configuration *corresponding to* the irradiated surface area 206 to capture the attenuated or reflected light from the tissue measurement site.

Originally-filed Specification, para. [0042] (emphasis added). The "irradiated surface area 206" is described in paragraph [0032] of the originally-filed specification, which discussed various exemplary shapes and dimensions that the irradiated surface area can have (for example, a rectangular shape). *See id.*, para. [0032], Figure 2.

As another example, paragraph [0051] of the originally-filed application states:

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The detector 710 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 710 can be arranged in an array with a spatial configuration *corresponding to* the irradiated surface area depicted in FIG. 7B by the light concentrator 708 to capture the reflected light from the tissue measurement site.

Id., para. [0051] (emphasis added). The "irradiated surface area depicted in FIG. 7B by the light concentrator 708" comprises a circular shape. Figure 7B of the Application is shown below.

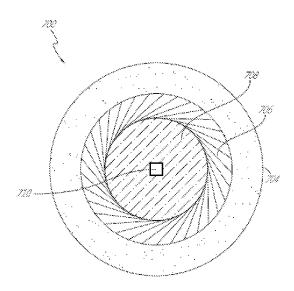


Figure 7B of Originally-filed Application

The ordinary meaning of the claim term "correspond" means to "have a close similarity; match or agree almost exactly" or "be analogous or equivalent in character, form, or function" or "represent." New Oxford American Dictionary, 390 (3rd Edition 2010). Consistent with this exemplary definition and the originally-filed application, the phrase "arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site" (see Claim 57) would be understood by a person having ordinary skill in the art as requiring a sufficient number of detectors such that, when arranged together in an array, can "match," "have a close similarity," or "represent" a "circular portion of the irradiated surface area." Similarly, the phrase "arranged in an array having a circular spatial configuration" (see Claims 67 and 77) would be understood by a person having ordinary skill in the art as including a sufficient number of detectors such that the array matches or represents a circular shape.

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In order for the claimed "plurality of detectors" to "match" or "represent" a circular shape, the "plurality of detectors" must include sufficient detectors to represent the circular shape. For example, six or more detectors could be arranged in a circular shape and meet the recited limitation. However, two detectors, for example, can only be arranged in a spatial configuration representing a line and three detectors, for example, can only be arranged in a spatial configuration representing a triangle. Thus, when read in view of the originally-filed application, the recited "plurality of detectors" would be understood by a person having ordinary skill in the art as including a sufficient number of detectors to represent the desired geometric shape.

C. Claim Objections

The Office Action objected to Claims 65, 75, and 80 and requested amending the term "spacial" to "spatial." *See* Office Action, p. 2. Applicant has cancelled Claims 65, 75, and 80 without prejudice or disclaimer and respectfully submits that the objections are thereby rendered moot.

D. Objection to the Drawings

In the Office Action, the Drawings are objected to under 37 C.F.R. § 1.84(p)(5) because they include the reference character 709 (see Figure 7A) which is not mentioned in the Specification. *See* Office Action, p. 2. Applicant has amended the Drawings as discussed above and respectfully requests that this objection be withdrawn.

E. Objection to the Specification

The Office Action objected to the Specification because of a typographical error and requested Applicant to amend "light concentrator 710" to "light concentrator 708" in paragraph [0053]. *See* Office Action, p. 2. Applicant thanks the Examiner for her careful review of the present application and has amended the Specification as shown above. Accordingly, Applicant respectfully requests this objection be withdrawn.

F. The Pending Claims Are Patentable over the Cited Art

Claims 57, 58, 60-62, 64-67, 69, 71-77, 79-82 and 84-86 stand rejected under 35 U.S.C. § 102(a)(1) as being anticipated by U.S. Patent No. 5,584,296 to Cui et al. (hereinafter "Cui"). Claims 57, 60-61, 63-68, 71-72, 74-80, 84-86 stand rejected as being unpatentable under 35 U.S.C. § 103 over U.S. Patent No. 8,452,364 to Hannula et al. ("Hannula") in view of U.S. Patent Pub. No. 2003/0036690 to Geddes et al. ("Geddes"). Applicant respectfully disagrees and -14-

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requests that the rejections of Claims 57-59, 61-64, 67-70, 72-74, 77-78, 81-83, and 85-86 be withdrawn and new Claims 87-95 be allowed for at least the following reasons.

1. Independent Claim 57

Amended Claim 57 recites, in part (emphasis added):

a light emission source comprising a plurality of emitters configured to *irradiate a circular portion of the tissue measurement site* by emitting light towards the tissue measurement site, the tissue measurement site being located on a wrist of the user, the plurality of emitters configured to emit one or more wavelengths;

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user; and

a light block forming an enclosing wall between the light emission source and the plurality of detectors, the light block defining the irradiated circular portion of the tissue measurement site, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to the circular portion of the irradiated tissue measurement site.

Applicant respectfully submits that the cited art, alone or in combination, fails to teach or suggest at least the above-recited limitations of Claim 57. For example, as discussed during the Interview, none of the cited art, alone or in combination, teaches or suggests the utilization of more than three detectors arranged in the recited configuration. For at least these reasons, Applicant respectfully requests withdrawal of the rejection of independent Claim 57 and allowance of the claim.

2. Independent Claim 67

Amended Claim 67 recites, in part (emphasis added):

irradiating a circular portion of a tissue measurement site by emitting, from a plurality of emitters of a light emission source of a physiological monitoring device, light of one or more wavelengths toward the tissue measurement site, the tissue measurement site located on a wrist of the user;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters of the light emission source after attenuation through tissue of the user at the tissue measurement site; and

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providing a cylindrical light block forming an enclosing wall between the light emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light;

Applicant respectfully submits that the cited art, alone or in combination, fails to teach or suggest at least the above-recited limitations of Claim 67. For example, as discussed during the Interview, none of the cited art, alone or in combination, teaches or suggests the utilization of more than three detectors arranged in the recited configuration. For at least these reasons, Applicant respectfully requests withdrawal of the rejection of independent Claim 67 and allowance of the claim.

3. Independent Claim 77

Amended Claim 77 recites, in part (emphasis added):

- a light emission source comprising a plurality of optical sources configured to *irradiate a circular portion of a tissue measurement site* by emitting light towards the tissue measurement site on a user, the tissue measurement site located on a wrist of the user, the plurality of optical sources configured to emit one or more wavelengths;
- a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, the plurality of detectors further configured to output at least one signal responsive to the detected light;
- a processor configured to receive the outputted at least one signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user; and
- a light block forming an enclosing wall between the light emission source and the plurality of detectors, the light emission source arranged proximate a first side of the enclosing wall and the plurality of detectors arranged proximate a second side of the enclosing wall, the first side being different than the second side, the light block forming a light isolation chamber defined by the enclosing wall, wherein the enclosing wall prevents at least a portion of light emitted from the light emission source from being detected by the plurality of detectors without attenuation by the tissue, and wherein the plurality of detectors are arranged in an array having a circular spatial configuration, the circular spatial configuration arranged to receive said attenuated light.

Applicant respectfully submits that the cited art, alone or in combination, fails to teach or suggest at least the above-recited limitations of Claim 77. For example, as discussed during the Interview, none of the cited art, alone or in combination, teaches or suggests the utilization of

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more than three detectors arranged in the recited configuration. For at least these reasons, Applicant respectfully requests withdrawal of the rejection of independent Claim 77 and allowance of the claim.

4. Dependent Claims 58-59, 61-64, 68-70, 72-74, 78, 81-83, and 85

Claims 58-64, 68-70, 72-74, 78, 81-83, and 85 depend directly or indirectly from Claims 57, 67, or 77 and are thus patentably distinct from the cited art of record for at least the reasons set forth above in regard to Claims 57, 67, or 77. In addition, Applicant notes that these claims, when taken in the context of Claims 57, 67, or 77, set forth a number of recitations not taught, disclosed, or suggested by the cited references, alone or in combination. For at least these additional reasons, Applicant respectfully requests that the rejections of Claims 58-64, 68-70, 72-74, 78, 81-83, and 85 be withdrawn and the claims allowed.

5. <u>New Claims 87-95</u>

Claims 87-95 were added in the present paper and our believed to be patentable over the cited art. Accordingly, Applicant respectfully requests that Claims 87-95 be indicated as allowable.

G. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 1, 2019 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404 Docket No.: MAS.1007C1 Customer No. 64735

INFORMATION DISCLOSURE STATEMENT

First Inventor: Ammar Al-Ali

App. No. : 16/226249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791 Conf. No. : 1002

Mail Stop Amendment

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

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Copies of any listed foreign and non-patent literature references are being submitted.

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed after receipt of a First Office Action, but before the mailing date of a Final Action and before the mailing date of a Notice of Allowance.

This Statement is accompanied by the fees set forth in 37 CFR 1.17(p). The Commissioner is hereby authorized to charge any additional fees which may be required or to credit any overpayment to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 1, 2019 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

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PTO/SB/08 Equivalent

| | Application No. | 16/226249 |
|---------------------------------------|----------------------|-------------------|
| INFORMATION DISCLOSURE | Filing Date | December 19, 2018 |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY AFFEIGANT | Art Unit | 3791 |
| (Multiple sheets used when necessary) | Examiner | Fardanesh, Marjan |
| SHEET 1 OF 1 | Attorney Docket No. | MAS.1007C1 |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|-------------|---|-----------------------------------|--------|--|--|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | | |
| | 1 | 5,830,137 | 11-03-1998 | Scharf | | | |

| | FOREIGN PATENT DOCUMENTS | | | | | | | |
|----------------------|--------------------------|--|-----------------------------------|------|---|----|--|--|
| Examiner Initials | Cite No. | Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T¹ | | |

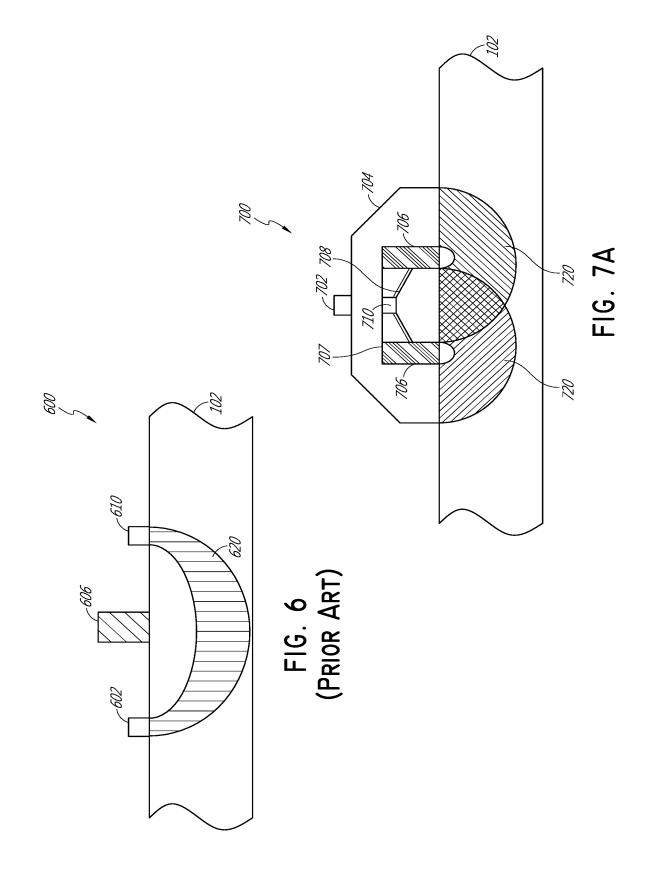
| NON PATENT LITERATURE DOCUMENTS | | | | |
|---------------------------------|-------------|---|----|--|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T¹ | |

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Examiner Signature Date Considered

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

T¹ - Place a check mark in this area when an English language Translation is attached.



| Electronic Patent Application Fee Transmittal | | | | | | | |
|---|--------------------------------------|--------------------------------|----------|--------|-------------------------|--|--|
| Application Number: | 16226249 | | | | | | |
| Filing Date: | 19 | Dec-2018 | | | | | |
| Title of Invention: | | ADVANCED PULSE OXIMETRY SENSOR | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | | | |
| Filed as Large Entity | | | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) | | |
| Basic Filing: | | | | | | | |
| Pages: | | | | | | | |
| Claims: | | | | | | | |
| Miscellaneous-Filing: | | | | | | | |
| Petition: | | | | | | | |
| Patent-Appeals-and-Interference: | | | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | | | |
| Extension-of-Time: | | | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
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| Miscellaneous: | | | | |
| SUBMISSION- INFORMATION DISCLOSURE STMT | 1806 | 1 | 240 | 240 |
| | Total in USD (\$) | | 240 | |
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| Electronic Acknowledgement Receipt | | | | | |
|--------------------------------------|-------------------------------------|--|--|--|--|
| EFS ID: | 36460609 | | | | |
| Application Number: | 16226249 | | | | |
| International Application Number: | | | | | |
| Confirmation Number: | 1002 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | |
| Customer Number: | 64735 | | | | |
| Filer: | Aaron Samuel Johnson/Evelyn Salcido | | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | |
| Receipt Date: | 01-JUL-2019 | | | | |
| Filing Date: | 19-DEC-2018 | | | | |
| Time Stamp: | 14:39:06 | | | | |
| Application Type: | Utility under 35 USC 111(a) | | | | |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$240 |
| RAM confirmation Number | 070219INTEFSW14394100 |
| Deposit Account | 111410 |
| Authorized User | Evelyn Salcido |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing: | | | | | |
|--------------------|---|-----------------------------------|--|---------------------|--------------------|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl. |
| | | | 105119 | | |
| 1 | | OAR_MAS1007C1.pdf | d54bd2461beb11027022825cea10c30a3e4 feab9 | yes | 18 |
| | Multip | part Description/PDF files in | zip description | | |
| | Document De | scription | Start | E | nd |
| | Amendment/Req. Reconsiderat | 1 | 1 | | |
| | Specificat | 2 | 2 | | |
| | Claims | | 3 | 9 | |
| | Drawings-only black and white line drawings | | 10 | 10 | |
| | Applicant summary of interview with examiner | | 11 | 11 | |
| | Applicant Arguments/Remarks | 12 | 18 | | |
| Warnings: | | | | | |
| momation. | | | 44968 | | |
| 2 | | IDS_MAS1007C1.pdf | 4b375a8c8aa60c06cae40512710f462514f4 244a | yes | 2 |
| | Multipart Description/PDF files in .zip description | | | | |
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| | Transmittal Letter | | 1 | 1 | |
| | Information Disclosure Statement (IDS) Form (SB08) | | 2 | 2 | |
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| | | | 62554 | | | | |
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| 3 | Drawings-only black and white line drawings | REPLACEMENT_MAS1007C1. pdf | c4dc3a082ace834b17f69214b4b5672203d 73b0a | no | 1 | | |
| Warnings: | | | | | | | |
| Information: | | | | | | | |
| | | | 30470 | | | | |
| 4 | Fee Worksheet (SB06) | fee-info.pdf | dab75d37fcf9d7aac9404760c1292189c010 3ae7 | no | 2 | | |
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| Information: | | | | | | | |
| | Total Files Size (in bytes) | | | 243111 | | | |

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New Applications Under 35 U.S.C. 111

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

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

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| Electronic Ack | knowledgement Receipt |
|--------------------------------------|-------------------------------------|
| EFS ID: | 36460609 |
| Application Number: | 16226249 |
| International Application Number: | |
| Confirmation Number: | 1002 |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR |
| First Named Inventor/Applicant Name: | Ammar Al-Ali |
| Customer Number: | 64735 |
| Filer: | Aaron Samuel Johnson/Evelyn Salcido |
| Filer Authorized By: | Aaron Samuel Johnson |
| Attorney Docket Number: | MAS.1007C1 |
| Receipt Date: | 01-JUL-2019 |
| Filing Date: | 19-DEC-2018 |
| Time Stamp: | 14:39:06 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$240 |
| RAM confirmation Number | 070219INTEFSW14394100 |
| Deposit Account | 111410 |
| Authorized User | Evelyn Salcido |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing: | | | | | |
|--------------------|------------------------------|------------------------------------|--|---------------------|--------------------|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl. |
| | | | 105119 | | |
| 1 | | OAR_MAS1007C1.pdf | d54bd2461beb11027022825cea10c30a3e4 feab9 | yes | 18 |
| | Multip | part Description/PDF files in | zip description | | |
| | Document De | scription | Start | E | nd |
| | Amendment/Req. Reconsiderat | ion-After Non-Final Reject | 1 | | 1 |
| | Specificat | 2 | 2 | | |
| | Claims | 3 | 9 | | |
| | Drawings-only black and | 10 | 10 | | |
| | Applicant summary of inte | 11 | 11 | | |
| | Applicant Arguments/Remarks | 12 | 18 | | |
| Warnings: | | | | | |
| | | | 44968 | | |
| 2 | | IDS_MAS1007C1.pdf | 4b375a8c8aa60c06cae40512710f462514f4 244a | yes | 2 |
| | Multip | ! part Description/PDF files in | zip description | | |
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| 4 | Fee Worksheet (SB06) | fee-info.pdf | dab75d37fcf9d7aac9404760c1292189c010 3ae7 | no | 2 |
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National Stage of an International Application under 35 U.S.C. 371

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

New International Application Filed with the USPTO as a Receiving Office

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PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERGE
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| PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875 Applicat | | | | | | | n or Docket Number 16/226,249 | Filing Date 12/19/2018 | To be Mailed |
|---|---|---|--------------------------|---|-------------------------------------|--------------|----------------------------------|---------------------------|----------------|
| | | | | | | | | LARGE SM | IALL MICRO |
| | | | | | ATION AS FII | LED - PAF | RTI | | |
| | FOR | | (Column IUMBER FI | / | (Column 2) NUMBER EXTRA | | RATE (\$) | | FEE (\$) |
| D BAGIO SEE | | | | | | | | + | ΓΕΕ (Φ) |
| | (37 CFR 1.16(a), (b), o | or (c)) | N/A | | N/A | | N/A | | |
| | SEARCH FEE (37 CFR 1.16(k), (i), o | r (m)) | N/A | | N/A | | N/A | | |
| | EXAMINATION FEE (37 CFR 1.16(o), (p), c | | N/A | | N/A | | N/A | | |
| | AL CLAIMS DFR 1.16(i)) | | mi | nus 20 = * | | | x \$100 = | | |
| | EPENDENT CLAIM DFR 1.16(h)) | IS | n | ninus 3 = * | | | x \$460 = | | |
| | APPLICATION SIZE DFR 1.16(s)) | FEE (37 of p for frac | aper, the small entit | ation and drawin application size t y) for each addit of. See 35 U.S.C | fee due is \$310 ional 50 sheets | (\$155 or | | | |
| | MULTIPLE DEPEN | DENT CLAIM PF | ESENT (3 | 7 CFR 1.16(j)) | | | | | |
| * If th | ne difference in co | olumn 1 is less | than zero | , enter "0" in colu | ımn 2. | | TOTAL | | |
| | | | | APPLICAT | TION AS AME | NDED - P | ART II | | |
| | | (Column 1) | | (Column 2) | (Column 3 | 3) | | | |
| AMENDMENT | 07/01/2019 | CLAIMS REMAINING AFTER AMENDMENT | ING NUMBER PREVIOUSLY | | PRESENT EX | (TRA | RATE (\$) ADDI | | IONAL FEE (\$) |
| I≅I | Total (37 CFR 1.16(i)) | * 30 | Minus | ** 30 | = 0 | | x \$100 = | | 0 |
| | Independent (37 CFR 1.16(h)) | * 3 | Minus | *** 3 | = 0 | | x \$460 = | | 0 |
| ¥ | | Size Fee (37 C | FR 1.16(s |)) | | | | | |
| | ☐ FIRST PRES | SENTATION C | F MULTIF | PLE DEPENDEN | IT CLAIM (37 CF | =R | | | |
| | | | | | | • | TOTAL ADD'L FE | E | 0 |
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| ₽ | CLAIMS REMAINING AFTER AMENDMENT CLAIMS HIGHEST NUMBER PREVIOUSLY PREVIOUSLY PAID FOR | | | | | | | ADDIT | IONAL FEE (\$) |
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| MENDMENT | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | | x \$0 = | | |
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| FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) | | | | | | | | | |
| | | | | TOTAL ADD'L FE | E | | | | |
| * If t | he entry in column | 1 is less than the | entry in col | umn 2, write "0" in | column 3. | | LIE | | |
| ** If | the "Highest Numbe | er Previously Pai | d For" IN T | HIS SPACE is less | than 20, enter "20 |)". | /TERRY BRY | ANT/ | |
| *** | f the "Highest Numb | per Previously Pa | id For" IN 7 | HIS SPACE is less | s than 3, enter "3". | | | | |
| The | The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1. | | | | | | | | |

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APPLICATION NUMBER 16/226,249

FILING OR 371(C) DATE 12/19/2018

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE

MAS.1007C1

Ammar Al-Ali

CONFIRMATION NO. 1002

PUBLICATION NOTICE

64735 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614

Title: ADVANCED PULSE OXIMETRY SENSOR

Publication No.US-2019-0117140-A1 Publication Date:04/25/2019

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.

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

page 1 of 1

Doc Code: ECOMM.AUTH/ECOMM.WTDW

Doc Description: Internet Communications Authorized/Internet Communications Authorization Withdrawn

PTO/SB/439 (11-15)

| AUTHORIZATION FOR INTERNET |
|-----------------------------------|
| COMMUNICATIONS IN A PATENT |
| APPLICATION OR REQUEST TO |
| WITHDRAW AUTHORIZATION FOR |
| INTERNET COMMUNICATIONS |

| Application No. | 16/226249 |
|-------------------------|-------------------|
| Filing Date | December 19, 2018 |
| First Named Inventor | Ammar Al-Ali |
| Art Unit | 3791 |
| Examiner Name | Fardanesh, Marjan |
| Practitioner Docket No. | MAS.1007C1 |

| INTERNET COMMUNICATIONS | Examiner Name | Fardanesh, Marjan |
|--|---|--|
| | Practitioner Docket No. | MAS.1007C1 |
| To: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 | | |
| I. To authorize permission for Internet Com | munications. | |
| with the undersigned and practitioners in ac | ccordance with 37 CFR ncing, instant messagin | nereby authorize the USPTO to communicate 1.33 and 37 CFR 1.34 concerning any subject g, or electronic mail. I understand that a copy of e. (MPEP 502.03) |
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| applicant. | | |
| attorney or agent of record. Reg | gistration number 74 , | 164 |
| attorney or agent acting under | 37 CFR 1.34. Registrati | on number |
| /Aaron S. Johnson/ | <u>4-1</u> | 8-2019 |
| Signature | | Date |
| Aaron S. Johnson | | 9) 760-0404 |
| Typed or printed name | | Telephone Number |
| must be represented by a patent practitioner (see 37 C | FR 1.31, which is applicable | r signature requirements and certifications. Juristic entities to any paper filed on or after September 16, 2012, that is t multiple forms if more than one signature is required, see |
| * Total of forms are submitted. | | |

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| Electronic Ack | knowledgement Receipt |
|--------------------------------------|----------------------------------|
| EFS ID: | 35764634 |
| Application Number: | 16226249 |
| International Application Number: | |
| Confirmation Number: | 1002 |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR |
| First Named Inventor/Applicant Name: | Ammar Al-Ali |
| Customer Number: | 64735 |
| Filer: | Aaron Samuel Johnson/Imran Ahmed |
| Filer Authorized By: | Aaron Samuel Johnson |
| Attorney Docket Number: | MAS.1007C1 |
| Receipt Date: | 18-APR-2019 |
| Filing Date: | 19-DEC-2018 |
| Time Stamp: | 13:42:49 |
| Application Type: | Utility under 35 USC 111(a) |

Payment information:

| Submitted with Payment | | | no | | | | |
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| File Listin | g: | | | | | | |
| Document Number | Document Description | | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) | |
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| 1 | Internet Communications Authorized | munications Authorized Internet-Comm- Autho_MAS1007C1.pdi | | 0e279929698a874a027a40f5eba5acfb2c4f 180f | no | 2 | |
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| Total Files Size (in bytes): | 75415 |

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New Applications Under 35 U.S.C. 111

the application.

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| | APPLICATION NO. FILING DATE FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|--|--|-------------------------------------|---------------------|-------------------|---------------|--|
| | 16/226,249 | 12/19/2018 | MAS.1007C1 | 1002 | | |
| | | 7590 03/29/201 RTENS, OLSON & BI | EXAM | IINER | | |
| MASIMO CORPORATION (MASIMO) 2040 MAIN STREET | | | | FARDANESH, MARJAN | | |
| | FOURTEENTH | | ART UNIT | PAPER NUMBER | | |
| IRVINE, CA 92614 | | | | 3791 | | |
| | | | | NOTIFICATION DATE | DELIVERY MODE | |
| | | | | 03/29/2019 | ELECTRONIC | |

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

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efiling@knobbe.com jayna.cartee@knobbe.com

| | 16/226,249 | Applicant(s) Al-Ali et al. | |
|--|---|---|--|
| Office Action Summary | Examiner MARJAN FARDANESH | Art Unit 3791 | AIA (FITF) Status Yes |
| The MAILING DATE of this communication app | ears on the cover sheet with the c | orrespondenc | e address |
| Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed after SIX (6 the mailing date of ED (35 U.S.C. § 133 | 6) MONTHS from the mailing this communication. |
| Status | | | |
| 1) Responsive to communication(s) filed on | <u></u> | | |
| A declaration(s)/affidavit(s) under 37 CFR 1.1 | 30(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 responsible. ; the restriction requirement and election | | | g the interview on |
| 4) Since this application is in condition for allowar | | | n the merits is |
| closed in accordance with the practice under E | | | y the monte to |
| Disposition of Claims* | | | |
| 5) ✓ Claim(s) 57-86 is/are pending in the appli | cation. | | |
| 5a) Of the above claim(s) is/are withdraw | wn from consideration. | | |
| 6) Claim(s) is/are allowed. | | | |
| 7) ✓ Claim(s) 57-86 is/are rejected. | | | |
| 8) Claim(s) is/are objected to. | | | |
| 9) Claim(s) are subject to restriction and | l/or election requirement | | |
| * If any claims have been determined <u>allowable</u> , you may be eli | | secution Highv | way program at a |
| participating intellectual property office for the corresponding ap | pplication. For more information, plea | ise see | |
| $\underline{\text{http://www.uspto.gov/patents/init_events/pph/index.jsp}} \text{ or send}$ | an inquiry to PPHfeedback@uspto | .gov. | |
| Application Papers | | | |
| 10) The specification is objected to by the Examine | er. | | |
| 11) The drawing(s) filed on is/are: a) acc | cepted or b) objected to by th | e Examiner. | |
| Applicant may not request that any objection to the d | rawing(s) be held in abeyance. See 3 | 7 CFR 1.85(a). | |
| Replacement drawing sheet(s) including the correction | on is required if the drawing(s) is obje | cted to. See 37 | CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign Certified copies: | priority under 35 U.S.C. § 119(a |)-(d) or (f). | |
| a) ☐ All b) ☐ Some** c) ☐ None of th | e: | | |
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| Certified copies of the priority docume | ents have been received in Applic | cation No | <u></u> . |
| 3. Copies of the certified copies of the prapplication from the International Bure | | eived in this N | ational Stage |
| ** See the attached detailed Office action for a list of the certific | ` ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' | | |
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| Attachment(s) | | | |
| 1) V Notice of References Cited (PTO-892) | 3) Interview Summary | | |
| 2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S | B/08b) Paper No(s)/Mail D 4) Other: | ale | |

Paper No(s)/Mail Date <u>1</u>
U.S. Patent and Trademark Office
PTOL-326 (Rev. 11-13)

Office Action Summary

Part of Paper No./Mail Date 20190219

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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.

Claim Objections

2. Claims 65, 75, 80 are objected to because of the following informalities: In line 2, change "spacial" to "spatial". Appropriate correction is required.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: reference character 709 in figure 7A not mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) 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. Each drawing sheet submitted after the filling 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

4. The disclosure is objected to because of the following informalities: In [0053], line 8, Applicant should change "light concentrator 710" to "light concentrator 708".

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Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

6. Claim(s) 57, 58, 60-62, 64-67, 69, 71-77, 79-82, and 84-86 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Cui et al. (USPN 5,584,296).

Regarding claims 57, 67, 77, Cui et al. discloses a wrist-worn physiological monitoring device configured for placement on a user at a tissue measurement site, the device comprising: a plurality of emitters configured to emit light towards the tissue measurement site (elements 36a-b, figures 7, 9-10, Col.11 line 2-Col.12 line 5), the tissue measurement site being located on a wrist of the user (the emitters are configured to irradiate any tissue of the user such a wrist of the user), the plurality of emitters comprising one or more light-emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength (Col.11 line 2-Col.12 line 5); a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light (elements 34,32, figures 7, 9-10, Col.11 line 2-Col.12 line 5); a processor configured to receive the at least one signal responsive to the

Page 4

output and determine a physiological parameter of the user (processor 18, Col.4 lines 26-50); and a light block forming an enclosing wall between the light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the wall prevents at least a portion of light emitted from the plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue (element 60 figure 10, Col.7 line 50-Col.8 line 43).

Regarding claims 58, 69, 82, Cui et al. discloses a display (element 22) configured to present information related to the determined physiological parameter to the user (Col.4 lines 26-50).

Regarding claims 60, 71, 84, Cui et al. discloses the enclosing wall of the light block is a circular wall (element 60 figure 10 Col.7 line 50-Col.8 line 43).

Regarding claims 61, 72, 85, Cui et al. discloses when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user (figure 9).

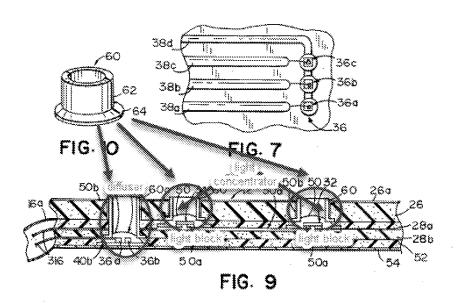
Regarding claims 62, 73,81, Cui et al. discloses a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site (the inside surface of element 60 a figure 9 acts as a diffuser since it has an optical reflective surface, Col.7 line 50-Col.8 line 43).

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Regarding claims 64, 74, 86, Cui et al. discloses the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate (Col.2 lines 5-45).

Regarding claims 65, 75, 79, 80, Cui et al. discloses the plurality of detectors are arranged in an array with a spatial configuration corresponding to an irradiated surface area (figure 9).

Regarding claims 66, 76, Cui et al. discloses the irradiated surface area comprises a circular shape (figures 9-10).



Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 57,60-61, 63-68,71-72, 74-80, 84-86, is/are rejected under 35 U.S.C. 103 as being unpatentable over Hannula et al. (USPN 8,452,364) in view of Geddes et al. (USPN 2003/0036690).

Regarding claims 57, 67, 77, Hannula et al. discloses a wrist-worn physiological monitoring device configured for placement on a user at a tissue measurement site, the device comprising: a plurality of emitters configured to emit light towards the tissue measurement site (elements 18 figure 1B), the tissue measurement site being located on a wrist of the user (the emitters are configured to irradiate any tissue of the user such a wrist of the user), the plurality of emitters comprising one or more light-emitting diodes (Col.4 lines 10-62) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength (Col.3 lines 50-64); detector (18) configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the detector comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light (Col.4 lines 10-62); a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user (Col.8 lines 22-50); and a light block forming an enclosing wall between the light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the wall prevents at least a portion of light emitted from the plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue (optical barrier 20, Col.4 line 36-Col.5 line 45). While Hannula et al. discloses two emitters and a detector or two detector and an emitter configurations, it fails to disclose

two emitters and two detectors. Geddes et al. discloses that the configuration of two emitters and one detector and the configuration of two detectors and one emitter can be combined resulting in two emitters and two detectors ([0040]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made before the effective filing date of the claimed invention (AIA) to have modified the configuration of the emitters and detector of Hannula et al. by including two detectors and two emitters, with a reasonable expectation of success, because the prior art teaches two emitters and a detector or two detector and an emitter configurations, as taught by Hannula et al., and since the configuration of two emitters and one detector and the configuration of two detectors and one emitter can be combined resulting in two emitters and two detectors would have been known in the art, as taught by Geddes et al.. The rationale would have been the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Regarding claims 60, 71, 84, Hannula et al. discloses the enclosing wall of the light block is a circular wall (optical barrier figures 3A, 5A).

Regarding claims 61, 72, 85, Hannula et al. discloses when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user (figures 1 and 5).

Regarding claims 63, 68, 78, the combination of Hannula et al. and Geddes et al. discloses the plurality of emitters (elements 18 figure 1B) are positioned outside the

enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors (elements 16) are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site (figure 1B).

Regarding claims 64, 74, 86, Hannula et al. discloses the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate (Col.8 lines 22-50).

Regarding claims 65, 75, 79, 80, the combination of Hannula et al. and Geddes et al discloses the plurality of detectors are arranged in an array with a spatial configuration corresponding to an irradiated surface area (figure 1B).

Regarding claims 66, 76, the combination of Hannula et al. and Geddes et al discloses the irradiated surface area comprises a circular shape (figures 1B, 3A, 5A).

9. Claims 59, 70, 83 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cui et al. (USPN 5,584,296) as applied to claims 58,69, 82 above, and further in view of Swenson et al. (USPN 5,623,925).

Cui et al. fails to disclose that the display is a touch-screen display. Swenson et al. discloses that the computer monitor has touch screen capabilities (Col.4 lines 54-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made before the effective filing date of the claimed invention (AIA) to have modified the display of Cui et al. by including touch screen capabilities, with a reasonable expectation of success, because the prior art teaches computer monitor 22 (figure 1), as taught by Cui et al., and since computer monitor with touch screen capabilities would have been known in the art, as taught by Swenson et al.. The

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rationale would have been the predictable use of prior art elements according to their established functions. KSR, 550, U.S. at 417.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Mallari can be reached on (571)272-4729. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC F WINAKUR/ Primary Examiner, Art Unit 3791

/MARJAN FARDANESH/ Examiner, Art Unit 3791

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| * | С | US-20030036690-A1 | 02-2003 | Geddes, Leslie A. | | | A61B5/02233 | 600/323 |
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

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Part of Paper No. 20190219

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| Searci | n Notes | 16/226,249 | Al-Ali et al. | | | | | |
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| | | MARJAN FARDANESH | 3791 | | | | | |
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| Search Notes PALM-inventor | | /CPC Group | | | | | | |
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| Index of Claims | 16/226,249 | Al-Ali et al. |
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| | MARJAN FARDANESH | 3791 |

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EAST Search History

EAST Search History (Prior Art)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
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| L1 | 1 | ("5584296").PN. | USPAT; USOCR | OR | OFF | 2019/03/04 11:33 |
| S1 | 1 | JP-2005192879-\$.did. | DERWENT | AND | ON | 2011/01/04 11:01 |
| S2 | 1 | "2002111544".pn. | DERWENT | AND | ON | 2011/01/04 11:14 |
| S3 | 2 | "2002111544".pn. | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | AND | ON | 2011/01/04 11:14 |
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| S13 | 139 | whitman michael.in. and "2002" | US-PGPUB; USPAT | AND | ON | 2011/01/04 13:39 |
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| S23 | 3 | takizawa.in. and (600/309-310).ccls. | US-PGPUB; USPAT | AND | ON | 2011/01/05 11:16 |
| S24 | 4 | kawano.in. and (600/309-310).ccls. | US-PGPUB; USPAT | AND | ON | 2011/01/05 11:18 |
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| S28 | 28 | (600/309-310).ccls. and pill | US-PGPUB; USPAT | AND | ON | 2011/01/05 11:26 |
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| S30 | 1597 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:09 |
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| S31 | 545 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:10 |
| S32 | 493 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:11 |
| S33 | 472 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor and (heat or thermal or temperature) | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:12 |
| S34 | 94 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor and (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:15 |
| S35 | 87 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:20 |
| S36 | 1 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) same (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:21 |
| S37 | 1 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) same usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:21 |
| S38 | 87 | (600/309,310,317,345,347,361).ccls. and (heat\$3 or dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:22 |
| S39 | 71 | (600/309,310,317,345,347,361).ccls. and (heat\$3 and dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB: USPAT | AND | ON | 2011/01/05 13:38 |
| S40 | 0 | (600/309,310,317,345,347,361).ccls. and (heat\$3 same dry\$3) and (recover\$3 or restore\$3 or resets3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:39 |
| S41 | 71 | (600/309,310,317,345,347,361).ccls. and (heat\$3 and dry\$3) and (recover\$3 or restore\$3 or reset\$3) and sensor same (heat or thermal or temperature) and usage | US-PGPUB; USPAT | AND | ON | 2011/01/05 13:39 |
| S42 | 65 | emitter same detector same (distance offset) and A61B5/\$.cpc. | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | AND | ON | 2018/12/28 17:00 |

| S43 | 1328 | emitter same detector same (distance offset) and A61B5/\$.cpc. | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | ON | 2018/12/28 17:02 |
|-----|------|--|--|-----|-----|-----------------------------|
| S46 | 1 | "20090105564".pn. | US-PGPUB; USPAT | AND | ON | 2019/01/02 12:56 |
| S47 | 7 | (("8277384") or ("4743107") or ("20020016533") or ("20140206980") or ("20170209047") or ("20090209834") or ("20120277559")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/02 15:30 |
| S48 | 1 | "15132279" | US-PGPUB; USPAT | OR | OFF | 2019/01/02 15:33 |
| S49 | 11 | (("4699376") or ("4583555") or ("8282579") or ("7785232") or ("6436058") or ("8341850") or ("20060064044") or ("20120226199") or ("20080132818") or ("20070043308") or ("20160000369")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/02 17:0 4 |
| S50 | 0 | "15581656" | US-PGPUB; USPAT | OR | OFF | 2019/01/02 17:43 |
| S51 | 0 | "15581656" | US-PGPUB; USPAT | OR | OFF | 2019/01/02 17:44 |
| S52 | 1 | "20060064044".pn. | US-PGPUB; USPAT | OR | OFF | 2019/01/02 17:48 |
| S53 | 1 | ("5833603").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/02 19:09 |
| S54 | 1 | ("20060249690").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/03 13:46 |
| S55 | 1 | ("20110133730").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/03 13:46 |
| S56 | 0 | "14957840" | US-PGPUB; USPAT | OR | OFF | 2019/01/03 13:47 |
| S61 | 3 | (("7941199") or ("8224411") or ("8385996")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/21 14:54 |
| S62 | 933 | (oximetry oximeter) and ratio same AC | US-PGPUB; USPAT | OR | ON | 2019/01/21 15:13 |
| S63 | 426 | (oximetry oximeter) and ratio same AC same wavelength\$1 | US-PGPUB; USPAT | OR | ON | 2019/01/21 15:13 |
| S64 | 19 | newberry.in. and ratio same AC same wavelength\$1 | US-PGPUB; USPAT | OR | ON | 2019/01/21 15:23 |
| S65 | 2 | newberry.in. and ratio same AC same wavelength\$1.clm. | US-PGPUB; USPAT | OR | ON | 2019/01/21 15:24 |
| S66 | 877 | AC same first same second same (spectral spectrum wavelength\$1 pulsating pulsatile pulse) same ratio | US-PGPUB; USPAT | OR | ON | 2019/01/22 11:00 |
| S67 | 110 | AC same first same second same (spectral spectrum wavelength\$1 pulsating pulsatile pulse) same ratio and A61B5/\$.cpc. | US-PGPUB; USPAT | | ON | 2019/01/22 11:01 |
| S68 | 46 | AC same first same second same | US-PGPUB; | OR | ON | 2019/01/22 |

| | | (spectral spectrum wavelength\$1 pulsating pulsatile pulse) same ratio and (hyperglycemi\$3 diabet\$3 hypoglycemi\$3 glucose) | USPAT | | | 11:23 |
|-----|-------|--|------------------------------|----|-----|---------------------|
| S69 | 1 | "15958620" and AC and (glucose hyperglycem\$4 hypoglycem\$4) and ratio and compar\$4 and threshold\$1 | US-PGPUB; USPAT | OR | ON | 2019/01/22 12:19 |
| S70 | 226 | ratio and wavelength and threshold and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:37 |
| S71 | 23 | lambert and threshold with compar\$5 and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:45 |
| S72 | 19 | lambert and AC and threshold same compar\$5 and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:47 |
| S73 | 20 | lambert and AC and threshold and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:51 |
| S74 | 1 | S73 not S72 | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:51 |
| S75 | 771 | AC and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:52 |
| S76 | 20 | AC and lambert and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:52 |
| S77 | 1 | S76 not S72 | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:52 |
| S78 | 204 | AC and DC and (alert\$4 alarm\$4) same (hyperglycem\$4 hypoglycem\$4) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/22 13:53 |
| S79 | 1 | newberry.in. and AC same compar\$4 same threshold\$4.clm. | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:03 |
| S80 | 4 | newberry.in. and AC.clm. | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:03 |
| S81 | 35060 | (LED diode light adj source) same switch\$4 with frequenc\$4 | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:43 |
| S82 | 18125 | (LED diode light adj source) with switch\$4 with frequenc\$4 | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:44 |
| S83 | 385 | (LED diode light adj source) with switch\$4 with frequenc\$4 and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:45 |
| S84 | 271 | frequenc\$5 with depend\$5 with switch\$5 and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:52 |
| S85 | 20 | frequenc\$5 with depend\$5 with switch\$5 same (light adj source LED diode) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/22 14:53 |
| S86 | 1 | "13985232" and encapsulat\$5 | US-PGPUB; USPAT | OR | ON | 2019/01/22 16:22 |
| S87 | 1 | "5217013".pn. | US-PGPUB; USPAT | OR | ON | 2019/01/22 16:27 |
| S88 | 220 | ("4321930" "4380240" "4510938" "4819752" "4825879" "4865038" "4880304" "4928691" "4964408" "5094240" "5111817").PN. OR ("5217013").URPN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/22 16:53 |
| S89 | 1 | "20100049018".pn. | US-PGPUB; | OR | OFF | 2019/01/22 |

| | | | USPAT; USOCR | | | 17:01 |
|------|------|--|------------------------------|----|-----|---------------------|
| S90 | 1 | "20090182209".pn. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/22 17:22 |
| S91 | 3 | (("20110245686") or ("20020115918") or ("20100252721")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/24 11:10 |
| S92 | 1 | "14773755" | US-PGPUB; USPAT | OR | OFF | 2019/01/24 11:18 |
| S93 | 314 | lens same fourier adj transform and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/24 11:43 |
| S94 | 6 | (("20110118571") or ("20070213607") or ("6921366") or ("20160356746") or ("20150005611") or ("7039446")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/29 09:34 |
| S95 | 1 | ("5217013").PN. | USPAT; USOCR | OR | OFF | 2019/01/29 15:46 |
| S96 | 1 | ("20100298678"). PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/29 15:58 |
| S97 | 0 | ("145309087").PN. | USPAT; USOCR | OR | OFF | 2019/01/29 16:26 |
| S98 | 0 | ("14309087").PN. | USPAT; USOCR | OR | OFF | 2019/01/29 16:26 |
| S99 | 1 | "14309087" | USPAT | OR | OFF | 2019/01/29 16:26 |
| S100 | 1 | "20100073669" | USPAT | OR | OFF | 2019/01/29 16:34 |
| S101 | 2 | "20100073669" | US-PGPUB; USPAT | OR | OFF | 2019/01/29 16:34 |
| S102 | 2 | "14108012" | US-PGPUB; USPAT | OR | OFF | 2019/01/30 11:40 |
| S103 | 3717 | electrical\$5 with conductive\$4 same (copper carbon) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/30 11:43 |
| S104 | 254 | electrical\$5 with conductive\$4 same (copper carbon) and A61B5/1455\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/01/30 11:51 |
| S105 | 532 | "6519487" | US-PGPUB; USPAT | OR | ON | 2019/01/30 12:38 |
| S106 | 1 | ("6519487").PN. | USPAT; USOCR | OR | OFF | 2019/01/30 12:38 |
| S107 | 0 | ("16030303").PN. | USPAT; USOCR | OR | OFF | 2019/01/30 14:52 |
| S108 | 1 | "16030303" | US-PGPUB; USPAT | OR | OFF | 2019/01/30 14:53 |
| S109 | 1 | "5217013".pn. | US-PGPUB; USPAT | OR | OFF | 2019/01/30 15:01 |
| S110 | 2 | (("20100049018") or ("20090182209")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/30 15:04 |
| S111 | 1 | "13985232" | US-PGPUB; USPAT | OR | OFF | 2019/01/30 15:06 |
| S112 | 1 | ("20100041969").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/30 15:22 |

| | 1 | and A61B5/\$.cpc. | USPAT | L | | 15:39 |
|------|-----|--|------------------------------|----|-----|---------------------|
| S114 | 1 | ("6097975").PN. | USPAT; USOCR | OR | OFF | 2019/01/30 15:41 |
| S115 | 1 | ("6067463").PN. | USPAT; USOCR | OR | OFF | 2019/01/30 15:42 |
| S116 | 205 | weighted same subtract\$5 same reference and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/01/30 15:49 |
| S117 | 0 | ("20090253996").PN. | USPAT; USOCR | OR | OFF | 2019/01/30 16:00 |
| S118 | 1 | ("20090253996").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/30 16:01 |
| S119 | 1 | ("20060264727").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/30 16:03 |
| S120 | 2 | "14108012" | US-PGPUB; USPAT | OR | OFF | 2019/01/30 16:48 |
| S121 | 7 | lee.in. and lifescan.asn. | US-PGPUB; USPAT | OR | OFF | 2019/01/30 16:49 |
| S122 | 0 | fardanesh.xa. and lifescan.asn. | US-PGPUB; USPAT | OR | OFF | 2019/01/30 16:50 |
| S123 | 2 | (("6097975") or ("6067463")).PN. | USPAT; USOCR | OR | OFF | 2019/01/31 10:43 |
| S124 | 77 | (remov\$4 filter\$4 subtract\$4) with weighted with reference and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/01/31 10:55 |
| S125 | 276 | (remov\$4 filter\$4 subtract\$4) with weighted same reference and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/01/31 11:01 |
| S126 | 199 | S125 not S124 | US-PGPUB; USPAT | OR | OFF | 2019/01/31 11:01 |
| S127 | 1 | ("20100073669").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/01/31 12:35 |
| S128 | 1 | "12110994" | USPAT | OR | OFF | 2019/01/31 17:54 |
| S129 | 270 | fardanesh.xa. | US-PGPUB; USPAT | OR | ON | 2019/01/31 18:39 |
| S130 | 1 | ("6067463").PN. | USPAT; USOCR | OR | OFF | 2019/01/31 18:53 |
| S131 | 1 | ("6097975").PN. | USPAT; USOCR | OR | OFF | 2019/01/31 18:53 |
| S132 | 1 | ("20130096403").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/01 12:30 |
| S133 | 1 | "15166702" and power adj sensor | US-PGPUB; USPAT | OR | OFF | 2019/02/01 12:32 |
| S134 | 3 | "13651173" | US-PGPUB; USPAT | OR | OFF | 2019/02/01 12:35 |
| S135 | 1 | ("20080275317").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/01 12:37 |
| S136 | 10 | ("20070203448" "20080027330" "20090105605" "20100009328" "20100298899" "20110181422" | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/01 12:38 |

| L | 1 | "7220220").PN. OR ("8996088").URPN. | | | | |
|------|------|---|------------------------------|----|-----|---------------------|
| S137 | 2 | (("20020151772") or ("20100202966")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 09:24 |
| S138 | 1 | ("20140051955").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 14:14 |
| S139 | 2 | (("20140187883") or ("20110112387")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 14:51 |
| S140 | 1 | ("9314197").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 16:01 |
| S141 | 1 | "15606666" and detector and reader | US-PGPUB; USPAT | OR | OFF | 2019/02/05 16:13 |
| S142 | 2 | ("0569186").PN. | USPAT; USOCR | OR | OFF | 2019/02/05 16:19 |
| S143 | 1 | ("5569186").PN. | USPAT; USOCR | OR | OFF | 2019/02/05 16:19 |
| S145 | 1 | ("6561978").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 16:33 |
| S146 | 273 | fardanesh.xa. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/05 16:34 |
| S147 | 1 | ("7275437").PN. | USPAT; USOCR | OR | OFF | 2019/02/06 11:10 |
| S148 | 2 | (("7827537") or ("7827437")).PN. | USPAT; USOCR | OR | OFF | 2019/02/06 11:11 |
| S149 | 1 | ("7827543").PN. | USPAT; USOCR | OR | OFF | 2019/02/06 11:11 |
| S150 | 1 | ("7827547").PN. | USPAT; USOCR | OR | OFF | 2019/02/06 11:12 |
| S151 | 0 | holker.in. and "7827"\$ | USPAT | OR | OFF | 2019/02/06 11:14 |
| S152 | 21 | holker.in. | USPAT | OR | OFF | 2019/02/06 11:14 |
| S153 | 1 | ("7003336").PN. | USPAT; USOCR | OR | OFF | 2019/02/06 12:02 |
| S154 | 0 | (("20060249690") or ("20110133730")).PN. | USPAT; USOCR | OR | OFF | 2019/02/06 13:21 |
| S155 | 2 | (("20060249690") or ("20110133730")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/06 13:21 |
| S156 | 2172 | tumor and (probe marker) same (circulation vessel) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/06 14:01 |
| S157 | 1127 | tumor and (probe marker) with (circulation vessel) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/06 14:02 |
| S158 | 199 | tumor same (probe marker) with (circulation vessel) and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/06 14:02 |
| S163 | 1 | ("9314197").PN. | USPAT; USOCR | OR | OFF | 2019/02/06 16:59 |
| S164 | 1 | ("20140200423").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/06 17:00 |

| S165 | 1 | ("20140051955").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/07 13:38 |
|------|-----|--|--|----|-----|---------------------|
| S166 | 1 | ("5817012").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/07 14:51 |
| S167 | 1 | ("20140046149").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/07 17:30 |
| S168 | 1 | ("4880441").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/07 17:31 |
| S169 | 7 | "2003052865" | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | OFF | 2019/02/07 17:32 |
| S170 | 352 | sweat and pump same permeable | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | OFF | 2019/02/07 17:34 |
| S171 | 78 | sweat and pump same permeable same water | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | OFF | 2019/02/07 17:35 |
| S172 | 61 | sweat and pump same permeable same water and sensor | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | OFF | 2019/02/07 17:35 |
| S173 | 63 | sweat and pump same permeable same water and sens\$4 | US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB | OR | OFF | 2019/02/07 17:35 |
| S174 | 1 | ("20020151772").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/15 14:16 |
| S175 | 1 | ("6561978").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/15 15:39 |
| S176 | 852 | ("4178916" "4509531" "4703756" "5062841" "5063081" "5077753" "5112614" "5113869" "5140985" "5279543" "5362307" "5458140" "5462051" "5507288" "5569186" "5636632" "5721783" "5730714" "5735273" "5771890" "5807375" | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/15 15:47 |

| | | "5827183" "5830132" "5875186" "5882300" "5897033" "5914701" "5954685" "5982297" "5989409" "5995860" "6023629" "6024699" "6049727" "6059736" "6134461" "6159147" "6175752" "6248067" "6277067").PN. OR ("6561978").URPN. | | | | |
|------|-----|---|------------------------------|----|-----|---------------------|
| S177 | 2 | "20100081906" | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/15 15:55 |
| S178 | 0 | (2002/0019587).CCLS. | USPAT; USOCR | OR | OFF | 2019/02/18 10:26 |
| S179 | 1 | ("20020019587").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/18 10:26 |
| S180 | 2 | (("20140148661") or ("5517987")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/19 09:27 |
| S181 | 4 | (("20130004972") or ("20140353503") or ("20050148834") or ("7133710")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/19 10:59 |
| S182 | 6 | (("20110118571") or ("20070213607") or ("6921366") or ("20160356746") or ("20150005611") or ("7039446")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/20 14:21 |
| S183 | 214 | (chang\$5 with speckle with pattern) with (variable vary\$4 coefficient analyte) | US-PGPUB; USPAT | OR | ON | 2019/02/20 14:36 |
| S184 | 1 | ("20130079618").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/28 12:07 |
| S185 | 1 | ("20150366490").PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/28 12:54 |
| S186 | 2 | (("20160007864") or ("20150031970")).PN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/02/28 14:42 |
| S187 | 0 | "20160007864".pn. same threshold same (acceler\$6) | US-PGPUB; USPAT | OR | OFF | 2019/02/28 14:46 |
| S188 | 0 | "20150031970".pn. same threshold same (acceler\$6) | US-PGPUB; USPAT | OR | OFF | 2019/02/28 14:46 |
| S189 | 0 | "20150031970".pn. same threshold and (acceler\$6) | US-PGPUB; USPAT | OR | OFF | 2019/02/28 14:46 |
| S190 | 0 | "20160007864".pn. same threshold and (acceler\$6) | US-PGPUB; USPAT | OR | OFF | 2019/02/28 14:46 |
| S191 | 1 | "15581803" | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:35 |
| S192 | 824 | (shoulder scapula) with motion and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:38 |
| S193 | 23 | (shoulder scapula) with motion and A61B5/4576.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:38 |
| S194 | 0 | (shoulder scapula) with motion and eiseman.xa. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:39 |
| S195 | 0 | (shoulder scapula) with motion and eiseman.xp. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:39 |
| S196 | 13 | (shoulder scapula) with motion and dougherty.xp. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:39 |
| S197 | 2 | (shoulder scapula) with motion and | US-PGPUB; | OR | OFF | 2019/02/28 |

| | | dougherty.xa. | USPAT | | | 15:39 |
|------|-----|---|---------------------|----|-----|---------------------|
| S198 | 27 | (shoulder scapula) with motion and A61B5/742.cpc. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:45 |
| S199 | 0 | (shoulder scapula) with motion and "minnesota.asn" | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:47 |
| S200 | 1 | (shoulder scapula) with motion and staker.in. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:48 |
| S201 | 1 | (shoulder scapula) with motion and ludewig.in. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:48 |
| S202 | 0 | ("2017/0281074").URPN. | USPAT | OR | OFF | 2019/02/28 15:48 |
| S203 | 0 | ("2017/0281074").URPN. | US-PGPUB; USPAT | OR | OFF | 2019/02/28 15:48 |
| S204 | 0 | (shoulder scapula) with motion with sens\$4 same orientation same (3-D 3D three-dimensional dimensional) same (smart-phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:12 |
| S205 | 2 | (shoulder scapula) with motion with sens\$4 and orientation same (3-D 3D three-dimensional dimensional) same (smart-phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:12 |
| S206 | 15 | (shoulder scapula) with motion with sens\$4 and orientation same (3-D 3D three-dimensional dimensional) and (smart-phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:14 |
| S207 | 1 | "14576581" | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:18 |
| S208 | 1 | (shoulder scapula) same motion same (3-D 3D three-dimensional dimensional) same (smart-phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:21 |
| S209 | 1 | (shoulder scapula) same (3-D 3D three- dimensional dimensional) same (smart- phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:21 |
| S210 | 138 | (shoulder scapula) same (3-D 3D three- dimensional dimensional) and (smart- phone (smart adj phone) smartphone)and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:22 |
| S211 | 1 | humeral with elevation with arm and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:56 |
| S212 | 11 | humeral with elevation and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:56 |
| S213 | 1 | humeral with elevation and degree with scapula and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:56 |
| S214 | 1 | humeral with elevation same degree and A61B5/\$.cpc. | US-PGPUB; USPAT | OR | ON | 2019/02/28 16:57 |
| S215 | 1 | "15195199" | US-PGPUB; USPAT | OR | ON | 2019/03/01 14:19 |
| S216 | 1 | "15195199" and ring | US-PGPUB; USPAT | OR | ON | 2019/03/01 14:19 |
| S217 | 3 | (("20170007330") or ("20150223941") or ("20160213924")).PN. | US-PGPUB; USPAT; | OR | OFF | 2019/03/01 14:54 |

| <u> </u> | | | USOCR | | <u></u> | |
|----------|-----|--|------------------------------|----|---------|---------------------|
| S218 | 277 | fardanesh.xa. | US-PGPUB; USPAT | OR | OFF | 2019/03/04 08:40 |
| S219 | 0 | "16226249" and wall | US-PGPUB; USPAT | OR | OFF | 2019/03/04 09:00 |
| S220 | 0 | "16226249" | US-PGPUB; USPAT | OR | OFF | 2019/03/04 09:00 |
| S221 | 32 | ("20030139672" "20040082842" "20040225206" "20050267346" "20060193550" "20070038126" "20070060809" "20080017800" "20090182209" "20100004719" "20100022856" "20120044484" "20120253153" "20130043551" "4867557" "4877322" "4880304" "5357954" "5584296" "5647359" "6177984" "6181959" "6763256" "6839585" "6859658" "6879850" "7356365" "7822453" "8116851" "8175667" "8311601" "8386000").PN. OR ("9883824").URPN. | US-PGPUB; USPAT; USOCR | OR | OFF | 2019/03/04 09:13 |

EAST Search History (Interference)

| Ref # | Hits | Search Query | DBs | Default Operator | Plurals | Time Stamp |
|----------|------|--|------------------------|---------------------|---------|---------------------|
| S44 | 86 | emitter same detector same (distance offset).clm. and A61B5/\$.cpc. | USPAT | OR | ON | 2018/12/28 17:02 |
| S45 | 190 | emitter same detector same (distance offset).clm. and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2018/12/28 17:02 |
| S57 | 1 | magnet\$4 same uniform with alignment and hydrogel and magnetometer | US- PGPUB; USPAT | OR | OFF | 2019/01/04 15:23 |
| S58 | 39 | magnet\$4 same uniform and hydrogel and magnetometer | US- PGPUB; USPAT | OR | OFF | 2019/01/04 15:25 |
| S59 | 3 | magnet\$4 same halbach and hydrogel and magnetometer | US- PGPUB; USPAT | OR | OFF | 2019/01/04 15:25 |
| S60 | 1 | "20090316137".pn. | US- PGPUB; USPAT | OR | OFF | 2019/01/04 17:00 |
| S159 | 73 | tumor same (probe marker) with (circulation vessel) and A61B5/\$.cpc. | USPAT | OR | ON | 2019/02/06 14:04 |
| S160 | 199 | tumor same (probe marker) with (circulation vessel) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/02/06 14:04 |
| S161 | 231 | tumor same (probe marker) with (circulation vessel vasculature) and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/02/06 14:05 |
| S162 | 8 | tumor same (probe marker) with (circulation vessel vasculature).clm. and A61B5/\$.cpc. | US- PGPUB; USPAT | OR | ON | 2019/02/06 14:07 |

3/4/2019 12:02:30 PM

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EAST Search History

| | Application No. | Unassigned |
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| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 1 OF 28 | Attorney Docket No. | MAS.1007C1 |

| | U.S. PATENT DOCUMENTS | | | | | | |
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| | 1 | 4,960,128 | 10/2/1990 | Gordon et al. | | | |
| | 2 | 4,964,408 | 10/23/1990 | Hink et al. | | | |
| | 3 | 5,041,187 | 8/20/1991 | Hink et al. | | | |
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| | 7 | 5,337,744 | 8/16/1994 | Branigan | | | |
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| | 9 | 5,377,676 | 1/3/1995 | Vari, et al. | | | |
| | 10 | 5,431,170 | 7/11/1995 | Mathews | | | |
| | 11 | 5,452,717 | 9/26/1995 | Branigan et al. | | | |
| | 12 | 5,456,252 | 10/10/1995 | Vari, et al. | | | |
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| | 16 | 5,494,043 | 2/27/1996 | O'Sullivan et al. | | | |
| | 17 | 5,533,511 | 7/9/1996 | Kaspari et al. | | | |
| | 18 | 5,534,851 | 7/9/1996 | Russek | | | |
| | 19 | 5,561,275 | 10/1/1996 | Savage, et al. | | | |
| | 20 | 5,562,002 | 10/8/1996 | Lalin | | | |
| | 21 | 5,590,649 | 1/7/1997 | Caro et al. | | | |
| | 22 | 5,602,924 | 2/11/1997 | Durand et al. | | | |
| | 23 | 5,632,272 | 5/27/1997 | Diab et al. | | | |
| | 24 | 5,638,816 | 6/17/1997 | Kiani-Azarbayjany et al. | | | |
| | 25 | 5,638,818 | 6/17/1997 | Diab et al. | | | |
| | 26 | 5,645,440 | 7/8/1997 | Tobler et al. | | | |
| | 27 | 5,685,299 | 11/11/1997 | Diab et al. | | | |
| | 28 | 5,743,262 | 4/28/1998 | Lepper, Jr. et al. | | | |
| | 29 | 5,758,644 | 6/2/1998 | Diab et al. | | | |

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| | 30 | 5,760,910 | 6/2/1998 | Lepper, Jr. et al. | | |
| | 31 | 5,769,785 | 6/23/1998 | Diab et al. | | |
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| | 57 | 6,128,521 | 10/3/2000 | Marro et al. | | |
| | 58 | 6,129,675 | 10/10/2000 | Jay | | |

| Examiner Signature /MARJAN FARDANESH/ | Date Considered | 02/06/2019 |
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| | 59 | 6,144,868 | 11/7/2000 | Parker | | | |
| | 60 | 6,151,516 | 11/21/2000 | Kiani-Azarbayjany et al. | | | |
| | 61 | 6,152,754 | 11/28/2000 | Gerhardt et al. | | | |
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| | 85 | 6,371,921 | 4/16/2002 | Caro et al. | | | |
| | 86 | 6,377,829 | 4/23/2002 | Al-Ali | | | |
| | 87 | 6,388,240 | 5/14/2002 | Schulz et al. | | | |

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| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY ALL LIDANT | Art Unit | Unassigned |
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| SHEET 7 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature /MARJAN FARDANESH/ | Date Considered 02/06/2019 |
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| | U.S. PATENT DOCUMENTS | | | | | |
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| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | |
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16/226,249 - GAU: 3791 Receipt date: 12/19/2018

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| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
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| SHEET 15 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| SHEET 17 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| SHEET 18 OF 28 | Attorney Docket No. | MAS.1007C1 |

| | | | U.S. PATENT | DOCUMENTS | |
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| Examiner Signature | /MARJAN FARDANESH/ | Date Considered | 02/06/2019 |
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| SHEET 19 OF 28 | Attorney Docket No. | MAS.1007C1 |

| | | | U.S. PATENT | DOCUMENTS | |
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16/226,249 - GAU: 3791 Receipt date: 12/19/2018

| | Application No. | Unassigned |
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| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
| STATEMENT BY APPLICANT | First Named Inventor | Ammar Al-Ali |
| STATEMENT BY ALL COANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 22 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature /MARJAN FARDANESH/ | Date Considered | 02/06/2019 |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
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| SHEET 23 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| STATEMENT BY ALL LIDANT | Art Unit | Unassigned |
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| SHEET 24 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| Examiner Signature /MARJAN FARDANESH/ | Date Considered | 02/06/2019 | |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 25 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
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| SHEET 26 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| SHEET 27 OF 28 | Attorney Docket No. | MAS.1007C1 |

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Receipt date: 12/19/2018

PTO/SB/08 Equivalent

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Examiner Signature /MARJAN FARDANESH/ Date Considered 02/06/2019

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MAS.1007C1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor: Ammar Al-Ali

App. No. : 16/226249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Fardanesh, Marjan

Art Unit : 3791 Conf. No. : 1002

SUPPLEMENTAL PRELIMINARY AMENDMENT

Mail Stop Amendment

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

Dear Commissioner:

Prior to examination of the above-identified application, please enter the amendments set forth herein.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

Filing Date: December 19, 2018

AMENDMENTS TO THE CLAIMS

1-56. (Cancelled)

57. (New) A wrist-worn physiological monitoring device configured for placement on a user at a tissue measurement site, the device comprising:

a plurality of emitters configured to emit light towards the tissue measurement site, the tissue measurement site being located on a wrist of the user, the plurality of emitters comprising one or more light-emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength;

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a processor configured to receive the at least one signal responsive to the output and determine a physiological parameter of the user; and

- a light block forming an enclosing wall between the light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the wall prevents at least a portion of light emitted from the plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue.
- 58. (New) The physiological monitoring device of Claim 57, further comprising a display configured to present information related to the determined physiological parameter to the user.
- 59. (New) The physiological monitoring device of Claim 58, wherein the display is a touch-screen display.
- 60. (New) The physiological monitoring device of Claim 57, wherein the enclosing wall of the light block is a circular wall.
- 61. (New) The physiological monitoring device of Claim 57, wherein, when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance

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measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.

- 62. (New) The physiological monitoring device of Claim 57, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 63. (New) The physiological monitoring device of Claim 57, wherein the plurality of emitters are positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.
- 64. (New) The physiological monitoring device of Claim 57, wherein the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate.
- 65. (New) The physiological monitoring device of Claim 57, wherein the plurality of detectors are arranged in an array with a spacial configuration corresponding to an irradiated surface area.
- 66. (New) The physiological monitoring device of Claim 65, wherein the irradiated surface area comprises a circular shape.
- 67. (New) A method of measuring a physiological parameter in a user's blood, the method comprising:

emitting, from a plurality of emitters of a physiological monitoring device, light of one or more wavelengths toward a tissue measurement site located on a wrist of the user, wherein the plurality of emitters comprise one or more light-emitting diodes (LEDs) and the one or more wavelengths comprises at least an infrared wavelength;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters after attenuation through tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes; and

providing a light block forming an enclosing wall between the light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring device is worn by the user, wherein the wall prevents at

Filing Date: December 19, 2018

least a portion of light emitted from the plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue;

outputting, from the plurality of detectors, at least one signal responsive to the detected light;

receiving, by a processor, the outputted at least one signal responsive to the detected light; and

processing, by the processor, the received at least one signal responsive to the detected light to determine a physiological parameter.

- 68. (New) The method of Claim 67, wherein the plurality of emitters are positioned outside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the enclosing wall when the physiological monitoring device is worn by the user at the tissue measurement site.
- 69. (New) The method of Claim 67, further comprising presenting, with a display of the physiological monitoring device, information related to the determined physiological parameter to the user.
 - 70. (New) The method of Claim 69, wherein the display is a touch-screen display.
- 71. (New) The method of Claim 67, wherein the enclosing wall of the light block comprises a circular wall.
- 72. (New) The method of Claim 67, wherein when the physiological monitoring device is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring device is worn by the user.
- 73. (New) The method of Claim 67, further comprising spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to the tissue measurement site.
- 74. (New) The method of Claim 67, wherein the physiological parameter is indicative of at least one of pulse rate, perfusion index, oxygen content, and total hemoglobin.
- 75. (New) The method of Claim 67, wherein the plurality of detectors are arranged in an array with a spacial configuration corresponding to an irradiated surface area.

Filing Date: December 19, 2018

76. (New) The method of Claim 75, wherein the irradiated surface area comprises a circular shape.

- 77. (New) A wrist-worn physiological monitoring sensor comprising:
- a plurality of optical sources configured to emit light towards a tissue measurement site on a user, the tissue measurement site located on a wrist of the user, the plurality of optical sources comprising one or more light-emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength;
- a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, the plurality of detectors further configured to output at least one signal responsive to the detected light;
- a processor configured to receive the outputted at least one signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user; and
- a light block forming an enclosing wall between the light emitted from the plurality of emitters at the tissue measurement site and the plurality of detectors when the physiological monitoring sensor is worn by the user, the light block forming a light isolation chamber defined by the enclosing wall, wherein the wall prevents at least a portion of light emitted from the plurality of emitters from being detected by the plurality of detectors without attenuation by the tissue.
- 78. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of optical sources are located outside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site, and wherein the plurality of detectors are arranged inside the enclosing wall when the physiological monitoring sensor is worn by the user at the tissue measurement site.
- 79. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of detectors are arranged in an array so as to capture the emitted light reflected from the tissue of the user at the tissue measurement site.

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- 80. (New) The physiological monitoring sensor of Claim 77, wherein the plurality of detectors are arranged with a spacial configuration corresponding to an irradiated surface area.
- 81. (New) The physiological monitoring sensor of Claim 77, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 82. (New) The physiological monitoring sensor of Claim 77, further comprising a display configured to present information related to the determined physiological parameter to the user.
- 83. **(New)** The physiological monitoring sensor of Claim 82, wherein the display is a touch-screen display.
- 84. (New) The physiological monitoring sensor of Claim 77, wherein the enclosing wall of the light block is a circular wall.
- 85. (New) The physiological monitoring sensor of Claim 77, wherein when the physiological monitoring sensor is worn by the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the physiological monitoring sensor is worn by the user.
- 86. (New) The physiological monitoring sensor of Claim 77, wherein the physiological parameter is selected from the group consisting of arterial oxygen saturation, glucose, and pulse rate.

Filing Date:

December 19, 2018

REMARKS

Prior to examination, please amend the Claims as shown herein.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims,

or characterizations of claim scope or referenced art, Applicant is not conceding in this

application that previously pending claims are not patentable. Rather, any alterations or

characterizations are being made to facilitate expeditious prosecution of this application.

Applicant reserves the right to pursue at a later date any previously pending or other broader or

narrower claims that capture any subject matter supported by the present disclosure, including

subject matter found to be specifically disclaimed herein or by any prior prosecution.

Accordingly, reviewers of this or any parent, child or related prosecution history shall not

reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter

supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or

credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 30, 2019

By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735

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| Electronic Patent Application Fee Transmittal | | | | | | | | | |
|---|--------------------------------------|----------|----------|--------|-------------------------|--|--|--|--|
| Application Number: | 16226249 | | | | | | | | |
| Filing Date: | 19-Dec-2018 | | | | | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | | | | |
| Filer: | Aaron Samuel Johnson/Daniel Escajeda | | | | | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | | | | | |
| Filed as Large Entity | | | | | | | | | |
| Filing Fees for Utility under 35 USC 111(a) | | | | | | | | | |
| Description | | Fee Code | Quantity | Amount | Sub-Total in USD(\$) | | | | |
| Basic Filing: | | | | | | | | | |
| Pages: | | | | | | | | | |
| Claims: | | | | | | | | | |
| CLAIMS IN EXCESS OF 20 | | 1202 | 10 | 100 | 1000 | | | | |
| Miscellaneous-Filing: | | | | | | | | | |
| Petition: | | | | | | | | | |
| Patent-Appeals-and-Interference: | | | | | | | | | |
| Post-Allowance-and-Post-Issuance: | | | | | | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD(\$) |
|--------------------|-------------------|----------|--------|-------------------------|
| Extension-of-Time: | | | | |
| Miscellaneous: | | | | |
| | Total in USD (\$) | | | 1000 |
| | | | | |

| Electronic Acknowledgement Receipt | | | | |
|--------------------------------------|-----------------------------------|--|--|--|
| EFS ID: | 35004602 | | | |
| Application Number: | 16226249 | | | |
| International Application Number: | | | | |
| Confirmation Number: | 1002 | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | |
| Customer Number: | 64735 | | | |
| Filer: | Aaron Samuel Johnson/Sandra Autry | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | |
| Attorney Docket Number: | MAS.1007C1 | | | |
| Receipt Date: | 30-JAN-2019 | | | |
| Filing Date: | 19-DEC-2018 | | | |
| Time Stamp: | 15:52:20 | | | |
| Application Type: | Utility under 35 USC 111(a) | | | |

Payment information:

| Submitted with Payment | yes |
|--|-----------------------|
| Payment Type | CARD |
| Payment was successfully received in RAM | \$1000 |
| RAM confirmation Number | 013119INTEFSW15524801 |
| Deposit Account | 111410 |
| Authorized User | Sandra Autry |

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

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing: | | | | | | | | |
|---|------------------------------|--------------------------------------|--|---------------------|---------------------|--|--|--|
| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) | | | |
| | | | 43063 | | | | | |
| 1 | | SupplementalPrelim_MAS1007 C1.pdf | 02d1b89940354061018472f6789653a083a 08fb5 | yes | 7 | | | |
| Multipart Description/PDF files in .zip description | | | | | | | | |
| | Document De | scription | Start | E | nd | | | |
| | Supplemental Response or Sup | oplemental Amendment | 1 | 1 | | | | |
| | Claims | 2 | 6 | | | | | |
| | Applicant Arguments/Remarks | 7 | | 7 | | | | |
| Warnings: | | | | | | | | |
| Information: | | | | | | | | |
| | | | 30208 | | | | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | b73fa1d795733f74c11eb7b4c3d09336c7d 4c20c | no | 2 | | | |
| Warnings: | | | | | | | | |
| Information: | | | | | | | | |
| | | Total Files Size (in bytes) | 7 | 3271 | | | | |

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

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. |
|-----------------|--------------------------------------|----------------------|---------------------|------------------|
| 16/226,249 | 12/19/2018 | MAS.1007C1 | 1002 | |
| | 7590 01/18/2019 RTENS, OLSON & BI | | EXAM | IINER |
| | RPORATION (MASIM | | | |
| FOURTEENTH | | | ART UNIT | PAPER NUMBER |
| IRVINE, CA 92 | 2614 | | 3791 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 01/18/2019 | 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):

efiling@knobbe.com jayna.cartee@knobbe.com

| | | | Application No. 16/226,249 | Applicant(s) Al-Ali et al. | | | | | |
|--|--|--|-----------------------------------|----------------------------|---|--|--|--|--|
| | | ed Examination (Track I) | Examiner BRIAN W BROWN | Art Unit OPET | AIA (First Inventor to File) Status Yes | | | | |
| 1. | 1. THE REQUEST FILED 19 December 2018 IS GRANTED . | | | | | | | | |
| | The above-identified application has met the requirements for prioritized examination A. for an original nonprovisional application (Track I). B. for an application undergoing continued examination (RCE). | | | | | | | | |
| 2. The above-identified application will undergo prioritized examination. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs: | | | | | | | | | |
| | Α. | filing a petition for extension of | time to extend the time pe | riod for filing a rep | oly; | | | | |
| | B. | filing an amendment to amend the application to contain more than four independent claims, more than thirty total claims , or a multiple dependent claim; | | | | | | | |
| | C. | filing a request for continued ex | amination ; | | | | | | |
| | D. | filing a notice of appeal; | | | | | | | |
| | E. | filing a request for suspension of action; | | | | | | | |
| | F. | mailing of a notice of allowance; | | | | | | | |
| | G. | mailing of a final Office action; | | | | | | | |
| | H. | completion of examination as defined in 37 CFR 41.102; or | | | | | | | |
| | I. | abandonment of the application. | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | Telephone inquiries with regard to this decision should be directed to BRIAN BROWN at (571)272-5338. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282. | | | | | | | | |
| | /BRIAN W BROWN/ Petitions Examiner, OPET | | | | | | | | |

U.S. Patent and Trademark Office PTO-2298 (Rev. 02-2012)

| | PAT | ENT APPL | | ON FEE DE titute for Form | | ION RECORI |) | | tion or Docket Num 6,249 | ber |
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| | FOR | NUMBE | R FILE | O NUMBE | R EXTRA | RATE(\$) | FEE(\$) |] | RATE(\$) | FEE(\$) |
| | IC FEE FR 1.16(a), (b), or (c)) | N N | I/A | ١ | J/A | N/A | | 1 | N/A | 300 |
| SEA | RCH FEE FR 1.16(k), (i), or (m)) | N N | I/A | ١ | J/A | N/A | | 1 | N/A | 660 |
| XΑ | MINATION FEE FR 1.16(o), (p), or (q)) | | I/A | N | J/A | N/A | | 1 | N/A | 760 |
| ОТ | AL CLAIMS FR 1.16(i)) | 20 | minus | 20 = * | | | | OR | x 100 = | 0.00 |
| NDE | PENDENT CLAII FR 1.16(h)) | MS 3 | minus | 3 = * | | | | 1 | x 460 = | 0.00 |
| APF | LICATION SIZ | E sheets of \$310 (\$15 50 sheets | oaper, th 5 for sm or fraction | and drawings e e application si: all entity) for ea on thereof. See CFR 1.16(s). | ze fee due is ch additional | | | | | 0.00 |
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| ' If th | ne difference in co | olumn 1 is less th | nan zero, | enter "0" in colur | nn 2. | TOTAL | | 1 | TOTAL | 1720 |
| A IN | Takal | (Column 1) CLAIMS REMAINING AFTER AMENDMENT | | (Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR | PRESENT EXTRA | RATE(\$) | ADDITIONAL FEE(\$) | | RATE(\$) | ADDITIONA FEE(\$) |
| AMENDMEN | Total (37 CFR 1.16(i)) | * | Minus | ** | = | x = | | OR | x = | |
| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | x = | | OR | x = | |
| 2 | Application Size Fe | ee (37 CFR 1.16(s) |) | | | | |] | | |
| | FIRST PRESENTA | TION OF MULTIP | LE DEPEN | DENT CLAIM (37 C | FR 1.16(j)) | | | OR | | |
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| | Independent (37 CFR 1.16(h)) | * | Minus | *** | = | x = | | OR | x = | |
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INFORMAL NOTICE

APPLICATION NUMBER 16/226,249

FILING OR 371(C) DATE 12/19/2018

FIRST NAMED APPLICANT Ammar Al-Ali

ATTY. DOCKET NO./TITLE MAS.1007C1

CONFIRMATION NO. 1002

64735 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR **IRVINE, CA 92614**

Date Mailed: 01/17/2019

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): Ammar Al-Ali Stephen Scruggs

> 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.

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UNITED STATES DEPARTMENT OF COMMERCE UNITED STATES DEFARIMENT OF COMM United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P. Dex 1450 Alexandria, Vigania 22313-1450 www.uspto.gov

FILING or GRP ART 371(c) DATE FIL FEE REC'D ATTY.DOCKET.NO TOT CLAIMS IND CLAIMS UNIT 16/226,249 12/19/2018 3791 1880 MAS.1007C1

64735 KNOBBE, MARTENS, OLSON & BEAR, LLP MASIMO CORPORATION (MASIMO) 2040 MAIN STREET FOURTEENTH FLOOR **IRVINE, CA 92614**

CONFIRMATION NO. 1002 FILING RECEIPT



Date Mailed: 01/17/2019

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)

Ammar Al-Ali, San Juan Capistrano, CA; Stephen Scruggs, Newport Beach, CA;

Applicant(s)

MASIMO CORPORATION, Irvine, CA;

Power of Attorney: The patent practitioners associated with Customer Number 64735

Domestic Priority data as claimed by applicant

This application is a CON of 15/195,199 06/28/2016 which claims benefit of 62/188.430 07/02/2015

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

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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

If Required, Foreign Filing License Granted: 01/15/2019

page 1 of 3

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/226.249**

Projected Publication Date: 04/25/2019

Non-Publication Request: No

Early Publication Request: No

Title

ADVANCED PULSE OXIMETRY SENSOR

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.

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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).

page 2 of 3

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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.

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

NOT GRANTED

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

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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.

page 3 of 3

Docket No.: MAS.1007C1 December 21, 2018

App. No.: 16/226,249 Page 1 of 2

Please Direct All Correspondence to Customer Number 64735

RESCISSION OF ANY PRIOR DISCLAIMERS AND REQUEST TO REVISIT ART

First : Ammar Al-Ali

Inventor

App. No : 16/226,249

Filed: December 19, 2018

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Unassigned

Art Unit : Unassigned

Conf # : 1002

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

Dear Commissioner:

The claims of the present application are different and possibly broader in scope than the claims pursued in the parent application(s). To the extent any prior amendments or characterizations of the scope of any claim or referenced art could be construed as a disclaimer of any subject matter supported by the present disclosure, Applicant hereby rescinds and retracts such disclaimer. Accordingly, the references previously considered in the parent application(s) may need to be re-visited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Docket No.: MAS.1007C1 December 21, 2018 App. No.: 16/226,249 Page 2 of 2

Please Direct All Correspondence to Customer Number 64735

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 21, 2018 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

| Electronic Acknowledgement Receipt | | | | | |
|--------------------------------------|-----------------------------------|--|--|--|--|
| EFS ID: | 34675367 | | | | |
| Application Number: | 16226249 | | | | |
| International Application Number: | | | | | |
| Confirmation Number: | 1002 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | |
| Customer Number: | 64735 | | | | |
| Filer: | Aaron Samuel Johnson/Blake Morgan | | | | |
| Filer Authorized By: | Aaron Samuel Johnson | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | |
| Receipt Date: | 21-DEC-2018 | | | | |
| Filing Date: | | | | | |
| Time Stamp: | 15:53:03 | | | | |
| Application Type: | Utility under 35 USC 111(a) | | | | |

Payment information:

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| File Listing: | | | | | | | | |
| Document Number | Document Description | | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) | | |
| | | | | 15830 | | | | |
| 1 | Miscellaneous Incoming Letter | | REQUEST-TO-REVISIT- ART_MAS1007C1.pdf | a11f2536bf3ec61935d526687652bf37c6e1 1104 | no | 2 | | |
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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number

and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

MAS.1007C1 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor: Ammar Al-Ali

App. No. : Unassigned

Filed : Filed herewith

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Unassigned

Art Unit : Unassigned

Conf. No. : Unassigned

PRELIMINARY AMENDMENT

Mail Stop Amendment

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

Dear Commissioner:

Prior to examination of the above-identified application, please enter the amendments set forth herein.

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

Amendments to the Claims are reflected in the listing of claims which begins on page 4 of this paper.

Remarks begin on page 9 of this paper.

| | Application No. | Unassigned |
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| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
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| SHEET 1 OF 28 | Attorney Docket No. | MAS.1007C1 |

| | U.S. PATENT DOCUMENTS | | | | |
|----------------------|-----------------------|---|-----------------------------------|--------------------------|--|
| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
| | 1 | 4,960,128 | 10/2/1990 | Gordon et al. | |
| | 2 | 4,964,408 | 10/23/1990 | Hink et al. | |
| | 3 | 5,041,187 | 8/20/1991 | Hink et al. | |
| | 4 | 5,069,213 | 12/3/1991 | Polczynski | |
| | 5 | 5,163,438 | 11/17/1992 | Gordon et al. | |
| | 6 | 5,319,355 | 6/7/1994 | Russek | |
| | 7 | 5,337,744 | 8/16/1994 | Branigan | |
| | 8 | 5,341,805 | 8/30/1994 | Stavridi, et al. | |
| | 9 | 5,377,676 | 1/3/1995 | Vari, et al. | |
| | 10 | 5,431,170 | 7/11/1995 | Mathews | |
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| | 12 | 5,456,252 | 10/10/1995 | Vari, et al. | |
| | 13 | 5,479,934 | 1/2/1996 | Imran | |
| | 14 | 5,482,036 | 1/9/1996 | Diab et al. | |
| | 15 | 5,490,505 | 2/13/1996 | Diab et al. | |
| | 16 | 5,494,043 | 2/27/1996 | O'Sullivan et al. | |
| | 17 | 5,533,511 | 7/9/1996 | Kaspari et al. | |
| | 18 | 5,534,851 | 7/9/1996 | Russek | |
| | 19 | 5,561,275 | 10/1/1996 | Savage, et al. | |
| | 20 | 5,562,002 | 10/8/1996 | Lalin | |
| | 21 | 5,590,649 | 1/7/1997 | Caro et al. | |
| | 22 | 5,602,924 | 2/11/1997 | Durand et al. | |
| | 23 | 5,632,272 | 5/27/1997 | Diab et al. | |
| | 24 | 5,638,816 | 6/17/1997 | Kiani-Azarbayjany et al. | |
| | 25 | 5,638,818 | 6/17/1997 | Diab et al. | |
| | 26 | 5,645,440 | 7/8/1997 | Tobler et al. | |
| | 27 | 5,685,299 | 11/11/1997 | Diab et al. | |
| | 28 | 5,743,262 | 4/28/1998 | Lepper, Jr. et al. | |
| | 29 | 5,758,644 | 6/2/1998 | Diab et al. | |

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| U.S. PATENT DOCUMENTS | | | | | |
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| | 30 | 5,760,910 | 6/2/1998 | Lepper, Jr. et al. | |
| | 31 | 5,769,785 | 6/23/1998 | Diab et al. | |
| | 32 | 5,782,757 | 7/21/1998 | Diab et al. | |
| | 33 | 5,785,659 | 7/28/1998 | Caro et al. | |
| | 34 | 5,791,347 | 8/11/1998 | Flaherty et al. | |
| | 35 | 5,810,734 | 9/22/1998 | Caro et al. | |
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| | 37 | 5,830,131 | 11/3/1998 | Caro et al. | |
| | 38 | 5,833,618 | 11/10/1998 | Caro et al. | |
| | 39 | 5,860,919 | 1/19/1999 | Kiani-Azarbayjany et al. | |
| | 40 | 5,890,929 | 4/6/1999 | Mills et al. | |
| | 41 | 5,904,654 | 5/18/1999 | Wohltmann et al. | |
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| | 45 | 5,995,855 | 11/30/1999 | Kiani et al. | |
| | 46 | 5,997,343 | 12/7/1999 | Mills et al. | |
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| | 53 | 6,081,735 | 6/27/2000 | Diab et al. | |
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| | 56 | 6,124,597 | 9/26/2000 | Shehada | |
| | 57 | 6,128,521 | 10/3/2000 | Marro et al. | |
| | 58 | 6,129,675 | 10/10/2000 | Jay | |

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| U.S. PATENT DOCUMENTS | | | | | |
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| Examiner Initials | Cite No. | Document Number Number - Kind Code (if known) Example: 1,234,567 B1 | Publication Date MM-DD-YYYY | Name | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
| | 59 | 6,144,868 | 11/7/2000 | Parker | |
| | 60 | 6,151,516 | 11/21/2000 | Kiani-Azarbayjany et al. | |
| | 61 | 6,152,754 | 11/28/2000 | Gerhardt et al. | |
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| | 63 | 6,165,005 | 12/26/2000 | Mills et al. | |
| | 64 | 6,184,521 | 2/6/2001 | Coffin, IV et al. | |
| | 65 | 6,206,830 | 3/27/2001 | Diab et al. | |
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| | 71 | 6,256,523 | 7/3/2001 | Diab et al. | |
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| | 81 | 6,343,224 | 1/29/2002 | Parker | |
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| | 86 | 6,377,829 | 4/23/2002 | Al-Ali | |
| | 87 | 6,388,240 | 5/14/2002 | Schulz et al. | |

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| | 88 | 6,397,091 | 5/28/2002 | Diab et al. | |
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| | 90 | 6,430,525 | 8/6/2002 | Weber et al. | |
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| | 111 | 6,650,917 | 11/18/2003 | Diab et al. | |
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| | 113 | 6,658,276 | 12/2/2003 | Kiani et al. | |
| | 114 | 6,661,161 | 12/9/2003 | Lanzo et al. | |
| | 115 | 6,671,531 | 12/30/2003 | Al-Ali et al. | |
| | 116 | 6,678,543 | 1/13/2004 | Diab et al. | |

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| | 117 | 6,684,090 | 1/27/2004 | Ali et al. | |
| | 118 | 6,684,091 | 1/27/2004 | Parker | |
| | 119 | 6,697,656 | 2/24/2004 | Al-Ali | |
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| | 136 | 6,822,564 | 11/23/2004 | Al-Ali | |
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| | 139 | 6,850,787 | 2/1/2005 | Weber et al. | |
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| | 141 | 6,852,083 | 2/8/2005 | Caro et al. | |
| | 142 | 6,861,639 | 3/1/2005 | Al-Ali | |
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| | 144 | 6,920,345 | 7/19/2005 | Al-Ali et al. | |
| | 145 | 6,931,268 | 8/16/2005 | Kiani-Azarbayjany et al. | |

| Examiner Signature | Date Considered |
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| | 146 | 6,934,570 | 8/23/2005 | Kiani et al. | |
| | 147 | 6,939,305 | 9/6/2005 | Flaherty et al. | |
| | 148 | 6,943,348 | 9/13/2005 | Coffin IV | |
| | 149 | 6,950,687 | 9/27/2005 | Al-Ali | |
| | 150 | 6,961,598 | 11/1/2005 | Diab | |
| | 151 | 6,970,792 | 11/29/2005 | Diab | |
| | 152 | 6,979,812 | 12/27/2005 | Al-Ali | |
| | 153 | 6,985,764 | 1/10/2006 | Mason et al. | |
| | 154 | 6,993,371 | 1/31/2006 | Kiani et al. | |
| | 155 | 6,996,427 | 2/7/2006 | Ali et al. | |
| | 156 | 6,999,904 | 2/14/2006 | Weber et al. | |
| | 157 | 7,003,338 | 2/21/2006 | Weber et al. | |
| | 158 | 7,003,339 | 2/21/2006 | Diab et al. | |
| | 159 | 7,015,451 | 3/21/2006 | Dalke et al. | |
| | 160 | 7,024,233 | 4/4/2006 | Ali et al. | |
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| | 164 | 7,041,060 | 5/9/2006 | Flaherty et al | |
| | 165 | 7,044,918 | 5/16/2006 | Diab | |
| | 166 | 7,067,893 | 6/27/2006 | Mills et al. | |
| | 167 | 7,096,052 | 8/22/2006 | Mason et al. | |
| | 168 | 7,096,054 | 8/22/2006 | Abdul-Hafiz et al. | |
| | 169 | 7,132,641 | 11/7/2006 | Schulz et al. | |
| | 170 | 7,142,901 | 11/28/2006 | Kiani et al. | |
| | 171 | 7,149,561 | 12/12/2006 | Diab | |
| | 172 | 7,186,966 | 3/6/2007 | Al-Ali | |
| | 173 | 7,190,261 | 3/13/2007 | Al-Ali | |
| | 174 | 7,215,984 | 5/8/2007 | Diab | |

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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 7 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| | 198 | 7,371,981 | 5/13/2008 | Abdul-Hafiz | |
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| | 200 | 7,373,194 | 5/13/2008 | Weber et al. | |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
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| | 232 | 7,601,123 | 10/13/2009 | Tweed, et al. | |

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| | 290 | 8,175,672 | 5/8/2012 | Parker | |

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| STATEMENT DI AFFEIGANT | Art Unit | Unassigned |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
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| STATEMENT BY ALL LICANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 26 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| INFORMATION DISCLOSURE | Filing Date | Filed herewith |
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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 27 OF 28 | Attorney Docket No. | MAS.1007C1 |

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| STATEMENT BY AFFEIGANT | Art Unit | Unassigned |
| (Multiple sheets used when necessary) | Examiner | Unassigned |
| SHEET 28 OF 28 | Attorney Docket No. | MAS.1007C1 |

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INFORMATION DISCLOSURE STATEMENT

First Inventor: Ammar Al-Ali

App. No. : Unassigned

Docket No.: MAS.1007C1

Filed : Filed herewith

For : ADVANCED PULSE OXIMETRY

SENSOR

Examiner : Unassigned

Art Unit : Unassigned

Conf. No. : Unassigned

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

References and Listing

Pursuant to 37 CFR 1.56, an Information Disclosure Statement listing references is provided herewith. Listed references are of record in U.S. patent application No. 15/195199, filed June 28, 2016, which is the parent of this Utility application, and is relied upon for an earlier filing date under 35 USC 120. Copies of the references are not submitted pursuant to 37 CFR 1.98(d).

No Disclaimers

To the extent that anything in the Information Disclosure Statement or the listed references could be construed as a disclaimer of any subject matter supported by the present application, Applicant hereby rescinds and retracts such disclaimer.

Timing of Disclosure

This Information Disclosure Statement is being filed within three months of the filing date or date of national phase entry, with an RCE or before receipt of a First Office Action after an RCE, and no fee is believed to be required.

Application No.: Unassigned Filing Date: Filed herewith

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 19, 2018 By: /Aaron S. Johnson/

Aaron S. Johnson Registration No. 74,164 Registered Practitioner Customer No. 64735 (949) 760-0404

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MAS.1007C1 PATENT

ADVANCED PULSE OXIMETRY SENSOR

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 15/195,199 filed June 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed July 2, 2015, entitled "Advanced Pulse Oximetry Sensor," which is incorporated by reference herein. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates to the field of non-invasive optical-based physiological monitoring sensors, and more particularly to systems, devices and methods for improving the non-invasive measurement accuracy of oxygen saturation, among other physiological parameters.

BACKGROUND

[0003] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_{λ} , the intensity of the incident light $I_{\theta,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ .

[0004] In generalized form, the Beer-Lambert law is expressed as:

$$I_{\lambda} = I_{o,\lambda} e^{-d_{\lambda} \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_{i} \tag{2}$$

where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve equations 1 and 2 is the number of significant absorbers that are present in the solution.

[0005] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters. Pulse oximetry relies on a sensor attached externally to the patient to output signals indicative of various physiological parameters, such as a patient's blood constituents and/or analytes, including for example a percent value for arterial oxygen saturation, among other physiological parameters. The sensor has an emitter that transmits optical radiation of one or more wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (HbO) in the blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a patient's oxygen supply.

[0006] A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site, such as a finger, toe, earlobe, nose, hand, foot, or other site having pulsatile blood flow which can be penetrated by light from the one or more emitters. The detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site. The detector outputs a detector signal to the monitor over the communication medium. The monitor processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO2) and/or pulse rate. A pulse oximetry sensor is described in U.S. Patent No. 6,088,607 entitled *Low Noise Optical Probe*; pulse oximetry signal processing is described in U.S. Patent Nos. 6,650,917 and 6,699,194 entitled *Signal Processing Apparatus* and *Signal Proc*

described in U.S. Patent No. 6,584,336 entitled *Universal/Upgrading Pulse Oximeter*; all of which are assigned to Masimo Corporation, Irvine, CA, and each is incorporated by reference herein in its entirety.

[0007] There are many sources of measurement error introduced to pulse oximetry systems. Some such sources of error include the pulse oximetry system's electronic components, including emitters and detectors, as well as chemical and structural physiological differences between patients. Another source of measurement error is the effect of multiple scattering of photons as the photons pass through the patient's tissue (arterial blood) and arrive at the sensor's light detector.

SUMMARY

[0008] This disclosure describes embodiments of non-invasive methods, devices, and systems for measuring blood constituents, analytes, and/or substances such as, by way of non-limiting example, oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like.

[0009] In an embodiment, an optical physiological measurement system includes an emitter configured to emit light of one or more wavelengths. The system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal indicative of the

detected light. The system also includes a processor configured to receive the transmitted signal indicative of the detected light and to determine, based on an amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.

[0010] In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others.

[0011] According to some embodiments, the optical physiological measurement system includes an optical filter having a light-absorbing surface that faces the tissue measurement site. The optical filter also has an opening that is configured to allow the spread light, after being attenuated by the tissue measurement site, to be received by the concentrator. In an embodiment, the opening has dimensions, wherein the dimensions of the opening are similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In an embodiment, the opening has dimensions that are larger than the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In other embodiments, the dimensions of the opening in the optical filter are not the same as the diffuser opening, but the dimensions are larger than the detector package.

[0012] In other embodiments of the present disclosure, the concentrator comprises glass, ground glass, glass beads, opal glass, or a compound parabolic concentrator. In some embodiments the concentrator comprises a cylindrical structure having a truncated circular conical structure on top. The truncated section is adjacent the detector. The light concentrator is structured to receive the emitted optical radiation, after reflection by the tissue measurement site, and to direct the reflected light to the detector.

[0013] In accordance with certain embodiments of the present disclosure, the processor is configured to determine an average level of the light detected by the detector. The average level of light is used to determine a physiological parameter in the tissue measurement site.

[0014] According to another embodiment, a method to determine a constituent or analyte in a patient's blood is disclosed. The method includes emitting, from an emitter, light of at least one wavelength; spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site; receiving, by a concentrator, the spread light after the spread light has been attenuated by the tissue measurement site; concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector; detecting, with the detector, the emitted concentrated light; transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

[0015] In some embodiments, the method to determine a constituent or analyte in a patient's blood includes filtering, with a light-absorbing detector filter, scattered portions of the emitted spread light. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of approximately 1-5 cm in width and approximately 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.25-3 cm in width and approximately 1-7 cm in length. In another embodiment, the light-absorbing detector filter is substantially square in shape and has outer dimensions in the range of approximately 0.25-10 cm², and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.1-8cm². In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of approximately 3 cm in width and approximately 6 cm in length, and has an opening through which emitted light may pass, the

opening having dimensions of approximately 1.5 cm in width and approximately 4 cm in length.

[0016] In still other embodiments of the method to determine a constituent or analyte in a patient's blood, spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser. In some embodiments the emitted spread light is emitted with a substantially uniform intensity profile. And in some embodiments, emitting the spread light from the diffuser to the tissue measurement site includes spreading the emitted light so as to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

[0017] According to yet another embodiment, a pulse oximeter is disclosed. The pulse oximeter includes an emitter configured to emit light at one or more wavelengths. The pulse oximeter also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light directed at a tissue measurement sight. The pulse oximeter also includes a detector configured to detect the emitted spread light after being attenuated by or reflected from the tissue measurement site and to transmit a signal indicative of the detected light. The pulse oximeter also includes a processor configured to receive the transmitted signal and to process the received signal to determine an average absorbance of a blood constituent or analyte in the tissue measurement site over a larger measurement site area than can be performed with a point light source or point detector. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site, and the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. According to some embodiments, the detector comprises an array of detectors configured to cover the detection area. In still other embodiments, the processor is further configured to determine an average of the detected light.

[0018] For purposes of summarizing, certain aspects, advantages and novel features of the disclosure have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the systems, devices and/or methods disclosed herein. Thus, the subject matter of the disclosure herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- **[0019]** Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the disclosure described herein and not to limit the scope thereof.
- **[0020]** FIG. 1 illustrates a conventional approach to [[2D]]-two-dimensional pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.
- **[0021]** FIG. 2 illustrates the disclosed **[[3D]]**-three-dimensional approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. 2AFIG. 1.
- **[0022]** FIG. 3 illustrates schematically a side view of a [[3D]]—three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0023]** FIG. 4A is a top view of a portion of a [[3D]]–three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0024]** FIG. 4B illustrates the top view of a portion of the [[3D]]-three-dimensional pulse oximetry sensor shown in FIG. 4A, with the addition of a tissue measurement site in operational position.
- **[0025]** FIG. 5 illustrates a top view of a [[3D]]-three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

- **[0026]** FIG. 6 illustrates a conventional [[2D]]-two-dimensional approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.
- **[0027]** FIG. 7A is a simplified schematic side view illustration of a reflective [[3D]]-three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0028]** FIG. 7B is a simplified schematic top view illustration of the **[[3D]]** three-dimensional reflective pulse oximetry sensor of FIG. 7A.
- **[0029]** FIG. 8 illustrates a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure.

DETAILED DESCRIPTION

[0030] FIG. 1 illustrates schematically a conventional pulse oximetry sensor having a two-dimensional (2D) approach to pulse oximetry. As illustrated, the emitter 104 is configured to emit optical radiation as a point optical source, i.e., an optical radiation source that has negligible dimensions such that it may be considered as a point. This approach is referred to herein as "two-dimensional" pulse oximetry because it applies a two-dimensional analytical model to the threedimensional space of the tissue measurement site 102 of the patient. Point optical sources feature a defined, freely selectable, and homogeneous light beam area. Light beams emitted from LED point sources often exhibit a strong focus which can produce a usually sharply-defined and evenly-lit illuminated spot often with high intensity dynamics. Illustratively, when looking at the surface of the tissue measurement site 102 (or "sample tissue"), which in this example is a finger, a small point-like surface area of tissue 204 is irradiated by a point optical source. In some embodiments, the irradiated circular area of the point optical source is in the range between 8 and 150 microns. Illustratively, the emitted point optical source of light enters the tissue measurement site 102 as a point of light. As the light penetrates the depth of the tissue 102, it does so as a line or vector, representing a

two-dimensional construct within a three-dimensional structure, namely the patient's tissue 102.

[0031] Use of a point optical source is believed to reduce variability in light pathlength which would lead to more accurate oximetry measurements. However, in practice, photons do not travel in straight paths. Instead, the light particles scatter, bouncing around between various irregular objects (such as, for example, red blood cells) in the patient's blood. Accordingly, photon pathlengths vary depending on, among other things, their particular journeys through and around the tissue at the measurement site 102. This phenomenon is referred to as "multiple scattering." In a study, the effects of multiple scattering were examined by comparing the results of photon diffusion analysis with those obtained using an analysis based on the Beer-Lambert law, which neglects multiple scattering in the determination of light pathlength. The study found that that the difference between the average lengths of the paths traveled by red and infrared photons makes the oximeter's calibration curve (based on measurements obtained from normal subjects) sensitive to the total attenuation coefficients of the tissue in the two wavelength bands used for pulse oximetry, as well as to absorption by the pulsating arterial blood.

[0032] FIG. 2 illustrates schematically the disclosed systems, devices, and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site 102 as compared to the 2D point optical source approach described with respect to FIG. 1. In an embodiment, again looking at the surface of the tissue measurement site 102, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape with dimensions in the range of approximately 0.25-3 cm in width and approximately 1-6 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 1.5 cm in width and approximately 2 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape

has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially square in shape and has dimensions in a range of approximately 0.25-9 cm². In certain embodiments, the irradiated surface area 206 of the measurement site 102 is within a range of approximately 0.5-2 cm in width, and approximately 1-4 cm in length. Of course a skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area 206 can be used. Advantageously, by irradiating the tissue measurement site 102 with a surface area 206, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient's sample tissue 102.

[0033] According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (*i.e.*, arterial blood). Advantageously, by irradiating a larger volume of tissue 102, a larger sample size of light attenuated (or reflected) by the tissue 102 is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. 1. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry systems, devices, and methods will yield a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0034] FIG. 3 illustrates schematically a side view of a pulse oximetry 3D sensor 300 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 300 irradiates the tissue measurement site 102 and detects the emitted light, after being attenuated by the tissue measurement site 102. In other embodiments, for example, as describe below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102. The 3D sensor 300 includes an emitter 302, a light diffuser 304, a light-absorbing detector filter 306, a light concentrator 308, and a detector

310. In some optional embodiments, the 3D sensor 300 further includes a reflector 305. The reflector 305 can be a metallic reflector or other type of reflector. Reflector 305 can be a coating, film, layer or other type of reflector. The reflector 305 can serve as a reflector to prevent emitted light from emitting out of a top portion of the light diffuser 304 such that light from the emitter 302 is directed in the tissue rather than escaping out of a side or top of the light diffuser 304. Additionally, the reflector 305 can prevent ambient light from entering the diffuser 304 which might ultimately cause errors within the detected light. The reflector 305 also prevent light piping that might occur if light from the detector 302 is able to escape from the light diffuser 304 and be pipped around a sensor securement mechanism to detector 310 without passing through the patient's tissue 102.

[0035] The emitter 302 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 302 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 302 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 302 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter 302 includes a single source optical radiation.

[0036] The light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area, such as the area 206 depicted in FIG. 2. In some embodiments, the light diffuser 304 is a beam shaper that can homogenize the input light beam from the emitter 302, shape the output intensity profile of the received light, and define the way (*e.g.*, the shape or pattern) the emitted light is distributed to the tissue measurement site 102. Examples of materials that can be used to realize the light diffuser 304 include, without limitation, a white surface, glass, ground glass, glass beads, polytetrafluoroethylene (also known as Teflon®, opal glass, and greyed glass, to name a few. Additionally, engineered diffusers can be used to realize the diffuser 304 by providing customized light shaping with respect to intensity and distribution. Such diffusers can, for

example, deliver substantially uniform illumination over a specified target area (such as, for example, irradiated surface area 206) in an energy-efficient manner. Examples of engineered diffusers can include molded plastics with specific shapes, patterns or textures designed to diffuse the emitter light across the entirety of the patient's tissue surface.

[0037] Advantageously, the diffuser 304 can receive emitted light in the form of a point optical source and spread the light to fit a desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 304 is made of ground glass which spreads the emitted light with a Gausian intensity profile. In another embodiment the diffuser 304 includes glass beads. In some embodiments, the diffuser 304 is constructed so as to diffuse the emitted light in a Lambertian pattern. A Lambertian pattern is one in which the radiation intensity is substantially constant throughout the area of dispersion. One such diffuser 304 is made from opal glass. Opal glass is similar to ground glass, but has one surface coated with a milky white coating to diffuse light evenly. In an embodiment, the diffuser 304 is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site 102) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution. In some embodiments, the efficiency, or the amount of light transmitted by the diffuser 304, is greater than 70% of the light emitted by the emitter 302. In some embodiments, the efficiency is greater than 90% of the emitted light. Other optical elements known in the art may be used for the diffuser 304.

[0038] In an embodiment, the diffuser 304 has a substantially rectangular shape having dimensions within a range of approximately 0.5-2 cm in width and approximately 1-4 centimeters in length. In another embodiment, the substantially rectangular shape of the diffuser 304 has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the diffuser's 304 substantially rectangular shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the diffuser 304 has a

substantially square shape with dimensions in the range of approximately 0.25-10 cm².

[0039] The light-absorbing detector filter 306, which is also depicted in FIG. 4A in a top view, is a planar surface having an opening 402 through which the emitted light may pass after being attenuated by the tissue measurement site 102. In the depicted embodiment, the opening 402 is rectangular-shaped, with dimensions substantially similar to the irradiated surface area 206. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 4 cm in width and 8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 2 cm in width and 5 cm in length. In another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of 1-3 cm in width and 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of 0.25-2 cm in width and 1-4 cm in length. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 3 cm in width and 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 1.5 cm in width and 4 cm in length.

[0040] The top surface of the light-absorbing filter 306 (facing the tissue measurement site 102 and the emitter 302) is coated with a material that absorbs light, such as, for example, black pigment. Many other types of light-absorbing materials are well known in the art and can be used with the detector filter 306. During operation, light emitted from the emitter 302 can reflect off of the tissue measurement site 102 (or other structures within the 3D sensor 300) to neighboring portions of the 3D sensor 300. If those neighboring portions of the 3D sensor 300 possess reflective surfaces, then the light can reflect back to the tissue measurement site 102, progress through the tissue and arrive at the detector 310. Such multiple scattering can result in detecting photons whose pathlengths are considerably longer than most of the light that is detected, thereby introducing variations in pathlength which will affect the accuracy of the measurements of the pulse oximetry 3D sensor 300. Advantageously, the light-absorbing filter 306

reduces or eliminates the amount of emitted light that is reflected in this manner because it absorbs such reflected light, thereby stopping the chain of scattering events. In certain embodiments, the sensor-facing surfaces of other portions of the 3D sensor 300 are covered in light-absorbing material to further decrease the effect of reflective multiple scattering.

[0041] The light concentrator 308 is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site 102, to collect and concentrate the dispersed optical radiation, and to direct the collected and concentrated optical radiation to the detector 310. In an embodiment, the light concentrator 308 is made of ground glass or glass beads. In some embodiments, the light concentrator 308 includes a compound parabolic concentrator.

[0042] As described above with respect to FIG. 1, the detector 310 captures and measures light from the tissue measurement site 102. For example, the detector 310 can capture and measure light transmitted from the emitter 302 that has been attenuated by the tissue in the measurement site 102. The detector 310 can output a detector signal responsive to the light captured or measured. The detector 310 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 310 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area 206 to capture the attenuated or reflected light from the tissue measurement site.

[0043] Referring to FIG. 4A, a top view of a portion of the 3D sensor 300 is provided. The light-absorbing detector filter 306 is illustrated having a top surface coated with a light-absorbing material. The light-absorbing material can be a black opaque material or coating or any other dark color or coating configured to absorb light. Additionally, a rectangular opening 402 is positioned relative to the light concentrator 308 (shown in phantom) and the detector 310 such that light may pass through the rectangular opening 402, into the light concentrator 308, and to the detector 310. FIG. 4B illustrates the top view of a portion of the 3D sensor 300 as in FIG. 4A, with the addition of the tissue measurement site 102 in operational position. Accordingly, the rectangular opening 402, the light concentrator 308 and the detector 310 are shown in phantom as being under the tissue measurement site

102. In FIGS. 4A and 4B, the light concentrator 308 is shown to have dimensions significantly larger than the dimensions of the rectangular opening 402. In other embodiments, the dimensions of the light concentrator 308, the rectangular opening 402, and the irradiated surface area 206 are substantially similar.

FIG. 5 illustrates a top view of a 3D pulse oximetry sensor 500 according to an embodiment of the present disclosure. The 3D sensor 500 is configured to be worn on a patient's finger 102. The 3D sensor 500 includes an adhesive substrate 502 having front flaps 504 and rear flaps 506 extending outward from a center portion 508 of the 3D sensor 500. The center portion 508 includes components of the 3D pulse oximetry sensor 300 described with respect to FIGS. 3, 4A and 4B. On the front side of the adhesive substrate 502 the emitter 302 and the light diffuser 304 are positioned. On the rear side of the adhesive substrate 502 the light-absorbent detector filter 306, the light concentrator 308 and the detector 310 are positioned. In use, the patient's finger serving as the tissue measurement site 102 is positioned over the rectangular opening 402 such that when the front portion of the adhesive substrate is folded over on top of the patient's finger 102, the emitter 302 and the light diffuser 304 are aligned with the measurement site 102, the filter 306, the light concentrator 308 and the detector 310. Once alignment is established, the front and rear flaps 504, 506 can be wrapped around the finger measurement site 102 such that the adhesive substrate 502 provides a secure contact between the patient's skin and the 3D sensor 500. Fig. 5 also illustrates an example of a sensor connector cable 510 which is used to connect the 3D sensor 500 to a monitor 809, as described with respect to FIG. 8.

[0045] FIG. 6 is a simplified schematic illustration of a conventional, 2D approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source. Reflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site 102. Light is emitted into a tissue measurement site 102 and attenuated. The emitted light passes into the tissue 102 and is then reflected back to the same side of the tissue measurement site 102 as the emitter. As illustrated in FIG. 6, a depicted reflective 2D pulse oximetry sensor 600 includes an emitter 602,

a light block 606, and a detector 610. The light block 606 is necessary because the emitter 602 and the detector 610 are located on the same side of the tissue measurement site 102. Accordingly, the light block 606 prevents incident emitter light, which did not enter the tissue measurement site 102, from arriving at the detector 610. The depicted 2D pulse oximetry sensor 600 is configured to emit light as a point source. As depicted in FIG. 6, a simplified illustration of the light path 620 of the emitted light from the emitter 602, through the tissue measurement site 102, and to the detector 610 is provided. Notably, a point source of light is emitted, and a point source of light is detected. As discussed above with respect to FIG. 1, use of a point optical source can result in substantial measurement error due to pathlength variability resulting from the multiple scatter phenomenon. The sample space provided by a 2D point optical emitter source is not large enough to account for pathlength variability, which will skew measurement results.

[0046] FIGS. 7A and 7B are simplified schematic side and top views, respectively, of a 3D reflective pulse oximetry sensor 700 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 700 irradiates the tissue measurement site 102 and detects the emitted light that is reflected by the tissue measurement site 102. The 3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter 702 and detector 710 are on located the same side of the tissue measurement site 102. The 3D sensor 700 includes an emitter 702, a light diffuser 704, a light block 706, a light concentrator 708, and a detector 710.

[0047] As previously described, the emitter 702 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 702 can include one or more sources of optical radiation. Such sources of optical radiation can include LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 702 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 702 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and

approximately 940 nm, respectively. In some embodiments, the emitter 702 includes a single source of optical radiation.

[0048] The light diffuser 704 receives the optical radiation emitted from the emitter 302 and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the area outlined by the light diffuser 704 as depicted in FIG. 7B. Advantageously, the diffuser 704 can receive emitted light in the form of a 2D point optical source (or any other form) and spread the light to fit the desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 704 is made of ground glass or glass beads. A skilled artisan will understand that may other materials can be used to make the light diffuser 704.

[0049] The light blocker 706 includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710. (For purposes of illustration, the light block cover 707 is not illustrated in FIG. 7B.) The light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708 and the detector 710. The light isolation chamber formed by the light blocker 706 and cover 708 ensures that the only light detected by the detector 710 is light that is reflected from the tissue measurement site.

[0050] The light concentrator 708 is a cylindrical structure with a truncated circular conical structure on top, the truncated section of which of which is adjacent the detector 710. The light concentrator 708 is structured to receive the emitted optical radiation, after reflection by the tissue measurement site 102, and to direct the reflected light to the detector 710. In an embodiment, the light concentrator 708 is made of ground glass or glass beads. In some embodiments, the light concentrator 708 includes a compound parabolic concentrator.

[0051] As previously described, the detector 710 captures and measures light from the tissue measurement site 102. For example, the detector 710 can capture and measure light transmitted from the emitter 702 that has been reflected from the tissue in the measurement site 102. The detector 710 can output a detector signal responsive to the light captured or measured. The detector 710 can be

implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 710 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area depicted in FIG. 7B by the light concentrator 708 to capture the reflected light from the tissue measurement site.

[0052] Advantageously, the light path 720 illustrated in FIG. 7A depicts a substantial sample of reflected light that enter the light isolation chamber formed by the light blocker 706 and cover 707. As previously discussed, the large sample of reflected light (as compared to the reflected light collected using the 2D point optical source approach) provides the opportunity to take an average of the detected light, to derive a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0053] Referring now to FIG. 7B, a top view of the 3D sensor 700 is illustrated with both the emitter 702 and the light blocker cover 707 removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser 704. As light is emitted from the emitter 702 (not shown in FIG. 7B), it is diffused homogenously and directed to the tissue measurement site 102. The light blocker 706 forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector 710. The light blocker cover 707 blocks incidental light from entering the light isolation chamber from above. The light concentrator 710 collects the reflected light from the tissue measurement site 102 and funnels it upward toward the detector 710 at the center of the 3D sensor 700.

[0054] FIG. 8 illustrates an example of an optical physiological measurement system 800, which may also be referred to herein as a pulse oximetry system 800. In certain embodiments, the pulse oximetry system 800 noninvasively measures a blood analyte, such as oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like. The system 800 can also measure additional blood

analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

[0055] The pulse oximetry system 800 can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or the like.

[0056] The pulse oximetry system 800 can include a sensor 801 (or multiple sensors) that is coupled to a processing device or physiological monitor 809. In an embodiment, the sensor 801 and the monitor 809 are integrated together into a single unit. In another embodiment, the sensor 801 and the monitor 809 are separate from each other and communicate with one another in any suitable manner, such as via a wired or wireless connection. The sensor 801 and monitor 809 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like.

[0057] In the depicted embodiment shown in FIG. 8, the sensor 801 includes an emitter 804, a detector 806, and a front-end interface 808. The emitter 804 can serve as the source of optical radiation transmitted towards measurement site 102. The emitter 804 can include one or more sources of optical radiation, such as light emitting diodes (LEDs), laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 804 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

[0058] The pulse oximetry system 800 also includes a driver 811 that drives the emitter 804. The driver 111 can be a circuit or the like that is controlled by the monitor 809. For example, the driver 811 can provide pulses of current to the emitter 804. In an embodiment, the driver 811 drives the emitter 804 in a progressive fashion, such as in an alternating manner. The driver 811 can drive the emitter 804 with a series of pulses for some wavelengths that can penetrate tissue relatively well and for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments. The driver 811 can be synchronized with other parts

of the sensor 801 to minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 804. In some embodiments, the driver 811 is capable of driving the emitter 804 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

[0059] The detector 806 captures and measures light from the tissue measurement site 102. For example, the detector 806 can capture and measure light transmitted from the emitter 804 that has been attenuated or reflected from the tissue at the measurement site 102. The detector 806 can output a detector signal 107 responsive to the light captured and measured. The detector 806 can be implemented using one or more photodiodes, phototransistors, or the like. In some embodiments, a detector 806 is implemented in detector package to capture and measure light from the tissue measurement site 102 of the patient. The detector package can include a photodiode chip mounted to leads and enclosed in an encapsulant. In some embodiments, the dimensions of the detector package are approximately 2 square centimeters. In other embodiments, the dimensions of the detector package are approximately 1.5 centimeters in width and approximately 2 centimeters in length.

[0060] The front-end interface 808 provides an interface that adapts the output of the detectors 806, which is responsive to desired physiological parameters. For example, the front-end interface 808 can adapt the signal 807 received from the detector 806 into a form that can be processed by the monitor 809, for example, by a signal processor 810 in the monitor 809. The front-end interface 808 can have its components assembled in the sensor 801, in the monitor 809, in a connecting cabling (if used), in combinations of the same, or the like. The location of the front-end interface 808 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

[0061] The front-end interface 808 can be coupled to the detector 806 and to the signal processor 810 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front-end interface 808 can also be at least partially integrated with various components, such as the detectors 806. For

example, the front-end interface 808 can include one or more integrated circuits that are on the same circuit board as the detector 806. Other configurations can also be used.

[0062] As shown in FIG. 8, the monitor 909 can include the signal processor 810 and a user interface, such as a display 812. The monitor 809 can also include optional outputs alone or in combination with the display 812, such as a storage device 814 and a network interface 816. In an embodiment, the signal processor 810 includes processing logic that determines measurements for desired analytes based on the signals received from the detector 806. The signal processor 810 can be implemented using one or more microprocessors or sub-processors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

[0063] The signal processor 810 can provide various signals that control the operation of the sensor 801. For example, the signal processor 810 can provide an emitter control signal to the driver 811. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 804. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 804 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front-end interface 808 is used, the control signal from the signal processor 810 can provide synchronization with an analog-to-digital converter (ADC) in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 813 can be included in the front-end interface 808 and/or in the signal processor 810. This memory 813 can serve as a buffer or storage location for the front-end interface 808 and/or the signal processor 810, among other uses.

[0064] The user interface 812 can provide an output, *e.g.*, on a display, for presentation to a user of the pulse oximetry system 800. The user interface 812 can be implemented as a touch-screen display, a liquid crystal display (LCD), an organic LED display, or the like. In alternative embodiments, the pulse oximetry system 800

can be provided without a user interface 812 and can simply provide an output signal to a separate display or system.

[0065] The storage device 814 and a network interface 816 represent other optional output connections that can be included in the monitor 809. The storage device 814 can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 814, which can be executed by the signal processor 810 or another processor of the monitor 809. The network interface 816 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 809 to communicate and share data with other devices. The monitor 809 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 812, to control data communications, to compute data trending, or to perform other operations.

[0066] Although not shown in the depicted embodiment, the pulse oximetry system 800 can include various other components or can be configured in different ways. For example, the sensor 801 can have both the emitter 804 and detector 806 on the same side of the tissue measurement site 102 and use reflectance to measure analytes.

[0067] Although the foregoing disclosure has been described in terms of certain preferred embodiments, many other variations than those described herein will be apparent to those of ordinary skill in the art.

[0068] Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for

deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

[0069] While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the systems, devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the disclosure described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

[0070] The term "and/or" herein has its broadest, least limiting meaning which is the disclosure includes A alone, B alone, both A and B together, or A or B alternatively, but does not require both A and B or require one of A or one of B. As used herein, the phrase "at least one of" A, B, "and" C should be construed to mean a logical A or B or C, using a non-exclusive logical or.

[0071] The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage. Although the foregoing disclosure has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of

Marked-Up Specification

ordinary skill in the art from the disclosure herein. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the description of the preferred embodiments, but is to be defined by reference to claims.

[0072] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be incorporated by reference.

MAS.1007C1 PATENT

ADVANCED PULSE OXIMETRY SENSOR

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 15/195,199 filed June 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed July 2, 2015, entitled "Advanced Pulse Oximetry Sensor," which is incorporated by reference herein. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates to the field of non-invasive optical-based physiological monitoring sensors, and more particularly to systems, devices and methods for improving the non-invasive measurement accuracy of oxygen saturation, among other physiological parameters.

BACKGROUND

[0003] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_{λ} , the intensity of the incident light $I_{\theta,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ .

[0004] In generalized form, the Beer-Lambert law is expressed as:

$$I_{\lambda} = I_{o,\lambda} e^{-d_{\lambda} \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_{i} \tag{2}$$

where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve equations 1 and 2 is the number of significant absorbers that are present in the solution.

[0005] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters. Pulse oximetry relies on a sensor attached externally to the patient to output signals indicative of various physiological parameters, such as a patient's blood constituents and/or analytes, including for example a percent value for arterial oxygen saturation, among other physiological parameters. The sensor has an emitter that transmits optical radiation of one or more wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (HbO) in the blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a patient's oxygen supply.

[0006] A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site, such as a finger, toe, earlobe, nose, hand, foot, or other site having pulsatile blood flow which can be penetrated by light from the one or more emitters. The detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site. The detector outputs a detector signal to the monitor over the communication medium. The monitor processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO2) and/or pulse rate. A pulse oximetry sensor is described in U.S. Patent No. 6,088,607 entitled *Low Noise Optical Probe*; pulse oximetry signal processing is described in U.S. Patent Nos. 6,650,917 and 6,699,194 entitled *Signal Processing Apparatus* and *Signal Proc*

described in U.S. Patent No. 6,584,336 entitled *Universal/Upgrading Pulse Oximeter*; all of which are assigned to Masimo Corporation, Irvine, CA, and each is incorporated by reference herein in its entirety.

[0007] There are many sources of measurement error introduced to pulse oximetry systems. Some such sources of error include the pulse oximetry system's electronic components, including emitters and detectors, as well as chemical and structural physiological differences between patients. Another source of measurement error is the effect of multiple scattering of photons as the photons pass through the patient's tissue (arterial blood) and arrive at the sensor's light detector.

SUMMARY

[0008] This disclosure describes embodiments of non-invasive methods, devices, and systems for measuring blood constituents, analytes, and/or substances such as, by way of non-limiting example, oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like.

[0009] In an embodiment, an optical physiological measurement system includes an emitter configured to emit light of one or more wavelengths. The system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal indicative of the

detected light. The system also includes a processor configured to receive the transmitted signal indicative of the detected light and to determine, based on an amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.

[0010] In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others.

[0011] According to some embodiments, the optical physiological measurement system includes an optical filter having a light-absorbing surface that faces the tissue measurement site. The optical filter also has an opening that is configured to allow the spread light, after being attenuated by the tissue measurement site, to be received by the concentrator. In an embodiment, the opening has dimensions, wherein the dimensions of the opening are similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In an embodiment, the opening has dimensions that are larger than the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In other embodiments, the dimensions of the opening in the optical filter are not the same as the diffuser opening, but the dimensions are larger than the detector package.

[0012] In other embodiments of the present disclosure, the concentrator comprises glass, ground glass, glass beads, opal glass, or a compound parabolic concentrator. In some embodiments the concentrator comprises a cylindrical structure having a truncated circular conical structure on top. The truncated section is adjacent the detector. The light concentrator is structured to receive the emitted optical radiation, after reflection by the tissue measurement site, and to direct the reflected light to the detector.

[0013] In accordance with certain embodiments of the present disclosure, the processor is configured to determine an average level of the light detected by the detector. The average level of light is used to determine a physiological parameter in the tissue measurement site.

[0014] According to another embodiment, a method to determine a constituent or analyte in a patient's blood is disclosed. The method includes emitting, from an emitter, light of at least one wavelength; spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site; receiving, by a concentrator, the spread light after the spread light has been attenuated by the tissue measurement site; concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector; detecting, with the detector, the emitted concentrated light; transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

[0015] In some embodiments, the method to determine a constituent or analyte in a patient's blood includes filtering, with a light-absorbing detector filter, scattered portions of the emitted spread light. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of approximately 1-5 cm in width and approximately 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.25-3 cm in width and approximately 1-7 cm in length. In another embodiment, the light-absorbing detector filter is substantially square in shape and has outer dimensions in the range of approximately 0.25-10 cm², and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.1-8cm². In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of approximately 3 cm in width and approximately 6 cm in length, and has an opening through which emitted light may pass, the

opening having dimensions of approximately 1.5 cm in width and approximately 4 cm in length.

[0016] In still other embodiments of the method to determine a constituent or analyte in a patient's blood, spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser. In some embodiments the emitted spread light is emitted with a substantially uniform intensity profile. And in some embodiments, emitting the spread light from the diffuser to the tissue measurement site includes spreading the emitted light so as to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

[0017] According to yet another embodiment, a pulse oximeter is disclosed. The pulse oximeter includes an emitter configured to emit light at one or more wavelengths. The pulse oximeter also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light directed at a tissue measurement sight. The pulse oximeter also includes a detector configured to detect the emitted spread light after being attenuated by or reflected from the tissue measurement site and to transmit a signal indicative of the detected light. The pulse oximeter also includes a processor configured to receive the transmitted signal and to process the received signal to determine an average absorbance of a blood constituent or analyte in the tissue measurement site over a larger measurement site area than can be performed with a point light source or point detector. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site, and the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. According to some embodiments, the detector comprises an array of detectors configured to cover the detection area. In still other embodiments, the processor is further configured to determine an average of the detected light.

[0018] For purposes of summarizing, certain aspects, advantages and novel features of the disclosure have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the systems, devices and/or methods disclosed herein. Thus, the subject matter of the disclosure herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- **[0019]** Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the disclosure described herein and not to limit the scope thereof.
- **[0020]** FIG. 1 illustrates a conventional approach to two-dimensional pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.
- **[0021]** FIG. 2 illustrates the disclosed three-dimensional approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. 1.
- **[0022]** FIG. 3 illustrates schematically a side view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0023]** FIG. 4A is a top view of a portion of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0024]** FIG. 4B illustrates the top view of a portion of the three-dimensional pulse oximetry sensor shown in FIG. 4A, with the addition of a tissue measurement site in operational position.
- **[0025]** FIG. 5 illustrates a top view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

- **[0026]** FIG. 6 illustrates a conventional two-dimensional approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.
- **[0027]** FIG. 7A is a simplified schematic side view illustration of a reflective three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0028]** FIG. 7B is a simplified schematic top view illustration of the three-dimensional reflective pulse oximetry sensor of FIG. 7A.
- **[0029]** FIG. 8 illustrates a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure.

DETAILED DESCRIPTION

[0030] FIG. 1 illustrates schematically a conventional pulse oximetry sensor having a two-dimensional (2D) approach to pulse oximetry. As illustrated, the emitter 104 is configured to emit optical radiation as a point optical source, i.e., an optical radiation source that has negligible dimensions such that it may be considered as a point. This approach is referred to herein as "two-dimensional" pulse oximetry because it applies a two-dimensional analytical model to the threedimensional space of the tissue measurement site 102 of the patient. Point optical sources feature a defined, freely selectable, and homogeneous light beam area. Light beams emitted from LED point sources often exhibit a strong focus which can produce a usually sharply-defined and evenly-lit illuminated spot often with high intensity dynamics. Illustratively, when looking at the surface of the tissue measurement site 102 (or "sample tissue"), which in this example is a finger, a small point-like surface area of tissue 204 is irradiated by a point optical source. In some embodiments, the irradiated circular area of the point optical source is in the range between 8 and 150 microns. Illustratively, the emitted point optical source of light enters the tissue measurement site 102 as a point of light. As the light penetrates the depth of the tissue 102, it does so as a line or vector, representing a two-dimensional construct within a three-dimensional structure, namely the patient's tissue 102.

[0031] Use of a point optical source is believed to reduce variability in light pathlength which would lead to more accurate oximetry measurements. However, in practice, photons do not travel in straight paths. Instead, the light particles scatter, bouncing around between various irregular objects (such as, for example, red blood cells) in the patient's blood. Accordingly, photon pathlengths vary depending on, among other things, their particular journeys through and around the tissue at the measurement site 102. This phenomenon is referred to as "multiple scattering." In a study, the effects of multiple scattering were examined by comparing the results of photon diffusion analysis with those obtained using an analysis based on the Beer-Lambert law, which neglects multiple scattering in the determination of light pathlength. The study found that that the difference between the average lengths of the paths traveled by red and infrared photons makes the oximeter's calibration curve (based on measurements obtained from normal subjects) sensitive to the total attenuation coefficients of the tissue in the two wavelength bands used for pulse oximetry, as well as to absorption by the pulsating arterial blood.

[0032] FIG. 2 illustrates schematically the disclosed systems, devices, and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site 102 as compared to the 2D point optical source approach described with respect to FIG. 1. In an embodiment, again looking at the surface of the tissue measurement site 102, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape with dimensions in the range of approximately 0.25-3 cm in width and approximately 1-6 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 1.5 cm in width and approximately 2 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape

has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially square in shape and has dimensions in a range of approximately 0.25-9 cm². In certain embodiments, the irradiated surface area 206 of the measurement site 102 is within a range of approximately 0.5-2 cm in width, and approximately 1-4 cm in length. Of course a skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area 206 can be used. Advantageously, by irradiating the tissue measurement site 102 with a surface area 206, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient's sample tissue 102.

[0033] According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (*i.e.*, arterial blood). Advantageously, by irradiating a larger volume of tissue 102, a larger sample size of light attenuated (or reflected) by the tissue 102 is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. 1. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry systems, devices, and methods will yield a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0034] FIG. 3 illustrates schematically a side view of a pulse oximetry 3D sensor 300 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 300 irradiates the tissue measurement site 102 and detects the emitted light, after being attenuated by the tissue measurement site 102. In other embodiments, for example, as describe below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102. The 3D sensor 300 includes an emitter 302, a light diffuser 304, a light-absorbing detector filter 306, a light concentrator 308, and a detector

310. In some optional embodiments, the 3D sensor 300 further includes a reflector 305. The reflector 305 can be a metallic reflector or other type of reflector. Reflector 305 can be a coating, film, layer or other type of reflector. The reflector 305 can serve as a reflector to prevent emitted light from emitting out of a top portion of the light diffuser 304 such that light from the emitter 302 is directed in the tissue rather than escaping out of a side or top of the light diffuser 304. Additionally, the reflector 305 can prevent ambient light from entering the diffuser 304 which might ultimately cause errors within the detected light. The reflector 305 also prevent light piping that might occur if light from the detector 302 is able to escape from the light diffuser 304 and be pipped around a sensor securement mechanism to detector 310 without passing through the patient's tissue 102.

[0035] The emitter 302 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 302 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 302 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 302 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter 302 includes a single source optical radiation.

[0036] The light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area, such as the area 206 depicted in FIG. 2. In some embodiments, the light diffuser 304 is a beam shaper that can homogenize the input light beam from the emitter 302, shape the output intensity profile of the received light, and define the way (e.g., the shape or pattern) the emitted light is distributed to the tissue measurement site 102. Examples of materials that can be used to realize the light diffuser 304 include, without limitation, a white surface, glass, ground glass, glass beads, polytetrafluoroethylene (also known as Teflon®, opal glass, and greyed glass, to name a few. Additionally, engineered diffusers can be used to realize the diffuser 304 by providing customized light shaping with respect to intensity and distribution. Such diffusers can, for

example, deliver substantially uniform illumination over a specified target area (such as, for example, irradiated surface area 206) in an energy-efficient manner. Examples of engineered diffusers can include molded plastics with specific shapes, patterns or textures designed to diffuse the emitter light across the entirety of the patient's tissue surface.

[0037] Advantageously, the diffuser 304 can receive emitted light in the form of a point optical source and spread the light to fit a desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 304 is made of ground glass which spreads the emitted light with a Gausian intensity profile. In another embodiment the diffuser 304 includes glass beads. In some embodiments, the diffuser 304 is constructed so as to diffuse the emitted light in a Lambertian pattern. A Lambertian pattern is one in which the radiation intensity is substantially constant throughout the area of dispersion. One such diffuser 304 is made from opal glass. Opal glass is similar to ground glass, but has one surface coated with a milky white coating to diffuse light evenly. In an embodiment, the diffuser 304 is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site 102) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution. In some embodiments, the efficiency, or the amount of light transmitted by the diffuser 304, is greater than 70% of the light emitted by the emitter 302. In some embodiments, the efficiency is greater than 90% of the emitted light. Other optical elements known in the art may be used for the diffuser 304.

[0038] In an embodiment, the diffuser 304 has a substantially rectangular shape having dimensions within a range of approximately 0.5-2 cm in width and approximately 1-4 centimeters in length. In another embodiment, the substantially rectangular shape of the diffuser 304 has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the diffuser's 304 substantially rectangular shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the diffuser 304 has a

substantially square shape with dimensions in the range of approximately 0.25-10 cm².

[0039] The light-absorbing detector filter 306, which is also depicted in FIG. 4A in a top view, is a planar surface having an opening 402 through which the emitted light may pass after being attenuated by the tissue measurement site 102. In the depicted embodiment, the opening 402 is rectangular-shaped, with dimensions substantially similar to the irradiated surface area 206. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 4 cm in width and 8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 2 cm in width and 5 cm in length. In another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of 1-3 cm in width and 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of 0.25-2 cm in width and 1-4 cm in length. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 3 cm in width and 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 1.5 cm in width and 4 cm in length.

[0040] The top surface of the light-absorbing filter 306 (facing the tissue measurement site 102 and the emitter 302) is coated with a material that absorbs light, such as, for example, black pigment. Many other types of light-absorbing materials are well known in the art and can be used with the detector filter 306. During operation, light emitted from the emitter 302 can reflect off of the tissue measurement site 102 (or other structures within the 3D sensor 300) to neighboring portions of the 3D sensor 300. If those neighboring portions of the 3D sensor 300 possess reflective surfaces, then the light can reflect back to the tissue measurement site 102, progress through the tissue and arrive at the detector 310. Such multiple scattering can result in detecting photons whose pathlengths are considerably longer than most of the light that is detected, thereby introducing variations in pathlength which will affect the accuracy of the measurements of the pulse oximetry 3D sensor 300. Advantageously, the light-absorbing filter 306

reduces or eliminates the amount of emitted light that is reflected in this manner because it absorbs such reflected light, thereby stopping the chain of scattering events. In certain embodiments, the sensor-facing surfaces of other portions of the 3D sensor 300 are covered in light-absorbing material to further decrease the effect of reflective multiple scattering.

[0041] The light concentrator 308 is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site 102, to collect and concentrate the dispersed optical radiation, and to direct the collected and concentrated optical radiation to the detector 310. In an embodiment, the light concentrator 308 is made of ground glass or glass beads. In some embodiments, the light concentrator 308 includes a compound parabolic concentrator.

[0042] As described above with respect to FIG. 1, the detector 310 captures and measures light from the tissue measurement site 102. For example, the detector 310 can capture and measure light transmitted from the emitter 302 that has been attenuated by the tissue in the measurement site 102. The detector 310 can output a detector signal responsive to the light captured or measured. The detector 310 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 310 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area 206 to capture the attenuated or reflected light from the tissue measurement site.

[0043] Referring to FIG. 4A, a top view of a portion of the 3D sensor 300 is provided. The light-absorbing detector filter 306 is illustrated having a top surface coated with a light-absorbing material. The light-absorbing material can be a black opaque material or coating or any other dark color or coating configured to absorb light. Additionally, a rectangular opening 402 is positioned relative to the light concentrator 308 (shown in phantom) and the detector 310 such that light may pass through the rectangular opening 402, into the light concentrator 308, and to the detector 310. FIG. 4B illustrates the top view of a portion of the 3D sensor 300 as in FIG. 4A, with the addition of the tissue measurement site 102 in operational position. Accordingly, the rectangular opening 402, the light concentrator 308 and the detector 310 are shown in phantom as being under the tissue measurement site

102. In FIGS. 4A and 4B, the light concentrator 308 is shown to have dimensions significantly larger than the dimensions of the rectangular opening 402. In other embodiments, the dimensions of the light concentrator 308, the rectangular opening 402, and the irradiated surface area 206 are substantially similar.

FIG. 5 illustrates a top view of a 3D pulse oximetry sensor 500 according to an embodiment of the present disclosure. The 3D sensor 500 is configured to be worn on a patient's finger 102. The 3D sensor 500 includes an adhesive substrate 502 having front flaps 504 and rear flaps 506 extending outward from a center portion 508 of the 3D sensor 500. The center portion 508 includes components of the 3D pulse oximetry sensor 300 described with respect to FIGS. 3, 4A and 4B. On the front side of the adhesive substrate 502 the emitter 302 and the light diffuser 304 are positioned. On the rear side of the adhesive substrate 502 the light-absorbent detector filter 306, the light concentrator 308 and the detector 310 are positioned. In use, the patient's finger serving as the tissue measurement site 102 is positioned over the rectangular opening 402 such that when the front portion of the adhesive substrate is folded over on top of the patient's finger 102, the emitter 302 and the light diffuser 304 are aligned with the measurement site 102, the filter 306, the light concentrator 308 and the detector 310. Once alignment is established, the front and rear flaps 504, 506 can be wrapped around the finger measurement site 102 such that the adhesive substrate 502 provides a secure contact between the patient's skin and the 3D sensor 500. Fig. 5 also illustrates an example of a sensor connector cable 510 which is used to connect the 3D sensor 500 to a monitor 809, as described with respect to FIG. 8.

[0045] FIG. 6 is a simplified schematic illustration of a conventional, 2D approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source. Reflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site 102. Light is emitted into a tissue measurement site 102 and attenuated. The emitted light passes into the tissue 102 and is then reflected back to the same side of the tissue measurement site 102 as the emitter. As illustrated in FIG. 6, a depicted reflective 2D pulse oximetry sensor 600 includes an emitter 602,

a light block 606, and a detector 610. The light block 606 is necessary because the emitter 602 and the detector 610 are located on the same side of the tissue measurement site 102. Accordingly, the light block 606 prevents incident emitter light, which did not enter the tissue measurement site 102, from arriving at the detector 610. The depicted 2D pulse oximetry sensor 600 is configured to emit light as a point source. As depicted in FIG. 6, a simplified illustration of the light path 620 of the emitted light from the emitter 602, through the tissue measurement site 102, and to the detector 610 is provided. Notably, a point source of light is emitted, and a point source of light is detected. As discussed above with respect to FIG. 1, use of a point optical source can result in substantial measurement error due to pathlength variability resulting from the multiple scatter phenomenon. The sample space provided by a 2D point optical emitter source is not large enough to account for pathlength variability, which will skew measurement results.

[0046] FIGS. 7A and 7B are simplified schematic side and top views, respectively, of a 3D reflective pulse oximetry sensor 700 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 700 irradiates the tissue measurement site 102 and detects the emitted light that is reflected by the tissue measurement site 102. The 3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter 702 and detector 710 are on located the same side of the tissue measurement site 102. The 3D sensor 700 includes an emitter 702, a light diffuser 704, a light block 706, a light concentrator 708, and a detector 710.

[0047] As previously described, the emitter 702 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 702 can include one or more sources of optical radiation. Such sources of optical radiation can include LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 702 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 702 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and

approximately 940 nm, respectively. In some embodiments, the emitter 702 includes a single source of optical radiation.

[0048] The light diffuser 704 receives the optical radiation emitted from the emitter 302 and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the area outlined by the light diffuser 704 as depicted in FIG. 7B. Advantageously, the diffuser 704 can receive emitted light in the form of a 2D point optical source (or any other form) and spread the light to fit the desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 704 is made of ground glass or glass beads. A skilled artisan will understand that may other materials can be used to make the light diffuser 704.

[0049] The light blocker 706 includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710. (For purposes of illustration, the light block cover 707 is not illustrated in FIG. 7B.) The light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708 and the detector 710. The light isolation chamber formed by the light blocker 706 and cover 708 ensures that the only light detected by the detector 710 is light that is reflected from the tissue measurement site.

[0050] The light concentrator 708 is a cylindrical structure with a truncated circular conical structure on top, the truncated section of which of which is adjacent the detector 710. The light concentrator 708 is structured to receive the emitted optical radiation, after reflection by the tissue measurement site 102, and to direct the reflected light to the detector 710. In an embodiment, the light concentrator 708 is made of ground glass or glass beads. In some embodiments, the light concentrator 708 includes a compound parabolic concentrator.

[0051] As previously described, the detector 710 captures and measures light from the tissue measurement site 102. For example, the detector 710 can capture and measure light transmitted from the emitter 702 that has been reflected from the tissue in the measurement site 102. The detector 710 can output a detector signal responsive to the light captured or measured. The detector 710 can be

implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 710 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area depicted in FIG. 7B by the light concentrator 708 to capture the reflected light from the tissue measurement site.

[0052] Advantageously, the light path 720 illustrated in FIG. 7A depicts a substantial sample of reflected light that enter the light isolation chamber formed by the light blocker 706 and cover 707. As previously discussed, the large sample of reflected light (as compared to the reflected light collected using the 2D point optical source approach) provides the opportunity to take an average of the detected light, to derive a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0053] Referring now to FIG. 7B, a top view of the 3D sensor 700 is illustrated with both the emitter 702 and the light blocker cover 707 removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser 704. As light is emitted from the emitter 702 (not shown in FIG. 7B), it is diffused homogenously and directed to the tissue measurement site 102. The light blocker 706 forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector 710. The light blocker cover 707 blocks incidental light from entering the light isolation chamber from above. The light concentrator 710 collects the reflected light from the tissue measurement site 102 and funnels it upward toward the detector 710 at the center of the 3D sensor 700.

[0054] FIG. 8 illustrates an example of an optical physiological measurement system 800, which may also be referred to herein as a pulse oximetry system 800. In certain embodiments, the pulse oximetry system 800 noninvasively measures a blood analyte, such as oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like. The system 800 can also measure additional blood

analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

[0055] The pulse oximetry system 800 can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or the like.

[0056] The pulse oximetry system 800 can include a sensor 801 (or multiple sensors) that is coupled to a processing device or physiological monitor 809. In an embodiment, the sensor 801 and the monitor 809 are integrated together into a single unit. In another embodiment, the sensor 801 and the monitor 809 are separate from each other and communicate with one another in any suitable manner, such as via a wired or wireless connection. The sensor 801 and monitor 809 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like.

[0057] In the depicted embodiment shown in FIG. 8, the sensor 801 includes an emitter 804, a detector 806, and a front-end interface 808. The emitter 804 can serve as the source of optical radiation transmitted towards measurement site 102. The emitter 804 can include one or more sources of optical radiation, such as light emitting diodes (LEDs), laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 804 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

[0058] The pulse oximetry system 800 also includes a driver 811 that drives the emitter 804. The driver 111 can be a circuit or the like that is controlled by the monitor 809. For example, the driver 811 can provide pulses of current to the emitter 804. In an embodiment, the driver 811 drives the emitter 804 in a progressive fashion, such as in an alternating manner. The driver 811 can drive the emitter 804 with a series of pulses for some wavelengths that can penetrate tissue relatively well and for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments. The driver 811 can be synchronized with other parts

of the sensor 801 to minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 804. In some embodiments, the driver 811 is capable of driving the emitter 804 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

[0059] The detector 806 captures and measures light from the tissue measurement site 102. For example, the detector 806 can capture and measure light transmitted from the emitter 804 that has been attenuated or reflected from the tissue at the measurement site 102. The detector 806 can output a detector signal 107 responsive to the light captured and measured. The detector 806 can be implemented using one or more photodiodes, phototransistors, or the like. In some embodiments, a detector 806 is implemented in detector package to capture and measure light from the tissue measurement site 102 of the patient. The detector package can include a photodiode chip mounted to leads and enclosed in an encapsulant. In some embodiments, the dimensions of the detector package are approximately 2 square centimeters. In other embodiments, the dimensions of the detector package are approximately 1.5 centimeters in width and approximately 2 centimeters in length.

[0060] The front-end interface 808 provides an interface that adapts the output of the detectors 806, which is responsive to desired physiological parameters. For example, the front-end interface 808 can adapt the signal 807 received from the detector 806 into a form that can be processed by the monitor 809, for example, by a signal processor 810 in the monitor 809. The front-end interface 808 can have its components assembled in the sensor 801, in the monitor 809, in a connecting cabling (if used), in combinations of the same, or the like. The location of the front-end interface 808 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

[0061] The front-end interface 808 can be coupled to the detector 806 and to the signal processor 810 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front-end interface 808 can also be at least partially integrated with various components, such as the detectors 806. For

example, the front-end interface 808 can include one or more integrated circuits that are on the same circuit board as the detector 806. Other configurations can also be used.

[0062] As shown in FIG. 8, the monitor 909 can include the signal processor 810 and a user interface, such as a display 812. The monitor 809 can also include optional outputs alone or in combination with the display 812, such as a storage device 814 and a network interface 816. In an embodiment, the signal processor 810 includes processing logic that determines measurements for desired analytes based on the signals received from the detector 806. The signal processor 810 can be implemented using one or more microprocessors or sub-processors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

[0063] The signal processor 810 can provide various signals that control the operation of the sensor 801. For example, the signal processor 810 can provide an emitter control signal to the driver 811. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 804. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 804 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front-end interface 808 is used, the control signal from the signal processor 810 can provide synchronization with an analog-to-digital converter (ADC) in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 813 can be included in the front-end interface 808 and/or in the signal processor 810. This memory 813 can serve as a buffer or storage location for the front-end interface 808 and/or the signal processor 810, among other uses.

[0064] The user interface 812 can provide an output, *e.g.*, on a display, for presentation to a user of the pulse oximetry system 800. The user interface 812 can be implemented as a touch-screen display, a liquid crystal display (LCD), an organic LED display, or the like. In alternative embodiments, the pulse oximetry system 800

can be provided without a user interface 812 and can simply provide an output signal to a separate display or system.

[0065] The storage device 814 and a network interface 816 represent other optional output connections that can be included in the monitor 809. The storage device 814 can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 814, which can be executed by the signal processor 810 or another processor of the monitor 809. The network interface 816 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (*e.g.*, WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 809 to communicate and share data with other devices. The monitor 809 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 812, to control data communications, to compute data trending, or to perform other operations.

[0066] Although not shown in the depicted embodiment, the pulse oximetry system 800 can include various other components or can be configured in different ways. For example, the sensor 801 can have both the emitter 804 and detector 806 on the same side of the tissue measurement site 102 and use reflectance to measure analytes.

[0067] Although the foregoing disclosure has been described in terms of certain preferred embodiments, many other variations than those described herein will be apparent to those of ordinary skill in the art.

[0068] Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for

deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

[0069] While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the systems, devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the disclosure described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

[0070] The term "and/or" herein has its broadest, least limiting meaning which is the disclosure includes A alone, B alone, both A and B together, or A or B alternatively, but does not require both A and B or require one of A or one of B. As used herein, the phrase "at least one of" A, B, "and" C should be construed to mean a logical A or B or C, using a non-exclusive logical or.

[0071] The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage. Although the foregoing disclosure has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of

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ordinary skill in the art from the disclosure herein. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the description of the preferred embodiments, but is to be defined by reference to claims.

[0072] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be incorporated by reference.

| Electronic Patent Application Fee Transmittal | | | | | | | | | |
|--|-----------------------|--------------|------------|-------------------------|--|--|--|--|--|
| Application Number: | | | | | | | | | |
| Filing Date: | | | | | | | | | |
| Title of Invention: | ADVANCED PULSE OX | IMETRY SENSC | PR | | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | | | | |
| Filer: Aaron Samuel Johnson/Daniel Escajeda | | | | | | | | | |
| Attorney Docket Number: | MAS.1007C1 | | | | | | | | |
| Filed as Large Entity | | | | | | | | | |
| Filing Fees for Track I Prioritized Examination - Nonp | rovisional Applicatio | n under 35 l | JSC 111(a) | | | | | | |
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| UTILITY APPLICATION FILING | 1011 | 1 | 300 | 300 | | | | | |
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| REQUEST FOR PRIORITIZED EXAMINATION | 1817 | 1 | 4000 | 4000 | | | | | |
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| Patent-Appeals-and-Interference: | | | | | | | | | |
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| EFS ID: | 34636172 | | | | | |
| Application Number: | 16226249 | | | | | |
| International Application Number: | | | | | | |
| Confirmation Number: | 1002 | | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | | |
| First Named Inventor/Applicant Name: | Ammar Al-Ali | | | | | |
| Customer Number: | 64735 | | | | | |
| Filer: | Aaron Samuel Johnson/Gustavo Lopez | | | | | |
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| Time Stamp: | 18:02:05 | | | | | |
| Application Type: | Utility under 35 USC 111(a) | | | | | |

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| Deposit Account | 111410 |
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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

37 CFR 1.17 (Patent application and reexamination processing fees)

| File Listing | n: | | | | | | |
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| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) | | |
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| 1 | TrackOne Request | TrackOneRequest_MAS1007C1. PDF | | | 2 | | |
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| 5 | Drawings-only black and white line drawings | drawings Diawings_MASTOO/CT.PDF | | rawings-only black and white line drawings Drawings_MAS1007C1.PDF ce66a69576ddc1dd5e49f14da746e9c185e | | no | 7 |

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| 8 | Specification | marked-Spec_MAS1007C1.pdf | 44b6ebbe701112d4e5d96b5d41422bf05c bdbe27 | no | 24 | |
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| Information: | | | | | |
| Total Files Size (in bytes): | | | 34 | 198718 | |

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.

Doc Code: TRACK1.REQ

Document Description: TrackOne Request

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| CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION |
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| UNDER 37 CFR 1.102(e) (Page 1 of 1) |

| (ago : 5. 1) | | | | | | | |
|------------------------|--------------------------------|---|------------|--|--|--|--|
| First Named Inventor: | Ammar Al-Ali | Nonprovisional Application Number (if known): | MAS.1007C1 | | | | |
| Title of Invention: | ADVANCED PULSE OXIMETRY SENSOR | | | | | | |

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

- 1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.
- 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.
- 3. The applicable box is checked below:
 - I. V Original Application (Track One) Prioritized Examination under § 1.102(e)(1)
- i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a).
 This certification and request is being filed with the utility application via EFS-Web.
 ---OR---
 - (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.
- ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.
 - II. Request for Continued Examination Prioritized Examination under § 1.102(e)(2)
- i. A request for continued examination has been filed with, or prior to, this form.
- ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
- iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
- iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
- v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

| Signature / Aaron Johnson / | _{Date} 2018-12-19 |
|---|---|
| Name (Print/Typed) Aaron Johnson | Practitioner 74,164 Registration Number |
| Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) f Submit multiple forms if more than one signature is required.* | or signature requirements and certifications. |
| *Total of forms are submitted. | |

Privacy Act Statement

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

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

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

| Application D | ata Sheet 37 CFF | 0 1 76 | Attorney Docket Number | | MAS.1007C1 | | | | | | |
|--|---|----------------------|------------------------------------|--------|------------|-----------|---------------|--------------|-----------|-------------|----------|
| Application Da | ata Sileet 37 Ci r | X 1.70 | Applicatio | n Nu | mber | - | | | | | |
| Title of Invention | ADVANCED PULSE | OXIMET | RY SENSOF | ₹ | | | | | | | |
| bibliographic data arra This document may b | neet is part of the provision nged in a format specified e completed electronically red and included in a pape | by the Un and sub | ited States Pat mitted to the C | ent an | id Trac | demark Of | ffice as outl | ined in 37 (| CFR 1.76. | | |
| Secrecy Orde | er 37 CFR 5.2: | | | | | | | | | | |
| | of the application association associately. App | | | | | | | | | | suant to |
| Inventor Info | mation: | | | | | | | | | | |
| Inventor 1 Legal Name | | | | | | | | Re | emove | | |
| | | | | | | | Family | Name | | | Suffix |
| ▼ Ammar | | | | | | | Al-Ali | | | | |
| Residence Infor | nation (Select One) | • US | Residency | | Nor | US Res | sidency | Activ | e US Mili | tary Servic | e |
| City San Juan C | Capistrano | State/ | Province | CA | - | Country | y of Resi | dence | US | | |
| Mailing Address o Address 1 Address 2 | f Inventor: 30312 Via B | ella | | | | | | | | | |
| City San | Juan Capistrano | | | | Sta | te/Prov | ince | CA | | | |
| Postal Code | 92675 | | | Cou | ıntry | i | us | | | | |
| Inventor 2 | | | | | | | | Re | emove | | |
| Legal Name | | | | | | | | | | | |
| Prefix Given Na | me | Mi | iddle Name | | | | Family | Name | | | Suffix |
| ▼ Stephen | | | | | | | Scruggs | | | | |
| Residence Infor | nation (Select One) | ⊚ ∪s | Residency | | Nor | US Res | sidency | Activ | e US Mili | tary Servic | 9 |
| City Newport Be | each | State/ | Province | CA | _ | Country | y of Resi | dence | US | | |
| | | = | | | | | | , | , | | |
| Mailing Address o | f Inventor: | | | | | | | | | | |
| Address 1 | 307 Snug Ha | arbor Roa | ad | | | | | | | | |
| Address 2 | | | | | | | | | | | |
| City New | port Beach | | | | Sta | te/Prov | ince | CA | | | |
| Postal Code | 92663 | | | Cou | intry | i | US | | | | |
| All Inventors Mus | st Be Listed - Addi | tional Ir | ventor Info | rmati | ion b | olocks r | may be | | Add | i | |

Correspondence Information:

generated within this form by selecting the Add button.

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

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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | | MAS.1007C1 | | | | | |
|--|-------------------------|--|------------------|--|-------------------------------|----------|--|-------------|-------|
| Application Da | La SIIC | et 37 CFK i | Application Num | | nber | | | | |
| Title of Invention | ADVAN | CED PULSE OX | XIMET | RY SENSOR | | | | | |
| ☐ An Address is | being p | provided for the | he co | rrespondence Ir | formation | of this | application. | | |
| Customer Numbe | г | 64735 | | | | | | | |
| Email Address | | efiling@knobb | e.com | | | | Add Email | Remove | Email |
| Application li | nform | ation: | | | | | | | |
| Title of the Invent | ion | ADVANCED F | PULSE | OXIMETRY SENS | OR | | | | |
| Attorney Docket N | lumber | MAS.1007C1 | | | Small En | tity Sta | atus Claimed 🔲 | | |
| Application Type | | Nonprovisiona | al | | | | | | ~ |
| Subject Matter | | Utility | | | | | | | • |
| Total Number of D |)rawing | Sheets (if any | y) | 7 | Suggest | ed Fig | ure for Publication | (if any) | |
| Filing By Refe Only complete this secti application papers inclu provided in the appropri | on when f ding a spe | iling an applicati ecification and an | ıy draw | ings are being filed. | Any domesti | c benefi | it or foreign priority info | rmation mu | |
| For the purposes of a fili reference to the previou Application number of filed application | sly filed a | oplication, subjec | ct to co | | _ | - | | | i_ |
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| Publication I | nform | ation: | | | | | | | |
| Request Early | Publica | tion (Fee requi | ired a | t time of Request | 37 CFR 1.2 | 219) | | | |
| ☐ 35 U.S.C. 122 | (b) and o | certify that the on filed in anot | inver | ntion disclosed in | the attache | d appli | ation not be publish ication has not and national agreement, | will not be | |
| Representativ | ve Info | ormation: | | | | | | | |
| this information in the | e Applicati er Numbe | ion Data Sheet or or complete the | does n he Rep | ot constitute a pow presentative Name | er of attorne section belo | y in the | f attorney in the app application (see 37 Cl oth sections are comp | FR 1.32). | _ |
| | | | | | | 1 | | | |
| Please Select One | | Customer N | lumbei | r US Pate | nt Practitione | er (| Limited Recognition | on (37 CFR | 11.9) |
| Customer Number | 6 | 4735 | | | | | | | |

| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | MAS.1007C1 |
|------------------------------------|-----------------------|------------------------|------------|
| | | Application Number | |
| Title of Invention | ADVANCED PULSE OXIMET | TRY SENSOR | |

Domestic Benefit/National Stage Information:

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

When referring to the current application, please leave the "Application Number" field blank.

| Prior Application Status | Pending Continuity Type | | Remove | | |
|--------------------------|-------------------------------|---|--------------------------|---------------------------------------|--|
| Application Number | | | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) | |
| | Continuation of | ▼ | 15/195199 | 2016-06-28 | |
| Prior Application Status | Expired | ~ | Remove | | |
| Application Number | Continuity Type | | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) | |
| 5/195199 | Claims benefit of provisional | - | 62/188430 | 2015-07-02 | |

Foreign Priority Information:

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

| | | | 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 | | | |

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

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

| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | MAS.1007C1 |
|------------------------------------|-----------------------|------------------------|------------|
| | | Application Number | |
| Title of Invention | ADVANCED PULSE OXIMET | TRY SENSOR | |

Authorization or Opt-Out of Authorization to Permit Access:

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

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

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

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

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

- 2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)
- A. Applicant <u>DOES NOT</u> authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.
- B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

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

| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | MAS.1007C1 |
|------------------------------------|-----------------------|------------------------|------------|
| | | Application Number | |
| Title of Invention | ADVANCED PULSE OXIMET | TRY SENSOR | |

Applicant Information:

| Providing assignment inform to have an assignment recor | | | for compliance with any | requirement of part 3 of Title 37 of CFR | | |
|--|--|---|--|--|--|--|
| Applicant 1 | | | | Remove | | |
| The information to be provided 1.43; or the name and address who otherwise shows sufficier applicant under 37 CFR 1.46 (| d in this sections of the assign of the assign of proprietary in (assignee, per | n is the name and addres nee, person to whom the in nterest in the matter who son to whom the inventor | s of the legal representa nventor is under an oblig is the applicant under 37 is obligated to assign, o | , this section should not be completed. tive who is the applicant under 37 CFR lation to assign the invention, or person CFR 1.46. If the applicant is an appropriate person who otherwise shows sufficient ors who are also the applicant should be | | |
| Assignee | | Legal Representative u | nder 35 U.S.C. 117 | Joint Inventor | | |
| Person to whom the invent | or is obligated | to assign. | Person who she | ows sufficient proprietary interest | | |
| If applicant is the legal repr | esentative, i | ndicate the authority to | file the patent applica | tion, the inventor is: | | |
| | | | | • | | |
| Name of the Deceased or | Legally Inca | pacitated Inventor: | | | | |
| If the Applicant is an Orga | nization che | ck here. | | | | |
| Organization Name | IASIMO COR | PORATION | | | | |
| Mailing Address Informa | ation For Ap | pplicant: | | | | |
| Address 1 | 52 Discove | егу | | | | |
| Address 2 | | | | | | |
| City | Irvine | | State/Province | CA | | |
| Country US | | | Postal Code | 92618 | | |
| Phone Number | | | Fax Number | | | |
| Email Address | | | | | | |
| Additional Applicant Data n | Additional Applicant Data may be generated within this form by selecting the Add button. | | | | | |

Assignee Information including Non-Applicant Assignee Information:

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

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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| Application Data Sheet 37 CFR 1.76 | | | Attorney Docket Number | | MAS.100 | MAS.1007C1 | | |
|--|------------------------------------|-----------------------|------------------------|------------------------------|----------------|----------------|---------|--|
| | | | Application Number | | | | | |
| Title of Invention ADVANCED PULSE OXIMETRY SENSOR | | | | | | | | |
| Assignee 1 | | | | | | | | |
| Complete this section application publication as an app patent application put | n. An assignee licant. For an a | e-applicant identifie | d in the "Applica | ant Information | n" section wil | l appear on th | | |
| | | | | | | F | Remove | |
| If the Assignee or | Non-Applica | nt Assignee is ar | Organization | check here. | | | | |
| Prefix | Giver | n Name | Middle Nan | ne | Family Na | me | Suffix | |
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| Mailing Address Ir | nformation F | or Assignee inc | uding Non- | Applicant As | signee: | <u> </u> | | |
| Address 1 | | | | | | | | |
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| Phone Number | | | | Fax Number | er | | | |
| Email Address | | | | | • | | | |
| Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. | | | | | | | | |
| | | | | | | | | |
| Signature: | | | | | | | | |
| NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the INITIAL filling of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c). This Application Data Sheet must be signed by a patent practitioner if one or more of the applicants is a juristic entity (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants. See 37 CFR 1.4(d) for the manner of making signatures and certifications. | | | | | | | | |
| Signature //Aaron S. Johnson/ | | | | Date (YYYY-MM-DD) 2018-12-19 | | | | |
| First Name Aard | on S. | Last Name | Johnson | | Registra | ation Numbe | r 74164 | |
| Additional Signature may be generated within this form by selecting the Add button. | | | | | | | | |

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| Application Data Sheet 37 CFR 1.76 | | Attorney Docket Number | MAS.1007C1 |
|------------------------------------|-----------------------|------------------------|------------|
| | | Application Number | |
| Title of Invention | ADVANCED PULSE OXIMET | RY SENSOR | |

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.
- 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.
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- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
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- 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.

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

| | | not be recognized in the application. | пе аррпсацоп ю м | mich the Fower of Attorney is | | | |
|---|-------------------------------|---|------------------------|-------------------------------|--|--|--|
| Application Number | | Filed herewith | | | | | |
| Filing Date | | Filed herewith | | | | | |
| First Named Inventor | | Ammar Al-Ali | | | | | |
| Title | | ADVANCED PULSE OXIMETRY SENSOR | | | | | |
| Art Unit | | Unassigned | | | | | |
| Examiner Name | | Unassigned | | | | | |
| Attorney Docket Number | | MAS.1007C1 | | | | | |
| SIGNATURE of Applicant or Patent Practitioner | | | | | | | |
| Signature | /Aaron S. Johnson/ | | Date (Optional) | 2018-12-19 | | | |
| Name | Aaron S. Johnson | | Registration Number | 74164 | | | |
| Title (if Applicant is a juristic entity) | | | | | | | |
| more than one applica | st be signed int, use mult | in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) | for signature requir | ements and certifications. If | | | |

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- 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.
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ABSTRACT OF THE DISCLOSURE

A non-invasive, optical-based physiological monitoring system is disclosed. One embodiment includes an emitter configured to emit light. A diffuser is configured to receive and spread the emitted light, and to emit the spread light at a tissue measurement site. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal representative of the detected light. A processor is configured to receive the transmitted signal and to determine a physiological parameter, such as, for example, arterial oxygen saturation, in the tissue measurement site.

WHAT IS CLAIMED IS:

1. An optical physiological measurement system comprising:

an emitter which emits light of a wavelength;

a diffuser which receives, spreads and emits the spread light, wherein the emitted spread light is directed at a tissue measurement site of a patient; and

a detector configured to detect the emitted light after attenuation by tissue of the patient, the detector further configured to transmit a signal responsive to the detected light.

- 2. The optical physiological measurement system of Claim 1, further comprising a concentrator which receives the spread light after attenuation by tissue of the patient, concentrates the received spread light and emits the concentrated light in the direction of the detector.
- 3. The optical physiological measurement system of Claim 1, further comprising a processor configured to receive the transmitted signal responsive to the detected light and to determine a physiological parameter.
- 4. The optical physiological measurement system of Claim 3, wherein the parameter is arterial oxygen saturation.
- 5. The optical physiological measurement system of Claim 1, wherein the diffuser comprises at least one of a glass diffuser, ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser.
- 6. The optical physiological measurement system of Claim 1, wherein the diffuser emits the spread light with a substantially uniform intensity profile.
- 7. The optical physiological measurement system of Claim 1, wherein the diffuser defines a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.
- 8. The optical physiological monitor of Claim 7, further comprising a detector filter having a light-absorbing surface facing the tissue measurement site and an opening, the opening having dimensions, wherein the dimensions of the opening are substantially similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site.

- 9. The optical physiological measurement system of Claim 7, wherein the surface area shape is rectangular.
- 10. The optical physiological measurement system of Claim 9, wherein the rectangular surface area shape has dimensions within a range of approximately 0.25 cm to 3 cm in width and a range of approximately 1 cm to 6 cm in length.
- 11. The optical physiological measurement system of Claim 9, wherein the rectangular surface area shape has dimensions in the range of approximately 0.1 cm to 2 cm in width and approximately 0.5 cm to 5 cm in length.
- 12. The optical physiological measurement system of Claim 9, wherein the rectangular surface area shape has dimensions of approximately 1 centimeter in width and approximately 1.5 centimeters in length.
- 13. The optical physiological measurement system of Claim 7, wherein the surface area shape is square.
- 14. The optical physiological measurement system of Claim 13, wherein the square surface area shape has dimensions in the range of approximately 0.25 cm² to 10 cm².
- 15. The optical physiological measurement system of Claim 9, further comprising a detector filter comprising a light-absorbing surface facing the tissue measurement site and an opening, the opening having dimensions, wherein the dimensions of the opening are substantially similar to dimensions of the rectangular shape.
- 16. The optical physiological measurement system of Claim 1, wherein the concentrator comprises at least one of glass, ground glass, glass beads, opal glass, and a compound parabolic concentrator.
- 17. The optical physiological measurement system of Claim 1, further comprising a detector filter comprising a light-absorbing surface facing the tissue measurement site and an opening, wherein the opening is configured to allow the spread light, after being attenuated by or reflected from the tissue measurement site, to be received by the concentrator.
- 18. A method to determine a constituent or analyte in a patient's blood, the method comprising:

emitting, from an emitter, light of a wavelength;

spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site, wherein the diffuser spreads the light over a greater area of the tissue measurement site than would otherwise be illuminated by the emitter directly emitting light at a tissue measurement site; and

detecting, with the detector, the emitted concentrated light.

- 19. The method of Claim 18, further comprising receiving, by a concentrator, the emitted spread light after the spread light has been attenuated by or reflected from the tissue measurement site and concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector.
- 20. The method of Claim 18, further comprising transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.
- 21. The method of Claim 18, further comprising filtering, with a lightabsorbing detector filter, scattered portions of the emitted spread light.
- 22. The method of Claim 18, wherein spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser.
- 23. The method of Claim 18, wherein spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site further comprises spreading the emitted light with a substantially uniform intensity profile.
- 24. The method of Claim 18, wherein spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site further comprises spreading the emitted light so as to define a surface area

shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

- 25. The method of Claim 18, wherein concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector is performed by at least one of a glass concentrator, a glass bead concentrator, an opal glass concentrator, and a compound parabolic concentrator.
 - 26. A pulse oximeter sensor comprising:an emitter configured to emit light at a wavelength;
 - a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light, wherein the emitted spread light is directed at a tissue measurement site; and
 - a detector configured to detect the emitted spread light, the spread light having been attenuated by the tissue measurement site, the detector further configured to output a signal responsive to the detected light.
- 27. The pulse oximeter sensor of Claim 26, further comprising a concentrator which concentrates the emitted light after it has been attenuated by the tissue measurement site and directs the concentrated light toward the detector.
- 28. The pulse oximeter sensor of Claim 26, wherein the detector is further configured to output the signal response to the detected light to a processor configured to receive the signal responsive to the detected light and to determine a physiological parameter.
- 29. The pulse oximeter sensor of Claim 26, wherein the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.
- 30. The pulse oximeter sensor of Claim 29, wherein the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site.
- 31. The pulse oximeter sensor of Claim 30, wherein the detector further comprises an array of detectors configured to cover the detection area.
 - 32. A pulse oximeter sensor comprising:

an emitter configured to emit light at a wavelength;

- a concentrator which concentrates the emitted light after it has been attenuated by the tissue measurement site; and
- a detector configured to detect the emitted spread, the spread light having been attenuated by or reflected from the tissue measurement site, the detector further configured to output a signal responsive to the detected light.
- 33. The pulse oximeter sensor of Claim 32, wherein the detector is further configured to transmit the output signal responsive to the detected light to a processor configured to receive the signal responsive to the detected light and to determine a physiological parameter.
- 34. The pulse oximeter sensor of Claim 32, wherein the concentrator is further configured to define a surface area shape by which the emitted spread light is received from a surface of the tissue measurement site.
- 35. The pulse oximeter sensor of Claim 34, wherein the concentrator is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site.
- 36. The pulse oximeter sensor of Claim 35, wherein the detector further comprises an array of detectors configured to cover the detection area.

MAS.1007C1 PATENT

ADVANCED PULSE OXIMETRY SENSOR

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 15/195,199 filed June 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed July 2, 2015, entitled "Advanced Pulse Oximetry Sensor," which is incorporated by reference herein. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE DISCLOSURE

[0002] The present disclosure relates to the field of non-invasive optical-based physiological monitoring sensors, and more particularly to systems, devices and methods for improving the non-invasive measurement accuracy of oxygen saturation, among other physiological parameters.

BACKGROUND

[0003] Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_{λ} , the intensity of the incident light $I_{\theta,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ .

[0004] In generalized form, the Beer-Lambert law is expressed as:

$$I_{\lambda} = I_{o,\lambda} e^{-d_{\lambda} \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_{i} \tag{2}$$

where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve equations 1 and 2 is the number of significant absorbers that are present in the solution.

[0005] A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters. Pulse oximetry relies on a sensor attached externally to the patient to output signals indicative of various physiological parameters, such as a patient's blood constituents and/or analytes, including for example a percent value for arterial oxygen saturation, among other physiological parameters. The sensor has an emitter that transmits optical radiation of one or more wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO₂) and deoxygenated hemoglobin (Hb) in the blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a patient's oxygen supply.

[0006] A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site, such as a finger, toe, earlobe, nose, hand, foot, or other site having pulsatile blood flow which can be penetrated by light from the one or more emitters. The detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site. The detector outputs a detector signal to the monitor over the communication medium. The monitor processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO2) and/or pulse rate. A pulse oximetry sensor is described in U.S. Patent No. 6,088,607 entitled *Low Noise Optical Probe*; pulse oximetry signal processing is described in U.S. Patent Nos. 6,650,917 and 6,699,194 entitled *Signal Processing Apparatus* and *Signal Proc*

described in U.S. Patent No. 6,584,336 entitled *Universal/Upgrading Pulse Oximeter*; all of which are assigned to Masimo Corporation, Irvine, CA, and each is incorporated by reference herein in its entirety.

[0007] There are many sources of measurement error introduced to pulse oximetry systems. Some such sources of error include the pulse oximetry system's electronic components, including emitters and detectors, as well as chemical and structural physiological differences between patients. Another source of measurement error is the effect of multiple scattering of photons as the photons pass through the patient's tissue (arterial blood) and arrive at the sensor's light detector.

SUMMARY

[0008] This disclosure describes embodiments of non-invasive methods, devices, and systems for measuring blood constituents, analytes, and/or substances such as, by way of non-limiting example, oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like.

[0009] In an embodiment, an optical physiological measurement system includes an emitter configured to emit light of one or more wavelengths. The system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal indicative of the

detected light. The system also includes a processor configured to receive the transmitted signal indicative of the detected light and to determine, based on an amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.

[0010] In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others.

[0011] According to some embodiments, the optical physiological measurement system includes an optical filter having a light-absorbing surface that faces the tissue measurement site. The optical filter also has an opening that is configured to allow the spread light, after being attenuated by the tissue measurement site, to be received by the concentrator. In an embodiment, the opening has dimensions, wherein the dimensions of the opening are similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In an embodiment, the opening has dimensions that are larger than the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In other embodiments, the dimensions of the opening in the optical filter are not the same as the diffuser opening, but the dimensions are larger than the detector package.

[0012] In other embodiments of the present disclosure, the concentrator comprises glass, ground glass, glass beads, opal glass, or a compound parabolic concentrator. In some embodiments the concentrator comprises a cylindrical structure having a truncated circular conical structure on top. The truncated section is adjacent the detector. The light concentrator is structured to receive the emitted optical radiation, after reflection by the tissue measurement site, and to direct the reflected light to the detector.

[0013] In accordance with certain embodiments of the present disclosure, the processor is configured to determine an average level of the light detected by the detector. The average level of light is used to determine a physiological parameter in the tissue measurement site.

[0014] According to another embodiment, a method to determine a constituent or analyte in a patient's blood is disclosed. The method includes emitting, from an emitter, light of at least one wavelength; spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site; receiving, by a concentrator, the spread light after the spread light has been attenuated by the tissue measurement site; concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector; detecting, with the detector, the emitted concentrated light; transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

[0015] In some embodiments, the method to determine a constituent or analyte in a patient's blood includes filtering, with a light-absorbing detector filter, scattered portions of the emitted spread light. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of approximately 1-5 cm in width and approximately 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.25-3 cm in width and approximately 1-7 cm in length. In another embodiment, the light-absorbing detector filter is substantially square in shape and has outer dimensions in the range of approximately 0.25-10 cm², and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.1-8cm². In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of approximately 3 cm in width and approximately 6 cm in length, and has an opening through which emitted light may pass, the

opening having dimensions of approximately 1.5 cm in width and approximately 4 cm in length.

[0016] In still other embodiments of the method to determine a constituent or analyte in a patient's blood, spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser. In some embodiments the emitted spread light is emitted with a substantially uniform intensity profile. And in some embodiments, emitting the spread light from the diffuser to the tissue measurement site includes spreading the emitted light so as to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

According to yet another embodiment, a pulse oximeter is [0017] disclosed. The pulse oximeter includes an emitter configured to emit light at one or more wavelengths. The pulse oximeter also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light directed at a tissue measurement sight. The pulse oximeter also includes a detector configured to detect the emitted spread light after being attenuated by or reflected from the tissue measurement site and to transmit a signal indicative of the detected light. The pulse oximeter also includes a processor configured to receive the transmitted signal and to process the received signal to determine an average absorbance of a blood constituent or analyte in the tissue measurement site over a larger measurement site area than can be performed with a point light source or point detector. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site, and the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. According to some embodiments, the detector comprises an array of detectors configured to cover the detection area. In still other embodiments, the processor is further configured to determine an average of the detected light.

[0018] For purposes of summarizing, certain aspects, advantages and novel features of the disclosure have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the systems, devices and/or methods disclosed herein. Thus, the subject matter of the disclosure herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- **[0019]** Throughout the drawings, reference numbers can be re-used to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the disclosure described herein and not to limit the scope thereof.
- **[0020]** FIG. 1 illustrates a conventional approach to 2D pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.
- **[0021]** FIG. 2 illustrates the disclosed 3D approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. 2A.
- **[0022]** FIG. 3 illustrates schematically a side view of a 3D pulse oximetry sensor according to an embodiment of the present disclosure.
- [0023] FIG. 4A is a top view of a portion of a 3D pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0024]** FIG. 4B illustrates the top view of a portion of the 3D pulse oximetry sensor shown in FIG. 4A, with the addition of a tissue measurement site in operational position.
- [0025] FIG. 5 illustrates a top view of a 3D pulse oximetry sensor according to an embodiment of the present disclosure.
- **[0026]** FIG. 6 illustrates a conventional 2D approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

[0027] FIG. 7A is a simplified schematic side view illustration of a reflective 3D pulse oximetry sensor according to an embodiment of the present disclosure.

[0028] FIG. 7B is a simplified schematic top view illustration of the 3D reflective pulse oximetry sensor of FIG. 7A.

[0029] FIG. 8 illustrates a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure.

DETAILED DESCRIPTION

[0030] FIG. 1 illustrates schematically a conventional pulse oximetry sensor having a two-dimensional (2D) approach to pulse oximetry. As illustrated, the emitter 104 is configured to emit optical radiation as a point optical source, i.e., an optical radiation source that has negligible dimensions such that it may be considered as a point. This approach is referred to herein as "two-dimensional" pulse oximetry because it applies a two-dimensional analytical model to the threedimensional space of the tissue measurement site 102 of the patient. Point optical sources feature a defined, freely selectable, and homogeneous light beam area. Light beams emitted from LED point sources often exhibit a strong focus which can produce a usually sharply-defined and evenly-lit illuminated spot often with high intensity dynamics. Illustratively, when looking at the surface of the tissue measurement site 102 (or "sample tissue"), which in this example is a finger, a small point-like surface area of tissue 204 is irradiated by a point optical source. In some embodiments, the irradiated circular area of the point optical source is in the range between 8 and 150 microns. Illustratively, the emitted point optical source of light enters the tissue measurement site 102 as a point of light. As the light penetrates the depth of the tissue 102, it does so as a line or vector, representing a two-dimensional construct within a three-dimensional structure, namely the patient's tissue 102.

[0031] Use of a point optical source is believed to reduce variability in light pathlength which would lead to more accurate oximetry measurements. However, in practice, photons do not travel in straight paths. Instead, the light particles scatter,

bouncing around between various irregular objects (such as, for example, red blood cells) in the patient's blood. Accordingly, photon pathlengths vary depending on, among other things, their particular journeys through and around the tissue at the measurement site 102. This phenomenon is referred to as "multiple scattering." In a study, the effects of multiple scattering were examined by comparing the results of photon diffusion analysis with those obtained using an analysis based on the Beer-Lambert law, which neglects multiple scattering in the determination of light pathlength. The study found that that the difference between the average lengths of the paths traveled by red and infrared photons makes the oximeter's calibration curve (based on measurements obtained from normal subjects) sensitive to the total attenuation coefficients of the tissue in the two wavelength bands used for pulse oximetry, as well as to absorption by the pulsating arterial blood.

[0032] FIG. 2 illustrates schematically the disclosed systems, devices, and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site 102 as compared to the 2D point optical source approach described with respect to FIG. 1. In an embodiment, again looking at the surface of the tissue measurement site 102, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape with dimensions in the range of approximately 0.25-3 cm in width and approximately 1-6 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 1.5 cm in width and approximately 2 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape and has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially rectangular in shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the irradiated surface area 206 of the measurement site 102 is substantially square in shape and has dimensions in a range of approximately 0.25-9 cm². In certain embodiments, the irradiated surface area 206 of the measurement site 102 is within a range of approximately 0.5-2 cm in width, and

approximately 1-4 cm in length. Of course a skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area 206 can be used. Advantageously, by irradiating the tissue measurement site 102 with a surface area 206, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient's sample tissue 102.

[0033] According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (*i.e.*, arterial blood). Advantageously, by irradiating a larger volume of tissue 102, a larger sample size of light attenuated (or reflected) by the tissue 102 is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. 1. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry systems, devices, and methods will yield a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0034] FIG. 3 illustrates schematically a side view of a pulse oximetry 3D sensor 300 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 300 irradiates the tissue measurement site 102 and detects the emitted light, after being attenuated by the tissue measurement site 102. In other embodiments, for example, as describe below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102. The 3D sensor 300 includes an emitter 302, a light diffuser 304, a light-absorbing detector filter 306, a light concentrator 308, and a detector 310. In some optional embodiments, the 3D sensor 300 further includes a reflector 305. The reflector 305 can be a metallic reflector or other type of reflector. Reflector 305 can be a coating, film, layer or other type of reflector. The reflector 305 can serve as a reflector to prevent emitted light from emitting out of a top portion of the light diffuser 304 such that light from the emitter 302 is directed in the

tissue rather than escaping out of a side or top of the light diffuser 304. Additionally, the reflector 305 can prevent ambient light from entering the diffuser 304 which might ultimately cause errors within the detected light. The reflector 305 also prevent light piping that might occur if light from the detector 302 is able to escape from the light diffuser 304 and be pipped around a sensor securement mechanism to detector 310 without passing through the patient's tissue 102.

[0035] The emitter 302 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 302 can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 302 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 302 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter 302 includes a single source optical radiation.

[0036] The light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area, such as the area 206 depicted in FIG. 2. In some embodiments, the light diffuser 304 is a beam shaper that can homogenize the input light beam from the emitter 302, shape the output intensity profile of the received light, and define the way (e.g., the shape or pattern) the emitted light is distributed to the tissue measurement site 102. Examples of materials that can be used to realize the light diffuser 304 include, without limitation, a white surface, glass, ground glass, glass beads, polytetrafluoroethylene (also known as Teflon®, opal glass, and greyed glass, to name a few. Additionally, engineered diffusers can be used to realize the diffuser 304 by providing customized light shaping with respect to intensity and distribution. Such diffusers can, for example, deliver substantially uniform illumination over a specified target area (such as, for example, irradiated surface area 206) in an energy-efficient manner. Examples of engineered diffusers can include molded plastics with specific shapes, patterns or textures designed to diffuse the emitter light across the entirety of the patient's tissue surface.

[0037] Advantageously, the diffuser 304 can receive emitted light in the form of a point optical source and spread the light to fit a desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 304 is made of ground glass which spreads the emitted light with a Gausian intensity profile. In another embodiment the diffuser 304 includes glass beads. In some embodiments, the diffuser 304 is constructed so as to diffuse the emitted light in a Lambertian pattern. A Lambertian pattern is one in which the radiation intensity is substantially constant throughout the area of dispersion. One such diffuser 304 is made from opal glass. Opal glass is similar to ground glass, but has one surface coated with a milky white coating to diffuse light evenly. In an embodiment, the diffuser 304 is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site 102) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution. In some embodiments, the efficiency, or the amount of light transmitted by the diffuser 304, is greater than 70% of the light emitted by the emitter 302. In some embodiments, the efficiency is greater than 90% of the emitted light. Other optical elements known in the art may be used for the diffuser 304.

[0038] In an embodiment, the diffuser 304 has a substantially rectangular shape having dimensions within a range of approximately 0.5-2 cm in width and approximately 1-4 centimeters in length. In another embodiment, the substantially rectangular shape of the diffuser 304 has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the diffuser's 304 substantially rectangular shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the diffuser 304 has a substantially square shape with dimensions in the range of approximately 0.25-10 cm².

[0039] The light-absorbing detector filter 306, which is also depicted in FIG. 4A in a top view, is a planar surface having an opening 402 through which the emitted light may pass after being attenuated by the tissue measurement site 102. In the depicted embodiment, the opening 402 is rectangular-shaped, with

dimensions substantially similar to the irradiated surface area 206. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 4 cm in width and 8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 2 cm in width and 5 cm in length. In another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of 1-3 cm in width and 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of 0.25-2 cm in width and 1-4 cm in length. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 3 cm in width and 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 1.5 cm in width and 4 cm in length.

[0040] The top surface of the light-absorbing filter 306 (facing the tissue measurement site 102 and the emitter 302) is coated with a material that absorbs light, such as, for example, black pigment. Many other types of light-absorbing materials are well known in the art and can be used with the detector filter 306. During operation, light emitted from the emitter 302 can reflect off of the tissue measurement site 102 (or other structures within the 3D sensor 300) to neighboring portions of the 3D sensor 300. If those neighboring portions of the 3D sensor 300 possess reflective surfaces, then the light can reflect back to the tissue measurement site 102, progress through the tissue and arrive at the detector 310. Such multiple scattering can result in detecting photons whose pathlengths are considerably longer than most of the light that is detected, thereby introducing variations in pathlength which will affect the accuracy of the measurements of the pulse oximetry 3D sensor 300. Advantageously, the light-absorbing filter 306 reduces or eliminates the amount of emitted light that is reflected in this manner because it absorbs such reflected light, thereby stopping the chain of scattering events. In certain embodiments, the sensor-facing surfaces of other portions of the 3D sensor 300 are covered in light-absorbing material to further decrease the effect of reflective multiple scattering.

[0041] The light concentrator 308 is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site 102, to collect and concentrate the dispersed optical radiation, and to direct the collected and concentrated optical radiation to the detector 310. In an embodiment, the light concentrator 308 is made of ground glass or glass beads. In some embodiments, the light concentrator 308 includes a compound parabolic concentrator.

[0042] As described above with respect to FIG. 1, the detector 310 captures and measures light from the tissue measurement site 102. For example, the detector 310 can capture and measure light transmitted from the emitter 302 that has been attenuated by the tissue in the measurement site 102. The detector 310 can output a detector signal responsive to the light captured or measured. The detector 310 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 310 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area 206 to capture the attenuated or reflected light from the tissue measurement site.

[0043] Referring to FIG. 4A, a top view of a portion of the 3D sensor 300 is provided. The light-absorbing detector filter 306 is illustrated having a top surface coated with a light-absorbing material. The light-absorbing material can be a black opaque material or coating or any other dark color or coating configured to absorb light. Additionally, a rectangular opening 402 is positioned relative to the light concentrator 308 (shown in phantom) and the detector 310 such that light may pass through the rectangular opening 402, into the light concentrator 308, and to the detector 310. FIG. 4B illustrates the top view of a portion of the 3D sensor 300 as in FIG. 4A, with the addition of the tissue measurement site 102 in operational position. Accordingly, the rectangular opening 402, the light concentrator 308 and the detector 310 are shown in phantom as being under the tissue measurement site 102. In FIGS. 4A and 4B, the light concentrator 308 is shown to have dimensions significantly larger than the dimensions of the rectangular opening 402. In other embodiments, the dimensions of the light concentrator 308, the rectangular opening 402, and the irradiated surface area 206 are substantially similar.

[0044] FIG. 5 illustrates a top view of a 3D pulse oximetry sensor 500 according to an embodiment of the present disclosure. The 3D sensor 500 is configured to be worn on a patient's finger 102. The 3D sensor 500 includes an adhesive substrate 502 having front flaps 504 and rear flaps 506 extending outward from a center portion 508 of the 3D sensor 500. The center portion 508 includes components of the 3D pulse oximetry sensor 300 described with respect to FIGS. 3, 4A and 4B. On the front side of the adhesive substrate 502 the emitter 302 and the light diffuser 304 are positioned. On the rear side of the adhesive substrate 502 the light-absorbent detector filter 306, the light concentrator 308 and the detector 310 are positioned. In use, the patient's finger serving as the tissue measurement site 102 is positioned over the rectangular opening 402 such that when the front portion of the adhesive substrate is folded over on top of the patient's finger 102, the emitter 302 and the light diffuser 304 are aligned with the measurement site 102, the filter 306, the light concentrator 308 and the detector 310. Once alignment is established, the front and rear flaps 504, 506 can be wrapped around the finger measurement site 102 such that the adhesive substrate 502 provides a secure contact between the patient's skin and the 3D sensor 500. Fig. 5 also illustrates an example of a sensor connector cable 510 which is used to connect the 3D sensor 500 to a monitor 809, as described with respect to FIG. 8.

approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source. Reflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site 102. Light is emitted into a tissue measurement site 102 and attenuated. The emitted light passes into the tissue 102 and is then reflected back to the same side of the tissue measurement site 102 as the emitter. As illustrated in FIG. 6, a depicted reflective 2D pulse oximetry sensor 600 includes an emitter 602, a light block 606, and a detector 610. The light block 606 is necessary because the emitter 602 and the detector 610 are located on the same side of the tissue measurement site 102. Accordingly, the light block 606 prevents incident emitter light, which did not enter the tissue measurement site 102, from arriving at the

detector 610. The depicted 2D pulse oximetry sensor 600 is configured to emit light as a point source. As depicted in FIG. 6, a simplified illustration of the light path 620 of the emitted light from the emitter 602, through the tissue measurement site 102, and to the detector 610 is provided. Notably, a point source of light is emitted, and a point source of light is detected. As discussed above with respect to FIG. 1, use of a point optical source can result in substantial measurement error due to pathlength variability resulting from the multiple scatter phenomenon. The sample space provided by a 2D point optical emitter source is not large enough to account for pathlength variability, which will skew measurement results.

[0046] FIGS. 7A and 7B are simplified schematic side and top views, respectively, of a 3D reflective pulse oximetry sensor 700 according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor 700 irradiates the tissue measurement site 102 and detects the emitted light that is reflected by the tissue measurement site 102. The 3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter 702 and detector 710 are on located the same side of the tissue measurement site 102. The 3D sensor 700 includes an emitter 702, a light diffuser 704, a light block 706, a light concentrator 708, and a detector 710.

[0047] As previously described, the emitter 702 can serve as the source of optical radiation transmitted towards the tissue measurement site 102. The emitter 702 can include one or more sources of optical radiation. Such sources of optical radiation can include LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 702 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter 702 transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter 702 includes a single source of optical radiation.

[0048] The light diffuser 704 receives the optical radiation emitted from the emitter 302 and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the area outlined by the light diffuser 704 as depicted in FIG.

7B. Advantageously, the diffuser 704 can receive emitted light in the form of a 2D point optical source (or any other form) and spread the light to fit the desired surface area on a plane defined by the surface of the tissue measurement site 102. In an embodiment, the diffuser 704 is made of ground glass or glass beads. A skilled artisan will understand that may other materials can be used to make the light diffuser 704.

[0049] The light blocker 706 includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710. (For purposes of illustration, the light block cover 707 is not illustrated in FIG. 7B.) The light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708 and the detector 710. The light isolation chamber formed by the light blocker 706 and cover 708 ensures that the only light detected by the detector 710 is light that is reflected from the tissue measurement site.

[0050] The light concentrator 708 is a cylindrical structure with a truncated circular conical structure on top, the truncated section of which of which is adjacent the detector 710. The light concentrator 708 is structured to receive the emitted optical radiation, after reflection by the tissue measurement site 102, and to direct the reflected light to the detector 710. In an embodiment, the light concentrator 708 is made of ground glass or glass beads. In some embodiments, the light concentrator 708 includes a compound parabolic concentrator.

[0051] As previously described, the detector 710 captures and measures light from the tissue measurement site 102. For example, the detector 710 can capture and measure light transmitted from the emitter 702 that has been reflected from the tissue in the measurement site 102. The detector 710 can output a detector signal responsive to the light captured or measured. The detector 710 can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors 710 can be arranged in an array with a spatial configuration corresponding to the irradiated surface area depicted in FIG. 7B by the light concentrator 708 to capture the reflected light from the tissue measurement site.

[0052] Advantageously, the light path 720 illustrated in FIG. 7A depicts a substantial sample of reflected light that enter the light isolation chamber formed by the light blocker 706 and cover 707. As previously discussed, the large sample of reflected light (as compared to the reflected light collected using the 2D point optical source approach) provides the opportunity to take an average of the detected light, to derive a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

[0053] Referring now to FIG. 7B, a top view of the 3D sensor 700 is illustrated with both the emitter 702 and the light blocker cover 707 removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser 704. As light is emitted from the emitter 702 (not shown in FIG. 7B), it is diffused homogenously and directed to the tissue measurement site 102. The light blocker 706 forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector 710. The light blocker cover 707 blocks incidental light from entering the light isolation chamber from above. The light concentrator 710 collects the reflected light from the tissue measurement site 102 and funnels it upward toward the detector 710 at the center of the 3D sensor 700.

[0054] FIG. 8 illustrates an example of an optical physiological measurement system 800, which may also be referred to herein as a pulse oximetry system 800. In certain embodiments, the pulse oximetry system 800 noninvasively measures a blood analyte, such as oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (*e.g.*, saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve IndexTM (ORITM) or many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like. The system 800 can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

[0055] The pulse oximetry system 800 can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a

measurement site 102. The measurement site 102 can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or the like.

[0056] The pulse oximetry system 800 can include a sensor 801 (or multiple sensors) that is coupled to a processing device or physiological monitor 809. In an embodiment, the sensor 801 and the monitor 809 are integrated together into a single unit. In another embodiment, the sensor 801 and the monitor 809 are separate from each other and communicate with one another in any suitable manner, such as via a wired or wireless connection. The sensor 801 and monitor 809 can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like.

[0057] In the depicted embodiment shown in FIG. 8, the sensor 801 includes an emitter 804, a detector 806, and a front-end interface 808. The emitter 804 can serve as the source of optical radiation transmitted towards measurement site 102. The emitter 804 can include one or more sources of optical radiation, such as light emitting diodes (LEDs), laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter 804 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

[0058] The pulse oximetry system 800 also includes a driver 811 that drives the emitter 804. The driver 111 can be a circuit or the like that is controlled by the monitor 809. For example, the driver 811 can provide pulses of current to the emitter 804. In an embodiment, the driver 811 drives the emitter 804 in a progressive fashion, such as in an alternating manner. The driver 811 can drive the emitter 804 with a series of pulses for some wavelengths that can penetrate tissue relatively well and for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments. The driver 811 can be synchronized with other parts of the sensor 801 to minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter 804. In some embodiments, the driver 811 is capable of driving the emitter 804 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

[0059] The detector 806 captures and measures light from the tissue measurement site 102. For example, the detector 806 can capture and measure light transmitted from the emitter 804 that has been attenuated or reflected from the tissue at the measurement site 102. The detector 806 can output a detector signal 107 responsive to the light captured and measured. The detector 806 can be implemented using one or more photodiodes, phototransistors, or the like. In some embodiments, a detector 806 is implemented in detector package to capture and measure light from the tissue measurement site 102 of the patient. The detector package can include a photodiode chip mounted to leads and enclosed in an encapsulant. In some embodiments, the dimensions of the detector package are approximately 2 square centimeters. In other embodiments, the dimensions of the detector package are approximately 1.5 centimeters in width and approximately 2 centimeters in length.

[0060] The front-end interface 808 provides an interface that adapts the output of the detectors 806, which is responsive to desired physiological parameters. For example, the front-end interface 808 can adapt the signal 807 received from the detector 806 into a form that can be processed by the monitor 809, for example, by a signal processor 810 in the monitor 809. The front-end interface 808 can have its components assembled in the sensor 801, in the monitor 809, in a connecting cabling (if used), in combinations of the same, or the like. The location of the front-end interface 808 can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

[0061] The front-end interface 808 can be coupled to the detector 806 and to the signal processor 810 using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front-end interface 808 can also be at least partially integrated with various components, such as the detectors 806. For example, the front-end interface 808 can include one or more integrated circuits that are on the same circuit board as the detector 806. Other configurations can also be used.

[0062] As shown in FIG. 8, the monitor 909 can include the signal processor 810 and a user interface, such as a display 812. The monitor 809 can also include optional outputs alone or in combination with the display 812, such as a storage device 814 and a network interface 816. In an embodiment, the signal processor 810 includes processing logic that determines measurements for desired analytes based on the signals received from the detector 806. The signal processor 810 can be implemented using one or more microprocessors or sub-processors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

[0063] The signal processor 810 can provide various signals that control the operation of the sensor 801. For example, the signal processor 810 can provide an emitter control signal to the driver 811. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter 804. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter 804 to follow a precise timing and consistent pattern. For example, when a transimpedance-based front-end interface 808 is used, the control signal from the signal processor 810 can provide synchronization with an analog-to-digital converter (ADC) in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory 813 can be included in the front-end interface 808 and/or in the signal processor 810. This memory 813 can serve as a buffer or storage location for the front-end interface 808 and/or the signal processor 810, among other uses.

[0064] The user interface 812 can provide an output, *e.g.*, on a display, for presentation to a user of the pulse oximetry system 800. The user interface 812 can be implemented as a touch-screen display, a liquid crystal display (LCD), an organic LED display, or the like. In alternative embodiments, the pulse oximetry system 800 can be provided without a user interface 812 and can simply provide an output signal to a separate display or system.

[0065] The storage device 814 and a network interface 816 represent other optional output connections that can be included in the monitor 809. The

storage device 814 can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device 814, which can be executed by the signal processor 810 or another processor of the monitor 809. The network interface 816 can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (*e.g.*, WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor 809 to communicate and share data with other devices. The monitor 809 can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface 812, to control data communications, to compute data trending, or to perform other operations.

[0066] Although not shown in the depicted embodiment, the pulse oximetry system 800 can include various other components or can be configured in different ways. For example, the sensor 801 can have both the emitter 804 and detector 806 on the same side of the tissue measurement site 102 and use reflectance to measure analytes.

[0067] Although the foregoing disclosure has been described in terms of certain preferred embodiments, many other variations than those described herein will be apparent to those of ordinary skill in the art.

[0068] Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not

exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

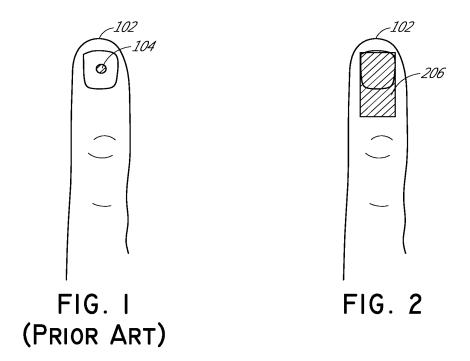
[0069] While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the systems, devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the disclosure described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

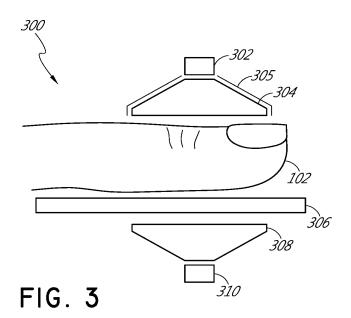
[0070] The term "and/or" herein has its broadest, least limiting meaning which is the disclosure includes A alone, B alone, both A and B together, or A or B alternatively, but does not require both A and B or require one of A or one of B. As used herein, the phrase "at least one of" A, B, "and" C should be construed to mean a logical A or B or C, using a non-exclusive logical or.

[0071] The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage. Although the foregoing disclosure has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to

be limited by the description of the preferred embodiments, but is to be defined by reference to claims.

[0072] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be incorporated by reference.





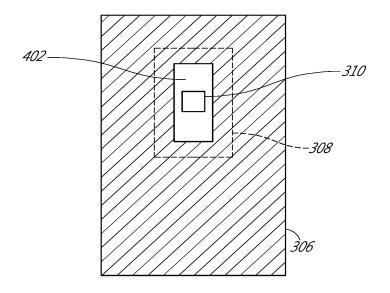


FIG. 4A

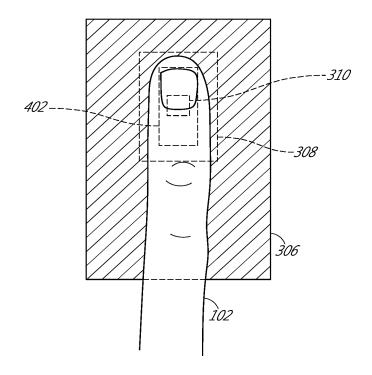
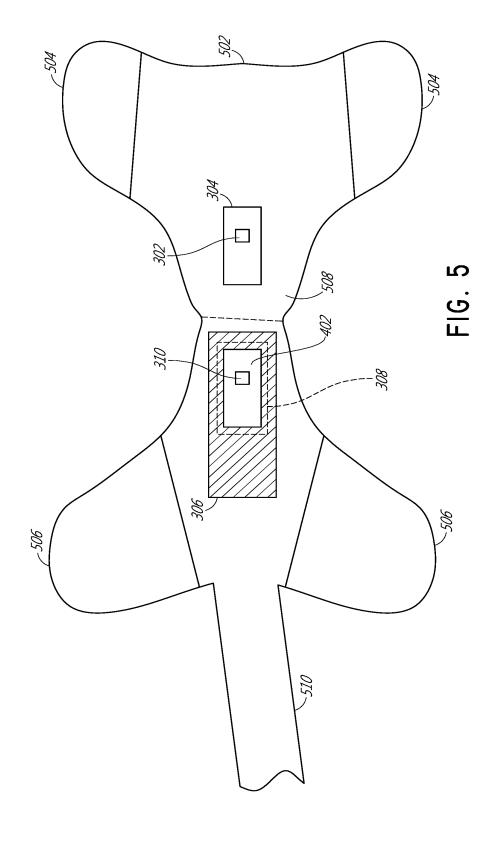
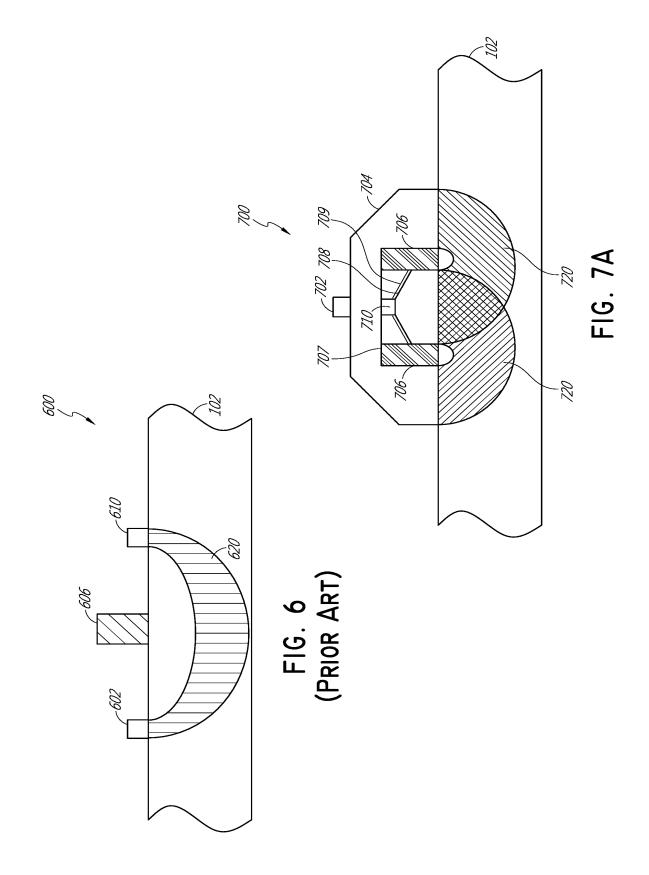


FIG. 4B





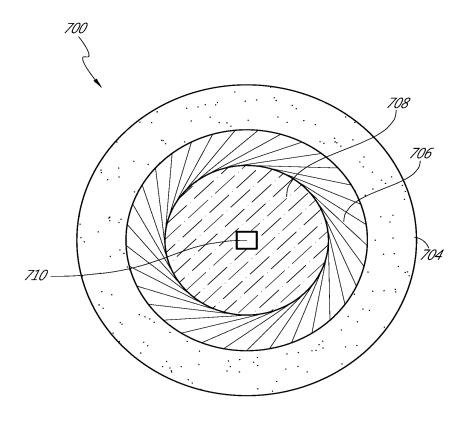
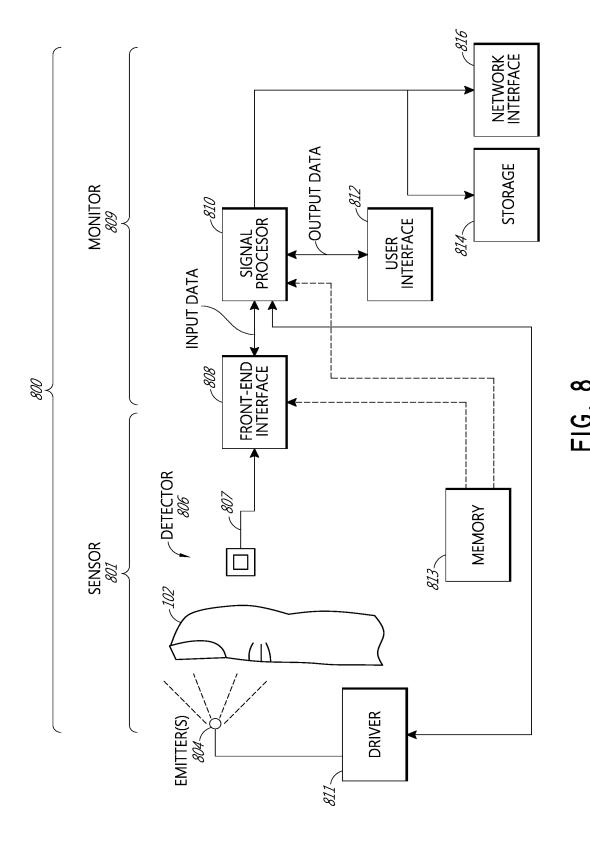


FIG. 7B



Application No.: Unassigned

Filing Date:

Filed herewith

REMARKS

Prior to examination, please amend the Specification and Claims as shown herein.

Accompanying this Amendment is both a marked up and clean version of the specification.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims,

or characterizations of claim scope or referenced art, Applicant is not conceding in this

application that previously pending claims are not patentable. Rather, any alterations or

characterizations are being made to facilitate expeditious prosecution of this application.

Applicant reserves the right to pursue at a later date any previously pending or other broader or

narrower claims that capture any subject matter supported by the present disclosure, including

subject matter found to be specifically disclaimed herein or by any prior prosecution.

Accordingly, reviewers of this or any parent, child or related prosecution history shall not

reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter

supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or

credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: December 19, 2018

By: /Aaron S. Johnson/

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AMENDMENTS TO THE CLAIMS

A complete listing of all claims is presented below with insertions underlined (e.g., <u>insertion</u>), and deletions struck through or in double brackets (e.g., <u>deletion</u> or [[deletion]]).

1-36. (Cancelled)

37. **(New)** A circular-shaped reflective pulse oximetry device configured for placement on a user at a tissue measurement site, the device comprising:

a plurality of emitters configured to emit light towards the tissue measurement site, the tissue measurement site being located on a wrist of the user, wherein pulsatile blood flows within tissue of the user at the tissue measurement site and the light emitted from the plurality of emitters penetrates the pulsatile blood flowing within the tissue when the circular-shaped reflective pulse oximetry device is in use, the plurality of emitters comprising one or more light-emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength, and wherein, when the circular-shaped reflective pulse oximetry device is placed on the user at the tissue measurement site, the plurality of emitters are arranged in a reflectance measurement configuration on a first side of the tissue measurement site;

a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by and reflection from the pulsatile blood flowing through tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the circular-shaped reflective pulse oximetry device is placed on the user, the plurality of detectors further configured to transmit a signal responsive to the detected light to a processor, the processor configured to receive the transmitted signal responsive to the detected light and determine a physiological parameter indicative of a state or trend of wellness of the user;

a light block comprising a circular wall, wherein the light block is positioned between the emitted light at the tissue measurement site and the plurality of detectors when the circular-shaped reflective pulse oximetry device is placed on the user, the light block forming a light isolation chamber defined by the circular wall, wherein the light

isolation chamber reduces an amount of incident light emitted from the plurality of emitters from being detected by the plurality of detectors; and

- a display configured to present information related to the determined physiological parameter to the user.
- 38. (New) The reflective pulse oximetry device of Claim 37, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 39. (New) The reflective pulse oximetry device of Claim 37, wherein the plurality of emitters are positioned outside the circular wall when the reflective pulse oximetry device is placed on the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the circular wall when the reflective pulse oximetry device is placed on the user at the tissue measurement site.
- 40. (New) The reflective pulse oximetry device of Claim 37, further comprising a concentrator which receives the light after attenuation by tissue of the user, concentrates the received light, and directs the concentrated light toward the plurality of detectors.
- 41. **(New)** The reflective pulse oximetry device of Claim 37, wherein the physiological parameter is arterial oxygen saturation.
- 42. (New) The reflective pulse oximetry sensor of Claim 37, wherein the plurality of detectors are arranged in an array with a spacial configuration corresponding to an irradiated surface area.
- 43. **(New)** The reflective pulse oximetry sensor of Claim 42, wherein the irradiated surface area comprises a circular shape.
- 44. **(New)** A method of measuring a physiological parameter in a user's blood, the method comprising:

emitting, from a plurality of emitters of a reflective pulse oximetry device, light of one or more wavelengths toward a tissue measurement site comprising pulsatile blood flow, the tissue measurement site located on a lower arm of the user, wherein the light emitted from the plurality of emitters penetrates the pulsatile blood flowing within tissue of the user at the tissue measurement site, and wherein the plurality of emitters comprise one or more light-emitting diodes (LEDs) and the one or more wavelengths comprises at

least an infrared wavelength, the plurality of emitters arranged in a reflectance measurement configuration on a first side of the tissue measurement site when the reflective pulse oximetry device is placed on the user at the tissue measurement site;

detecting, with a plurality of detectors, the light emitted by the plurality of emitters after attenuation by and reflection from the pulsatile blood flowing through tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the reflective pulse oximetry device is placed on the user at the tissue measurement site; and

providing a light block comprising a circular wall, wherein the light block is positioned between the emitted light at the tissue measurement site and the plurality of detectors when the reflective pulse oximetry device is placed on the user, the light block forming a light isolation chamber defined by the circular wall, and wherein the light isolation chamber reduces an amount of incident light emitted from the plurality of emitters from being detected by the plurality of detectors;

transmitting, from the plurality of detectors, a signal responsive to the detected light;

receiving, by a processor, the transmitted signal responsive to the detected light; and

processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

- 45. (New) The method of Claim 44, wherein the plurality of emitters are positioned outside the circular wall when the reflective pulse oximetry device is placed on the user at the tissue measurement site, and wherein the plurality of detectors are positioned inside the circular wall when the reflective pulse oximetry device is placed on the user at the tissue measurement site.
- 46. **(New)** The method of Claim 44, further comprising presenting, with a display of the reflective pulse oximetry device, information related to the determined physiological parameter to the user.

- 47. **(New)** The reflective pulse oximetry sensor of Claim 44, further comprising spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to the tissue measurement site.
- 48. **(New)** The reflective pulse oximetry sensor of Claim 44, wherein the physiological parameter is indicative of at least one of pulse rate, perfusion index, oxygen content, and total hemoglobin.
- 49. **(New)** The reflective pulse oximetry sensor of Claim 44, wherein the plurality of detectors are arranged in an array with a spacial configuration corresponding to an irradiated surface area.
- 50. (New) The reflective pulse oximetry sensor of Claim 49, wherein the irradiated surface area comprises a circular shape.
 - 51. (New) A reflective pulse oximetry sensor comprising:
 - a plurality of optical sources configured to emit light towards a tissue measurement site on a user, the tissue measurement site located on a wrist of the user, wherein pulsatile blood flows within tissue of the user at the tissue measurement site and the light emitted from the plurality of optical sources penetrates the pulsatile blood flowing within the tissue when the reflective pulse oximetry device is in use, the plurality of optical sources comprising one or more light-emitting diodes (LEDs) configured to emit one or more wavelengths, the one or more wavelengths comprising at least an infrared wavelength, and wherein, when the reflective pulse oximetry device is placed on the user at the tissue measurement site, the plurality of optical sources are arranged in a reflectance measurement configuration on a first side of the tissue measurement site;
 - a plurality of detectors configured to detect the light emitted by the plurality of emitters after attenuation by and reflection from the pulsatile blood flowing through tissue of the user at the tissue measurement site, wherein the plurality of detectors comprise one or more photodiodes, and wherein the plurality of detectors are arranged in a reflectance measurement configuration on the first side of the tissue measurement site when the reflective pulse oximetry device is placed on the user, the plurality of detectors further configured to transmit a signal responsive to the detected light to a processor, the processor configured to receive the transmitted signal responsive to the detected light and

determine a physiological parameter indicative of a state or trend of wellness of the user; and

- a light block comprising a circular wall, wherein the light block is positioned between the emitted light at the tissue measurement site and the plurality of detectors when the reflective pulse oximetry device is placed on the user, the light block forming a light isolation chamber defined by the circular wall, wherein the light isolation chamber reduces an amount of incident light emitted from the plurality of emitters from arriving at the plurality of detectors.
- 52. (New) The reflective pulse oximetry sensor of Claim 51, wherein the plurality of optical sources are user outside the circular wall when the reflective pulse oximetry sensor is placed on the user at the tissue measurement site, and wherein the plurality of detectors are arranged inside the circular wall when the reflective pulse oximetry sensor is placed on the user at the tissue measurement site.
- 53. (New) The reflective pulse oximetry sensor of Claim 51, wherein the plurality of detectors are arranged in an array so as to capture the emitted light reflected from the tissue of the user at the tissue measurement site.
- 54. **(New)** The reflective pulse oximetry sensor of Claim 51, wherein the plurality of detectors are arranged with a spacial configuration corresponding to an irradiated surface area.
- 55. (New) The reflective pulse oximetry sensor of Claim 51, further comprising a diffuser which receives, spreads, and emits the spread light, wherein the emitted spread light is directed at the tissue measurement site.
- 56. (New) The reflective pulse oximetry sensor of Claim 51, further comprising a display configured to present information related to the determined physiological parameter to the user.

AMENDMENTS TO THE SPECIFICATION

Please amend the originally filed specification as set forth below.

Please amend Paragraph [0020] as follows:

[0020] FIG. 1 illustrates a conventional approach to [[2D]]two-dimensional pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

Please amend Paragraph [0021] as follows:

[0021] FIG. 2 illustrates the disclosed [[3D]]three-dimensional approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. 2AFIG. 1.

Please amend Paragraph [0022] as follows:

[0022] FIG. 3 illustrates schematically a side view of a [[3D]]three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

Please amend Paragraph [0023] as follows:

[0023] FIG. 4A is a top view of a portion of a [[3D]]three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

Please amend Paragraph [0024] as follows:

[0024] FIG. 4B illustrates the top view of a portion of the [[3D]]three-dimensional pulse oximetry sensor shown in FIG. 4A, with the addition of a tissue measurement site in operational position.

Please amend Paragraph [0025] as follows:

[0025] FIG. 5 illustrates a top view of a [[3D]]three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

Please amend Paragraph [0026] as follows:

[0026] FIG. 6 illustrates a conventional [[2D]]two-dimensional approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

Please amend Paragraph [0027] as follows:

[0027] FIG. 7A is a simplified schematic side view illustration of a reflective [[3D]]three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

Please amend Paragraph [0028] as follows:

[0028] FIG. 7B is a simplified schematic top view illustration of the [[3D]]three-dimensional reflective pulse oximetry sensor of FIG. 7A.