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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 December 2024 (12.12.2024)

WIPO | PCT

(10) International Publication Number
WO 2024/253936 A1

(51) International Patent Classification:
A61B 5/1455 (2006.01) *A61B 5/0205* (2006.01)

(21) International Application Number:
PCT/US2024/031626

(22) International Filing Date:
30 May 2024 (30.05.2024)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/506,763 07 June 2023 (07.06.2023) US

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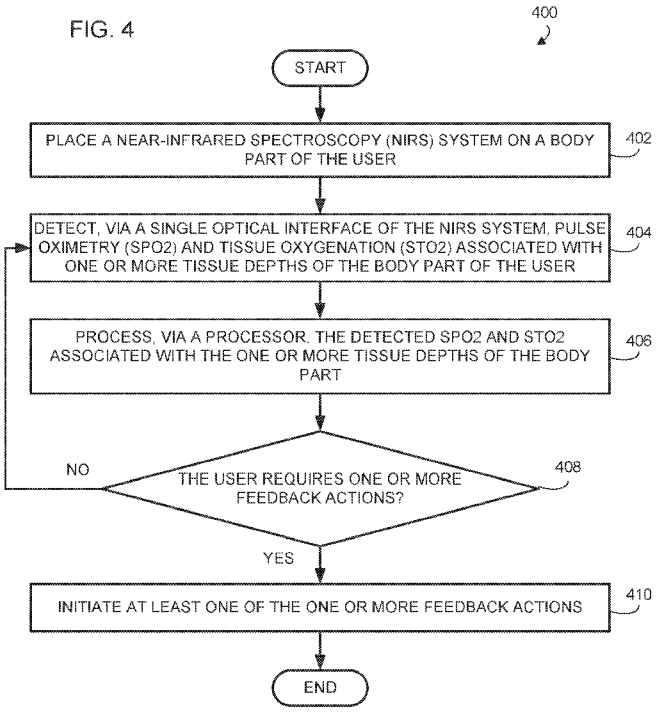
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,

(54) Title: SYSTEMS AND METHODS FOR DETECTING OXIMETRY PARAMETERS OF A USER

FIG. 4



(57) Abstract: A method may include placing a NIRS system on a body part of the user. The method may include detecting, via a single optical interface of the NIRS system, SpO2 and StO2 associated with the body part of the user. The method may include detecting the SpO2 and StO2 associated with one or more tissue depths of the body part of the user. The method may include processing, via a processor, the detected SpO2 and StO2 associated with the one or more tissue depths of the body part. The method may include determining, based on the processed SpO2 and StO2, whether the user requires one or more feedback actions. Responsive to determining the user requires the one or more feedback actions, the method may include initiating at least one of the one or more feedback actions.

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[Continued on next page]

TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

SYSTEMS AND METHODS FOR DETECTING OXIMETRY PARAMETERS OF A USER

RELATED APPLICATIONS

[0001] This Application is a Patent Cooperation Treaty (PCT) application of, and claims priority under Article 8 of the PCT to, U.S. Provisional Patent Application No. 63/506,763, filed June 7, 2023, entitled "SYSTEMS AND METHODS FOR DETECTING OXIMETRY PARAMETERS OF A USER," the entire contents of which are fully incorporated herein by reference for all purposes.

[0002] The following applications are related applications, and each is incorporated by reference in its entirety for all purposes: U.S. Provisional Patent Application No. 63/170,201, filed April 2, 2021, entitled "NEAR-INFRARED SPECTROSCOPY SYSTEMS AND METHODS," U.S. Provisional Patent Application No. 63/351,237, filed June 10, 2022, entitled "SYSTEMS AND METHODS FOR DETECTING BIOMETRIC PARAMETERS," U.S. Provisional Patent Application No. 63/356,740, filed June 29, 2022, entitled "SYSTEMS AND METHODS FOR DETECTING BIOMETRIC AND NEUROPHYSIOLOGICAL PARAMETERS," and U.S. Provisional Patent Application No. 63/389,282, filed July 14, 2022, entitled "MODULATING USER BEHAVIOR AND BIOFEEDBACK USING A NEUROIMAGING AND NEUROSTIMULATING SYSTEM."

TECHNICAL FIELD

[0003] The present disclosure relates generally to systems and methods for detecting oximetry parameters of a user. In particular, the present disclosure relates to systems and methods for detecting pulse oximetry and tissue oxygenation of a user via a single device.

BACKGROUND

[0004] Near-infrared spectroscopy (NIRS) devices interrogate biological tissue using a selection of light wavelengths in the red and near-infrared (NIR) region of the electromagnetic spectrum. These wavelengths are particularly well suited for deep light penetration through tissue, versus lower wavelengths of light that are scattered or absorbed by confounding factors in the body and thus cannot reach the tissue depth of these red and NIR wavelengths. NIRS devices generally feature at least two wavelengths of light output in this range and at least one detector, and including additional optical elements can allow different depths of sensing.

[0005] Red and near-infrared wavelengths are particularly effective for non-invasively sensing different molecular states of hemoglobin in various body tissues. Unfortunately, existing NIRS devices are typically expensive, large desktop units with disintegrated sensor and processing systems. This lack of portability limits the usefulness of NIRS outside of the surgical suite, laboratory, and research environments. Some portable solutions include a sensor-only patch with wired communication to a separate portable, pocketable, or head-worn processing and communications unit. These changes represent only a nominal improvement, as the processing unit is itself not fully wearable and risks physically detaching from the sensor unit through movement or cable weight. These limitations greatly decrease the wearability and utility of such systems. These semi-ambulatory systems are also typically not designed to be used in parallel, where individual NIRS sensor systems work in tandem across the body or across a population to continually sense physiological features at multiple places using a common interface. Non-ambulatory systems can have more sensor inputs, but these are limited by the total number of ports designed into the physical system itself. Therefore, there exists a need for integrated NIRS systems and methods of using those systems to interrogate biological tissue.

[0006] Additionally, existing tissue oximeters continuously and non-invasively estimate tissue oxygenation (StO2) using NIRS technology. Photoplethysmography (PPG) monitors periodic oscillations of reflected light from the pulsation of arterial blood to continuously estimate arterial oxygen saturation through pulse oximetry (SpO2) as well as pulse rate (PR), respiratory rate (RR), perfusion, blood pressure, and other metrics using red and near infrared optical components.

SUMMARY

[0007] In some embodiments, a method of detecting oximetry parameters of a user is disclosed. The method may include placing a NIRS system on a body part of the user. The method may include detecting, via a single optical interface of the NIRS system, SpO2 and StO2 associated with the body part of the user.

[0008] In some embodiments, the method may include detecting the SpO2 and StO2 associated with one or more tissue depths of the body part of the user. The method may include processing, via a processor, the detected SpO2 and StO2 associated with the one or more tissue depths of the body part. The method may include determining, based on the processed SpO2

and StO2, whether the user requires one or more feedback actions. Responsive to determining the user requires the one or more feedback actions, the method may include initiating at least one of the one or more feedback actions.

[0009] In some embodiments, the NIRS system may be a miniaturized, ingress-protected, crush-resistant, wireless, autonomous, and self-contained NIRS monitoring wearable system.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

[0011] FIG. 1 depicts an embodiment of a system used for detecting oximetry parameters of a user, in accordance with the present disclosure.

[0012] FIG. 2 depicts an embodiment of a substrate of the system of FIG. 1, in accordance with the present disclosure.

[0013] FIG. 3 depicts an embodiment of an electronics module of the system of FIG. 1, in accordance with the present disclosure.

[0014] FIG. 4 is a flowchart of a method for detecting oximetry parameters of a user, in accordance with the present disclosure.

DETAILED DESCRIPTION

[0015] This disclosure is not limited to the particular systems, devices, and methods described, as these may vary. The terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope of the disclosure.

[0016] The following terms shall have, for the purposes of this application, the respective meanings set forth below. Unless otherwise defined, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Nothing in this disclosure is to be construed as an admission that the embodiments described in this disclosure are not entitled to antedate such disclosure by virtue of prior invention.

[0017] As used herein, the singular forms "a," "an," and "the" include plural references, unless the context clearly dictates otherwise. Thus, for example, reference to a "fiber" is a

reference to one or more fibers and equivalents thereof known to those skilled in the art, and so forth.

[0018] As used herein, the term "about" means plus or minus 10% of the numerical value of the number with which it is being used. For example, about 50 mm means in the range of 45 mm to 55 mm.

[0019] As used herein, the term "consists of" or "consisting of" means that the device or method includes only the elements, steps, or ingredients specifically recited in the particular claimed embodiment or claim.

[0020] In embodiments or claims where the term "comprising" is used as the transition phrase, such embodiments can also be envisioned with replacement of the term "comprising" with the terms "consisting of" or "consisting essentially of."

[0021] It is to be understood that the mention of one or more method steps does not preclude the presence of additional method steps or intervening method steps between those steps expressly identified. It is also to be understood that the listing of one or more method steps in any order does not preclude the performance of such one or more methods steps in alternative orders, nor does it preclude the simultaneous performance of any such one or more method steps. Similarly, it is also to be understood that the mention of one or more components in a device or system does not preclude the presence of additional components or intervening components between those components expressly identified.

[0022] It will be understood by those within the art that, in general, terms used herein are generally intended as "open" terms (for example, the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," et cetera). While various compositions, methods, and devices are described in terms of "comprising" various components or steps (interpreted as meaning "including, but not limited to"), the compositions, methods, and devices can also "consist essentially of" or "consist of" the various components and steps, and such terminology should be interpreted as defining essentially closed-member groups.

[0023] In addition, even if a specific number is explicitly recited, those skilled in the art will recognize that such recitation should be interpreted to mean at least the recited number (for example, the bare recitation of "two components," without other modifiers, means at least

two components, or two or more components). Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, et cetera" is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, "a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). In those instances where a convention analogous to "at least one of A, B, or C, et cetera" is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, sample embodiments, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

[0024] Furthermore, where features of the disclosure are described in terms of Markush groups, those skilled in the art will recognize that the disclosure is also thereby described in terms of any individual member or subgroup of members of the Markush group.

[0025] As will be understood by one skilled in the art, for any and all purposes, such as in terms of providing a written description, all ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal halves, thirds, quarters, fifths, tenths, et cetera. As a non-limiting example, each range discussed herein can be readily broken down into a lower third, middle third and upper third, et cetera. As will also be understood by one skilled in the art all language such as "up to," "at least," and the like include the number recited and refer to ranges that can be subsequently broken down into subranges as discussed above. Finally, as will be understood by one skilled in the art, a range includes each individual member. Thus, for example, a group having 1-3 components refers to groups having 1, 2, or 3 components. Similarly, a group having 1-5 components refers to groups having 1, 2, 3, 4, or 5 components, and so forth.

[0026] With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

[0027] Near-infrared spectroscopy devices interrogate biological tissue using a selection of light wavelengths in the red and NIR region of the electromagnetic spectrum. These wavelengths are particularly well suited for deep light penetration through tissue, versus lower wavelengths of light that are scattered or absorbed by confounding factors in the body and thus cannot reach the tissue depth of these red and NIR wavelengths. NIRS devices generally feature at minimum two wavelengths of light output in this range and at least one detector, and including additional optical elements can allow different depths of sensing.

[0028] Red and near-infrared wavelengths are particularly effective for non-invasively sensing different molecular states of hemoglobin in various body tissues. Hemoglobin is a strong absorber of light in the middle of the visible light spectrum but has a low optical extinction coefficient within the higher wavelengths of the visible range. Within the NIR wavelengths, for hemoglobin's oxygenation states, deoxy- and oxyhemoglobin's absorption spectra cross at an isosbestic point near 805 nm, allowing NIRS systems to differentiate oxygenation states of hemoglobin using light sources above and below this wavelength. With this differentiation, NIRS can be used for a variety of sensing mechanisms related to the body's circulatory and other functional systems.

[0029] Hemoglobin also allows for binding of ligands other than oxygen. These other molecular states of hemoglobin, such as carboxyhemoglobin and methemoglobin, have unique optical absorption characteristics in the NIR range. Investigating these molecular states can elucidate competitive binding and indicate histologic changes in tissue oxygenation such as tissue poisoning. Hemoglobin has a competitive binding efficiency for many molecules, such as carbon monoxide (CO), cyanide (CN-), sulfur monoxide (SO), sulfide (S2-), and others in these groups. Nitric oxide (NO) also binds to hemoglobin and can be detected optically. Investigating the NIR spectra of these additional bound states of hemoglobin can indicate tissue status and toxicity by inhibiting oxygen binding as well as enable sophisticated physiological monitoring of body systems.

[0030] NIRS systems may calculate oxygenation levels using the modified Beer-Lambert law (mBLL), which only requires one bank of light sources. Using the mBLL offers the translation of raw optical signals into actionable oxygenation details. Alternatively, NIRS systems may employ spatially resolved spectroscopy (SRS), which can use both short- and long-distance measurements. Separately, short channel information can be subtracted from long channel information to more accurately isolate, for example, brain activity and the contributions from internal (e.g., cerebral) vasculature and external (e.g., skin) vasculature.

[0031] Unfortunately, existing NIRS devices are typically expensive, large desktop units with disintegrated sensor and processing systems. This lack of portability limits the usefulness of NIRS outside of the surgical suite, laboratory, and research environments. Even in such controlled environments, these devices sometimes fail because they are difficult to integrate into a user's system when the planned testing involves any form of motion.

[0032] Some portable solutions include a sensor-only patch with wired communication to a separate portable, pocketable, or head-worn processing and communications unit. These changes represent only a nominal improvement, as the processing unit is itself not fully wearable and risks physically detaching the sensor unit through movement or cable weight. These limitations greatly decrease the wearability and utility of such systems. These semi-ambulatory systems are also typically not designed to be used in parallel, where individual NIRS sensor systems work in tandem across the body or across a population to continually sense physiological features at multiple places using a common interface. Non-ambulatory systems can have more sensor inputs, but these are limited by the total number of ports designed into the physical system itself. Therefore, there exists a need for integrated NIRS systems and methods of using those systems to interrogate biological tissue.

[0033] Additionally, existing tissue oximeters can be used to continuously and non-invasively estimate StO2 using NIRS technology. Photoplethysmography (PPG) monitors periodic oscillations of reflected light from the pulsation of arterial blood to continuously estimate arterial oxygen saturation through SpO2, as well as PR, RR, perfusion, blood pressure, and other metrics using red and near infrared optical components. Pulse oximetry (SpO2) provides a systematic biomarker (i.e., not tissue-specific) of arterial blood oxygenation, while StO2 can provide mixed venous oxygenation at specific body sites (e.g., cerebral oxygenation, muscle oxygenation, and other specific organs). Both of these optical monitoring techniques

are noninvasive, and their combination in a single optical interface can improve not only monitoring of general patient biometrics, but also the combination and comparison of these two oximetry parameters on the same tissue at the same time.

[0034] Hemodynamic coherence is a measurement associated with microvascular and macrovascular tissue beds, and the simultaneous measurement of both superficial and deep oximetry measures at the same anatomical site can provide continuous and real-time information to healthcare providers about tissue perfusion in multiple vascular beds simultaneously. Measuring hemodynamic coherence drawn from NIRS and PPG in the same device can increase medical decision-making power in numerous situations including patient triage, resuscitation, emergency medicine, and trauma patient management (e.g., for patients at risk of hemorrhagic shock), neurotrauma patients, patients with crush injuries that lead to ischemic risks such as compartment syndrome, and measures of wound healing around burns, grafts, transplants, and other instances of high vascular stress.

[0035] A system that records both PPG and NIRS measures at the same location can also adapt its measurements as the patient and/or their environment evolve. For example, patients who are decompensating due to blood loss, hypothermia, or other instances of shock, may suffer from reduced pulse strength, which can increase the error in superficial PPG measurements. Reading and comparing PPG and NIRS at the same site can enable a combined system to both adapt its performance to optimize signal-to-noise ratio, as well as contrast the signal behavior at various tissue depths to determine decompensation and stratify and predict further risks.

[0036] Measuring both PPG and NIRS from the same location allows for isolation and analysis of waveforms not currently monitored extensively in medical or commercial wearable systems. For instance, pulsatile waveforms at different tissue depths may exhibit varying contributions from pulsatile components, respiratory variations, pulse transit characteristics, Mayer wave contributions, or other variations that may provide relevant physiological information. Measuring these physiological signals at the same location can enable monitoring for these or other valuable biomarkers as well as correlations and changes in combinations thereof.

[0037] Accordingly, the systems and methods disclosed herein may provide a single optical interface of a NIRS system that is configured to detect both SpO2 and StO2 associated

with a body part (e.g., the forehead, sternum, thigh, etc.) of a user (e.g., a patient). The detecting of these parameters may correspond to monitoring patient neurological function associated with one or more patient conditions, such as trauma, a disease, an injury, etc. The single optical interface may further be configured to process the detected SpO2 and StO2 at one or more tissue depths of the body part, such that the system may determine, based on the detected SpO2 and StO2, whether the user requires one or more feedback actions (e.g., providing feedback to a remote caregiver, adapting a parameter of the system's own performance, delivering a stimulation to a user, etc.). The system may be further configured to initiate the one or more feedback actions responsive to determining the user does require such feedback.

[0038] In some embodiments, the NIRS systems disclosed herein may be configured to measure three or more wavelengths at three or more optical depths, as further discussed herein. In some embodiments, the NIRS systems disclosed herein may weigh approximately 2.0 ounces or less (e.g., approximately 2.1 ounces, 1.9 ounces, 1.6 ounces, 1.4 ounces, 1.2 ounces, 1.0 ounces, 0.8 ounces, 0.6 ounces, 0.4 ounces, 0.2, ounces, etc.). In some embodiments, the NIRS systems disclosed herein may have a volume of approximately 30 cm^3 or less (e.g., approximately 28.5 cm^3, 26.0 cm^3, 22.0 cm^3, 20.0 cm^3, 17.0 cm^3, 15.5 cm^3, 13.0 cm^3, 9.0 cm^3, 7.5 cm^3, 4.0 cm^3, 2.5 cm^3, etc.). In some embodiments, the NIRS systems disclosed herein may have a battery life of at least approximately 12.0 hours.

[0039] In some embodiments, the NIRS systems disclosed herein may have the ability to adapt their gain and performance based on location, need, and/or environment. In some embodiments, the NIRS systems disclosed herein may be configured to operate autonomously, such as by automatically detecting, setting, and/or alerting based on one or more internal thresholds, e.g., stored locally or inputted by a user. In some embodiments, the NIRS systems disclosed herein may include a user interface configured to display one or more system statuses to a user (e.g., alerts, notifications, etc.)

[0040] In some embodiments, the systems disclosed herein may incorporate one or more of the systems, devices, and/or components as described in U.S. Provisional Application Nos. 63/170,201, 63/351,237, 63/356,740, and 63/389,282, which are each incorporated herein by reference in their entirety, and portions of which included herein as Appendices to the present application.

[0041] Reference will now be made in detail to example embodiments of the disclosed technology that are illustrated in the accompanying drawings and disclosed herein. Wherever convenient, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0042] FIG. 1 depicts an embodiment of a system 100 used for detecting oximetry parameters of a user, in accordance with the present disclosure. The system 100 may include a substrate 202 configured to communicate with an electronics module 302 over a network 402, as further discussed below with respect to FIGS. 2-3.

[0043] FIG. 2 depicts an embodiment of a substrate 202 used for detecting oximetry parameters of a user, in accordance with the present disclosure. In some embodiments, the substrate 202 may be configured to be placed on a body part of a user (e.g., a patient). For example, substrate 202 may be coupled to (e.g., placed on top of or embedded within) a flexible material, such that substrate 202 may be placed (e.g., with an adhesive) on a body part of a user and conform to the shape of that body part (e.g., a forehead, sternum, leg, etc.). In some embodiments, the substrate 202 and/or the flexible material may also provide for electrical insulation and/or optical isolation of any NIRS and/or PPG optics, and/or any electrical connection lines to electrodes mounted on substrate 202.

[0044] In some embodiments, the substrate 202 may include one or more materials, such as silicone, nylon, epoxy, a bioinert polymer, a biocompatible polymer, a woven or nonwoven textile, an adhesive film, a flexible circuit board, flexible sensors and electronics, or a combination thereof. In some embodiments, the substrate 202 and any components mounted onto the substrate 202 may be configured to provide mechanical flexibility, allowing the substrate 202 to conform to and/or adhere to a surface. In some embodiments, the substrate 202 may be configured to be integrated into clothing or other equipment designed to be worn or applied to a user.

[0045] In some embodiments, the shape and/or dimensions of the substrate 202 may be different depending on the specific patient and/or use case. Additionally, substrate 202 may also be configured of any size.

[0046] As shown in FIG. 2, the substrate 202 may include a processor 210, a sensor or detector 212, a source 214 (e.g., a light source, an electrode, an ultrasound transducer), a

terminal 216, an input/output (I/O) device 218, and/or a power source 220 (e.g., a battery) configured to power the substrate 202.

[0047] Detector 212 may be configured to sense or detect oximetry parameters of a user, such as SpO2 and StO2. Detector 212 may be configured to detect these parameters at various tissue depths associated with the applicable body part, as discussed herein.

[0048] The I/O device 218 may be configured to connect the substrate 202 to one or more other components of system 100 or one or more components external to system 100, such as a computing device (e.g., a laptop or other "smart" device).

[0049] The source 214 may include a single light source. In other embodiments, the source 214 may include multiple light sources, such as 2 light sources, 3 light sources, 4 light sources, 5 light sources, and so on. In some embodiments, each light source may include one or more light emitting diodes (LEDs). In some embodiments, each light source may include a single tunable light source such as a broadband LED coupled with a miniature monochromator. In some embodiments, each light source may include one or more laser diodes. In an embodiment, the source 214 may include a light source driver capable of selecting between the different light sources or selecting a wavelength from a tunable light source. In some embodiments, the source 214 may include ultrasound or electrode sources.

[0050] In some embodiments, the source 214 may be capable of emitting a first set of wavelengths of red or near-infrared light. In some embodiments, each light source within the source 214 may be capable of independently emitting a wavelength. The first set of wavelengths may comprise 1 wavelength, 2 wavelengths, 3 wavelengths, 4 wavelengths, 5 wavelengths, 6 wavelengths, 7 wavelengths, 8 wavelengths, 9 wavelengths, 10 wavelengths, or any other number of wavelengths known in the art. In some embodiments, each wavelength within the first set of wavelengths may independently be from about 650 nm to about 950 nm. Each wavelength may be, for example, about 650 nm, about 655 nm, about 660 nm, about 665 nm, about 670 nm, about 675 nm, about 680 nm, about 685 nm, about 690 nm, about 695 nm, about 700 nm, about 705 nm, about 710 nm, about 715 nm, about 720 nm, about 725 nm, about 730 nm, about 735 nm, about 740 nm, about 745 nm, about 750 nm, about 755 nm, about 760 nm, about 765 nm, about 770 nm, about 775 nm, about 780 nm, about 785 nm, about 790 nm, about 795 nm, about 800 nm, about 805 nm, about 810 nm, about 815 nm, about 820 nm, about 825 nm, about 830 nm, about 835 nm, about 840 nm, about 845 nm, about 850 nm, about 855

nm, about 860 nm, about 865 nm, about 870 nm, about 875 nm, about 880 nm, about 885 nm, about 890 nm, about 895 nm, about 900 nm, about 905 nm, about 910 nm, about 915 nm, about 920 nm, about 925 nm, about 930 nm, about 935 nm, about 940 nm, about 945 nm, about 950 nm, or any range between any two of these values, including endpoints. In some embodiments, each wavelength within the first set of wavelengths may be greater than about 805 nm. In some embodiments, the average of the first set of wavelengths may be greater than about 805 nm. In certain embodiments, the first set of wavelengths may include five individual wavelengths to interrogate the targeted tissue: one in the red region below 730 nm, one in the NIR region below the 805 nm isosbestic point, one near or at the 805 nm isosbestic point, and two in the NIR region above the isosbestic point.

[0051] Turning to FIG. 3, system 100 may include one or more electronics modules 302. Each electronics module 302 may be configured with the same or similar components; however, in some embodiments, different electronics modules 302 may be configured to detect and process different types of parameters of a user. For example, a first electronics module 302 may be configured to detect and process optical biometric properties of a user, while a second electronics module 302 may be configured to detect and process non-optical biometric properties of a user. In some embodiments, system 100 may include a single electronics module 302 that may include the hardware and functionality of a first and second electronics module 302, and may be configured to carry out the program instructions for both electronics modules within a single, integrated package.

[0052] In some embodiments, electronics module 302 may be communicatively coupled to the substrate 202 (e.g., via network 402, as shown in FIG. 1), and may include a processor 310, a memory device 324, and instructions stored on the memory device 324 that may direct the processor 310 to perform one or more actions. The electronics module 302 may be configured to receive a signal from one or more detectors 212 mounted on the substrate 202, and to process the received signal based on one or more predefined algorithms. Based on the processed signal, the electronics module 302 may be configured to determine whether the user, e.g., on or to which substrate 202 is coupled, requires one or more feedback actions, as further discussed below.

[0053] As shown in FIG. 3, the electronics module 302 may further include one or more environmental sensors 312, a communication interface 314, a light source 316, a detector 318,

an I/O device 320, and/or an energy storage device 322 (e.g., a battery) configured to power the electronics module 302. Memory device 324 may include an operating system (OS) 326 and program 328, and a database 330. Operating system 326 may be a real-time operating system (RTOS) or program instructions in system firmware operating on the processor 310. Program 328 may include stored instructions that direct the processor 310 to perform one or more steps toward processing signals received from substrate 202, as discussed herein.

[0054] In some embodiments, the processor 310 may be configured to select emitted set(s) of wavelengths, as discussed above, and respective distance(s) of the source 214 from the detector 212. The input parameter may include, for example, a temperature, a lighting condition, a velocity, an acceleration, a change in acceleration, a pressure, a change in pressure, a volume, a change in volume, a measurement made, recorded, or calculated by the system, a communication from another device or system, or a combination thereof.

[0055] In some embodiments, the environmental sensor(s) 312 can measure parameters surrounding the patient and not the patient directly. Environmental properties may include, for example, temperature, humidity, pressure, motion, chemical composition, ambient light intensity, sound, etc., of the external environment in which the patient is positioned. For example, if the patient's body temperature is calculated as being too high, such as above some predetermined threshold, the electronics module 302, e.g., via the processor 310, may be configured to adjust a thermostat located in the room in which the patient is located. As another example, environmental sensor(s) 312 may include a microphone configured to receive spoken instructions informing the electronics module 302 how to operate.

[0056] In some embodiments, the communication or connection interface 314 (which may also or instead be included on substrate 202) can facilitate connections that can be, for example, a wireless connection, a wired connection, a Bluetooth connection, a near-field communication (NFC) connection, a radio frequency identification (RFID) connection, or a combination thereof. In some embodiments, data processing and real-time feedback may occur within the components onboard the substrate 202, or offboard through communication with an external computing device, as discussed below. The external computing device may comprise, for example, a smartphone, a charging or communications base station, a display screen, a tablet, a computer, a mobile or web-based application, or another device.

[0057] FIG. 4 is a flowchart of a method 400 for detecting oximetry parameters of a user, in accordance with the present disclosure. Method 400 may be conducted using one or more components of system 100, such as substrate 202, electronics module 302, or any of the devices or systems discussed herein. It should be understood that certain embodiments of the disclosed technology may omit one or more blocks as being optional

[0058] In block 402, the method may include placing a NIRS system on a body part of the user. The NIRS system may be any of the devices or systems as discussed herein. For example, the NIRS system may include a sensor (e.g., detector 212 of substrate 202) configured to detect one or more optical properties of the body part. The NIRS system may further include a non-transitory memory device (e.g., memory 324 of electronics module 302) configured to receive data from the sensor, the data corresponding to the one or more optical properties (e.g., SpO2, StO2).

[0059] In some embodiments, the body part of the user may be an individual body part, such as the sternum, forehead, leg, etc., or may include multiple body parts.

[0060] In block 404, the method may include detecting, via a single optical interface of the NIRS system, SpO2 and StO2 associated with the body part of the user. Pulse oximetry (SpO2) may be a proxy measure (e.g., calculated by fitting a trend line to experimental data) for arterial oxygen saturation (SaO2), which can be calculated by measuring the content of dissolved oxygen gas in the blood. In some embodiments, the use of a single optical interface of the NIRS system for detecting oximetry parameters may allow for the detecting of SpO2 alone, StO2 alone, both SpO2 and StO2 together, or the derived metrics of NIRS and PPG individually, or combinations thereof.

[0061] The use of a single optical interface for detecting the SpO2 and the StO2 may allow for measuring of the hemodynamic coherence associated with both the macrovasculature and microvasculature tissue beds of the body part being evaluated. In some embodiments, measuring the hemodynamic properties and vascular bed coherence may also be conducted through the use of ultrasound in combination with the NIRS system.

[0062] In some embodiments, the system may be configured to record both PPG and NIRS measurements at the same anatomical location of the user, between different locations of the user, and/or between different sites of multiple users. In some embodiments, the system

may be configured to record either NIRS or PPG, or both, depending on the instantaneous and trend measures of the user, such as based on patient history and/or current state of the patient.

[0063] In some embodiments, the system may be configured to remotely record and report paired NIRS and PPG data into patient medical data systems such that remote providers (e.g., those not physically present) can provide medical review and assistance to patients, as further discussed below. These remote providers may be using automated tools (e.g., algorithms, robotics) to manage patient care. This pairing of NIRS and PPG data may further provide the ability to continuously report instantaneous values and trend values drawn from NIRS and PPG, and to adapt system performance as the signals (including their noise levels) and metrics of comparison between the individual biometric signals evolve. These noise levels may evolve for physiological reasons. For example, the patient's condition might be worsening (e.g., losing more blood) or improving (e.g., showing signs that resuscitation is working successfully), the patient might be getting cold and shunting peripheral blood to the deeper tissue, or the patient might be reacting in some fashion to environmental factors (e.g., the patient's skin might be flushing in response to increased environment temperature, there may be more ambient light to cause the signal-to-noise ratio to be temporarily diminished).

[0064] In some embodiments, detecting SpO2 and StO2 may include detecting the SpO2 and the StO2 as a function of a depth of a tissue associated with the body part. This may involve normalizing the StO2 measurement based on the SpO2 measurement. For example, since SpO2, which is measured within the first few millimeters of body tissue, reflects 100:0 arterial:venous blood mix, and StO2, which is measured more than a centimeter into tissue, reflects 25-30:75-70 blood mix, StO2 could be normalized to reflect only venous oxygenation. In some embodiments, measuring SpO2 and StO2 as a function of tissue depth may provide for the integration of multi-depth oxygenation kinetics with other measures of physiology across different patient types, such as healthy patients, chronically sick patients, and trauma cases as well as comparison using an 8mm emitter/detector distance, while StO2 may be measured using a 30mm, 35mm, or 40mm emitter/detector distances, or a combination of these.

[0065] In some embodiments, detecting SpO2 and StO2 as a function of tissue depth may allow for measurement of one or more perfusion indexes (PIs) corresponding to the body part. A perfusion index (PI) may include a ratio of pulsing to non-pulsing blood in a patient's body

part as a monitor of oxygenated blood delivery and tissue oxygen consumption. The PIs that may be measured as part of the disclosed method may be associated with cardiac activity, pulmonary activity, and/or neurological activity. In some embodiments, the PIs may be measured as a function of emitter-detector distance, corresponding to tissue depth, which can provide for evaluating the difference in PIs across detectors. For example, SpO2 may be measured using an 8mm emitter/detector distance, while StO2 may be measured using a 30mm, 35mm, or 40mm emitter/detector distances, or a combination of these. The system may also be configured to provide other measures of cardiac activity, such as electrocardiography (ECG) and cardiac output (e.g., as measured by ultrasound), and/or other measures of pulmonary activity, such as pulmonary function monitoring.

[0066] In block 406, the method may include processing, via a processor (e.g., processor 310 of electronics module 302), the detected SpO2 and StO2, such as those associated with the one or more tissue depths of the body part. In some embodiments, processing the detected SpO2 and StO2 may be conducted via one or more predetermined algorithms. In some embodiments, processing the detected SpO2 and StO2 may involve optimizing a respective signal-to-noise ratio associated with each of the detected SpO2 and StO2. Signal processing for each respective waveform may involve high- or low-pass filtering, gain stage modulation, varying analog-to-digital conversion (ADC) processes, ambient light rejection, signal averaging, outlier rejection, motion correction, spectral compensation, tissue characteristic compensation including for melanin, water, or fat, or others, or a combination of these processes.

[0067] In block 408, the method may include determining, based on the processed SpO2 and StO2, whether the user requires one or more feedback actions. In some embodiments, this determination may be based on the respective signal-to-noise ratio associated with the detected SpO2 and StO2, discussed above.

[0068] In some embodiments, the feedback action(s) may involve adaptation of the system itself, such as making a change to a sensing parameter, recording parameter, operating parameter, etc., of the system. For example, the system may be an adaptive system wherein the system can determine that some parameter should be changed, such as the brightness of the source 214, the sensitivity of the detector 212, a sampling frequency, an alert threshold, the alert priority level, the predetermined algorithms being used, etc.

[0069] In some embodiments, the feedback action(s) may involve transmitting or otherwise providing the processed data to a remote system (e.g., associated with a medical data system) or user, such as a caregiver or provider (e.g., a physician) of the user such that the caregiver or provider may provide, for example, medical advice or monitoring for the user.

[0070] In some embodiments, the feedback action(s) may involve taking another oximetry reading. In some embodiments, the feedback action(s) may involve providing the user with one or more types of stimulation. For example, the system may include one or more terminals (e.g., terminal 216 of substrate 202) capable of providing a user with the one or more types of stimulation, which may include one or more of transcranial direct current stimulation (tDCS), transcranial alternating current stimulation (tACS), vagus nerve stimulation (nVNS), transcutaneous electrical nerve stimulation (TENS), transcranial magnetic stimulation (TMS), ultrasound stimulation, optical stimulation, mechanical stimulation, or other types of invasive or non-invasive stimulation.

[0071] In some embodiments, the feedback action(s) may be provided to the user by changes in a real or virtual environment of the user (e.g., via a virtual reality device), by pharmacological changes (e.g., through intravascular, intramuscular, intraosseous, and/or other routes), through changes in notifications to a caregiver (as discussed above), and/or via an environmental property. The environmental property may include one or more of temperature, pressure, chemical composition, sound (e.g., continuous sound waves with changing pitch), light, motion, smell, feel, taste, or combinations thereof.

[0072] In block 410, responsive to determining the user requires the one or more feedback actions the method may include initiating at least one of the one or more feedback actions, as discussed above.

[0073] In some embodiments, the user may be a patient experiencing some type of shock, such as distributive shock, hypovolemic shock, cardiogenic shock, obstructive shock, and/or thermal shock. In such embodiments, the systems and methods discussed herein may be configured to provide a user (including the patient) with feedback that might assist the patient in healing, recovery, etc., and/or assist a remote caregiver in providing medical assistance to the patient, whether immediate, short term, and/or long-term assistance.

[0074] In some embodiments, the system 100 may further include an external computing device including a memory and a computer processor. The external computing device may be

connected to at least a portion of at least one of the processor and the memory device via a connection, wherein at least a portion of the program instructions is also stored on the external computing device.

[0075] In some embodiments, the systems disclosed herein can be networked for concurrent monitoring of different physiological conditions of a user, the same or different physiological conditions at different locations on the body of a user, one or more physiological conditions of a group of wearers in a population, or a combination thereof.

[0076] Although some of the processing systems described herein can be embodied in software or code executed by general purpose hardware as discussed above, as an alternative the same can also be embodied in dedicated hardware or a combination of software/general purpose hardware and dedicated hardware. If embodied in dedicated hardware, each can be implemented as a circuit or state machine that employs any one of or a combination of a number of technologies. These technologies can include, but are not limited to, discrete logic circuits having logic gates for implementing various logic functions upon an application of one or more data signals, application specific integrated circuits (ASICs) having appropriate logic gates, field-programmable gate arrays (FPGAs), or other components, etc.

[0077] In some embodiments, the systems and methods described herein include independent wireless devices communicating oximetry information about different areas of tissue (e.g., the brain) simultaneously. In some embodiments, the systems and methods described herein include scanning a single device over different areas of the body and continuously imaging tissue, changing methods based on determined tissue state or changes in patient condition.

[0078] In some embodiments, the systems and methods described herein include two or more independent systems that can simultaneously interrogate multiple areas of cerebral and somatic tissue to interrelate physiological status (for example, tissue oxygenation) in each area. These areas may have significantly different oxygenation signatures at any given time and simultaneously sampling these is particularly important to understand situations of local or central fatigue or recovery onset by the user. Simultaneous imaging of different body systems can also elucidate generalized physiological condition, for instance indicating systemic response to exogenous conditions such as carbon monoxide poisoning or endogenous conditions such as hemorrhage. The independently sampled processed data from each area of

the body may then send signals to a user interface if a specific tissue level, condition, or status is reached, or stream data to the external processing module for real-time interpretation, or both.

[0079] In some embodiments, the NIRS systems and methods described herein include independent wireless devices communicating multi-point physiological information (e.g., oxygenation) about the brain and body simultaneously.

[0080] In some embodiments, the systems and methods described herein include multiple systems that can be worn by multiple different individuals whose data is integrated to form a comprehensive image of a group of individuals' health. This integration can be simultaneous for co-located users or asynchronous for disparate groups, or another combination. For example, comparing real-time physiological monitoring across multiple individuals can enable population monitoring and a more holistic image of group performance and wellness. Such continuous imaging can identify early threats or enhancements and increase risk or opportunity for better group performance and outcome.

[0081] Where any component discussed herein is implemented in the form of firmware and/or software, any one of a number of programming languages may be employed such as, for example, C, C++, C#, Objective C, Java®, JavaScript®, Perl, PHP, Visual Basic®, Python®, Ruby, Flash®, or other programming languages. A number of firmware and/or software components are stored in the memory and are executable by the processor. In this respect, the term "executable" means a program file that is in a form that can ultimately be run by the processor. Examples of executable programs can be, for example, a compiled program that can be translated into machine code in a format that can be loaded into a random access portion of the memory and run by the processor, source code that can be expressed in proper format such as object code that is capable of being loaded into a random access portion of the memory and executed by the processor, or source code that can be interpreted by another executable program to generate instructions in a random access portion of the memory to be executed by the processor, etc. An executable program can be stored in any portion or component of the memory including, for example, random access memory (RAM), read-only memory (ROM), hard drive, solid-state drive, USB flash drive, memory card, optical disc such as compact disc (CD) or digital versatile disc (DVD), floppy disk, magnetic tape, or other memory components.

[0082] The memory is defined herein as including both volatile and nonvolatile memory and data storage components. Volatile components are those that do not retain data values upon loss of power. Nonvolatile components are those that retain data upon a loss of power. Thus, the memory can include, for example, random access memory (RAM), read-only memory (ROM), hard disk drives, solid-state drives, USB flash drives, memory cards accessed via a memory card reader, floppy disks accessed via an associated floppy disk drive, optical discs accessed via an optical disc drive, magnetic tapes accessed via an appropriate tape drive, and/or other memory components, or a combination of any two or more of these memory components. In addition, the RAM can include, for example, static random access memory (SRAM), dynamic random access memory (DRAM), or magnetic random access memory (MRAM) and other such devices. The ROM may comprise, for example, a programmable read-only memory (PROM), an erasable programmable read-only memory (EPROM), an electrically erasable programmable read-only memory (EEPROM), or other like memory device.

[0083] Also, the processor can represent multiple processors and/or multiple processor cores and the memory can represent multiple memories that operate in parallel processing circuits, respectively. In such a case, the local interface can be an appropriate network that facilitates communication between any two of the multiple processors, between any processor and any of the memories, or between any two of the memories, etc. The local interface can include additional systems designed to coordinate this communication, including, for example, performing load balancing. The processor can be of electrical or of some other available construction.

[0084] Although some of the processing systems described herein can be embodied in software or code executed by general purpose hardware as discussed above, as an alternative the same can also be embodied in dedicated hardware or a combination of software/general purpose hardware and dedicated hardware. If embodied in dedicated hardware, each can be implemented as a circuit or state machine that employs any one of or a combination of a number of technologies. These technologies can include, but are not limited to, discrete logic circuits having logic gates for implementing various logic functions upon an application of one or more data signals, application specific integrated circuits (ASICs) having appropriate logic gates, field-programmable gate arrays (FPGAs), or other components, etc.

[0085] It should be understood that any logic or application described herein that incorporates software or code can be embodied in any non-transitory computer-readable medium for use by or in connection with an instruction execution system such as, for example, a processor in a computer system or other system. In this sense, the logic can include, for example, statements including instructions and declarations that can be fetched from the computer-readable medium and executed by the instruction execution system. In the context of the present disclosure, a "computer-readable medium" can be any medium that can contain, store, or maintain the logic or application described herein for use by or in connection with the instruction execution system. The computer-readable medium can incorporate any one of many physical media such as, for example, magnetic, optical, or semiconductor media. More specific examples of a suitable computer-readable medium include, but are not limited to, magnetic tapes, magnetic floppy diskettes, magnetic hard drives, memory cards, solid-state drives, USB flash drives, or optical discs. Also, the computer-readable medium can be a random access memory (RAM) including, for example, static random access memory (SRAM) and dynamic random access memory (DRAM), or magnetic random access memory (MRAM). In addition, the computer-readable medium can be a read-only memory (ROM), a programmable read-only memory (PROM), an erasable programmable read-only memory (EPROM), an electrically erasable programmable read-only memory (EEPROM), or other type of memory device.

[0086] Further, any logic or application described herein can be implemented and structured in a variety of ways. For example, one or more applications described can be implemented as modules or components of a single application. Further, one or more applications described herein can be executed in shared or separate computing devices or a combination thereof. For example, a plurality of the applications described herein can execute in the same computing device, or in multiple computing devices in the same computing environment. Additionally, it is understood that terms such as “application,” “service,” “system,” “engine,” “module,” and so on may be interchangeable and are not intended to be limiting.

[0087] While various illustrative embodiments incorporating the principles of the present teachings have been disclosed, the present teachings are not limited to the disclosed embodiments. Instead, this application is intended to cover any variations, uses, or adaptations of the present teachings and use its general principles. Further, this application is intended to

cover such departures from the present disclosure that are within known or customary practice in the art to which these teachings pertain.

[0088] In the above detailed description, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the present disclosure are not meant to be limiting. Other embodiments may be used, and other changes may be made, without departing from the spirit or scope of the subject matter presented herein. It will be readily understood that various features of the present disclosure, as generally described herein, and illustrated in the Figures, can be arranged, substituted, combined, separated, and designed in a wide variety of different configurations, all of which are explicitly contemplated herein.

[0089] The present disclosure is not to be limited in terms of the particular embodiments described in this application, which are intended as illustrations of various features. Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds, compositions or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

[0090] Various of the above-disclosed and other features and functions, or alternatives thereof, may be combined into many other different systems or applications. Various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art, each of which is also intended to be encompassed by the disclosed embodiments.

CLAIMS

What Is Claimed Is:

1. A method of detecting oximetry parameters of a user, the method comprising:

placing a miniaturized, ingress-protected, crush-resistant, wireless, autonomous, and self-contained near-infrared spectroscopy (NIRS) monitoring wearable system on a body part of the user; and

detecting, via a single optical interface of the NIRS system, pulse oximetry (SpO2) and tissue oxygenation (StO2) associated with the body part of the user.

2. The method of claim 1, wherein the NIRS system is configured to measure three or more wavelengths at three or more optical depths, and comprises:

a weight of up to approximately 2.0 ounces;

a volume of up to approximately 30.0 cm^3; and

a battery life of at least approximately 12.0 hours.

3. The method of claim 1, wherein the NIRS system comprises:

a sensor configured to detect one or more optical properties of the body part; and

a non-transitory memory device configured to receive data from the sensor, the data corresponding to the one or more optical properties.

4. The method of claim 3, wherein the NIRS system further comprises:

a substrate;

a first light source bank capable of emitting a first set of wavelengths of red and/or near-infrared light, the first light source bank mounted on the substrate;

the sensor capable of detecting the first set of wavelengths, the sensor mounted on the substrate at a first distance from the first light source bank;

a processor in electronic communication with at least one of the first light source bank and the sensor, the processor mounted on the substrate;

the non-transitory memory device in electronic communication with the processor, the non-transitory memory device mounted on the substrate;

a battery in electronic communication with at least one of the first light source bank, the sensor, the processor, and the non-transitory memory device; and

program instructions stored on the non-transitory memory device that, when executed, direct the processor to:

select, based on an input parameter, the first set of wavelengths;

select, based on the input parameter, the first distance from the first light source bank;

process a signal from the sensor to calculate an oxygenation level;

compare the oxygenation level to a predetermined threshold; and

at least one of:

filter the signal from the sensor;

activate a feedback device when the oxygenation level is below the predetermined threshold; and

store at least one of the signal and the oxygenation level on the non-transitory memory device.

5. The method of claim 3, wherein the NIRS system further comprises:

a substrate comprising one or more detectors capable of detecting one or more biometric properties; and

an electronics module communicatively and removably coupled to the substrate and comprising:

a processor;

the non-transitory memory device;

an energy storage device configured to power the substrate and the electronics module; and

instructions stored on the non-transitory memory device that, when executed, direct the processor to:

identify a type of the one or more detectors of the substrate; and

process a signal from the identified one or more detectors to calculate one or more biometric parameters.

6. The method of claim 3, wherein the NIRS system further comprises:

a substrate in contact with the user and comprising:

the sensor; and

one or more second sensors capable of detecting one or more non-optical biometric properties of the user;

a first electronics module communicatively coupled to the substrate and comprising:

a first processor;

the non-transitory memory device; and

first instructions stored on the non-transitory memory device that, when executed, direct the first processor to:

receive a first signal from the sensor;

process the first signal based on one or more first predefined algorithms; and

determine, based on the processed first signal, whether the user requires one or more first feedback actions; and

a second electronics module communicatively coupled to the substrate and comprising:

a second processor;

a second memory device; and

second instructions stored on the second memory device that, when executed, direct the second processor to:

receive a second signal from the one or more second sensors;

process the second signal based on one or more second predefined algorithms; and

determine, based on the processed second signal, whether the user requires one or more second feedback actions;

wherein at least one of the first processor and the second processor:

responsive to at least one of the determining instructions,

determine that the user requires no feedback actions,

initiate at least one of the one or more first feedback actions, or

initiate at least one of the one or more second feedback actions.

7. The method of claim 1, wherein detecting the SpO2 and the StO2 via the single optical interface allows for implementation of a measurement of hemodynamic coherence associated with a macrovasculature and a microvasculature of the body part.

8. The method of claim 1, wherein detecting the SpO2 and the StO2 comprises detecting the SpO2 and the StO2 as a function of a depth of a tissue associated with the body part.

9. The method of claim 8, wherein detecting the SpO2 and the StO2 as a function of the depth of the tissue comprises normalizing a first value of the StO2 based on a second value of the SpO2.

10. The method of claim 8, wherein detecting the SpO2 and the StO2 as a function of the depth of the tissue allows for measurement of one or more perfusion indexes (PIs) corresponding to the body part.

11. The method of claim 10, wherein the one or more PIs are associated with cardiac activity, pulmonary activity, neurological activity, or combinations thereof.

12. The method of claim 1, further comprising:

processing, via a processor, the detected SpO2 and StO2;

determining, based on the processed SpO2 and StO2, whether the user requires one or more feedback actions; and

responsive to determining the user requires the one or more feedback actions, initiating at least one of the one or more feedback actions.

13. The method of claim 1, wherein detecting the SpO2 and the StO2 via the single optical interface allows for detecting only the SpO2 or for detecting only the StO2.

14. The method of claim 1, further comprising:

transmitting the detected SpO2 and StO2 to a remote device associated with a medical data system.

15. A method of detecting oximetry parameters of a user, the method comprising:

placing a near-infrared spectroscopy (NIRS) system on a body part of the user;

detecting, via a single optical interface of the NIRS system, pulse oximetry (SpO2) and tissue oxygenation (StO2) associated with one or more tissue depths of the body part of the user;

processing, via a processor, the detected SpO2 and StO2 associated with the one or more tissue depths of the body part;

determining, based on the processed SpO2 and StO2, whether the user requires one or more feedback actions; and

responsive to determining the user requires the one or more feedback actions, initiating at least one of the one or more feedback actions.

16. The method of claim 15, wherein the user is a patient experiencing shock, and wherein the shock comprises distributive shock, hypovolemic shock, cardiogenic shock, obstructive shock, hypothermic shock, or combinations thereof.

17. The method of claim 15, wherein processing the detected SpO2 and StO2 comprises optimizing a respective signal-to-noise ratio associated with each of the detected SpO2 and StO2 by adapting one or more system settings.

18. The method of claim 17, wherein determining whether the user requires the one or more feedback actions is based on the respective signal-to-noise ratio associated with each of the detected SpO2 and StO2.

19. The method of claim 15, wherein the one or more feedback actions comprise an oximetry parameter reading, one or more types of stimulation, a change in an environmental property, a change in a sensing parameter of the system, a change in a recording parameter of the system, a change in an operating parameter of the system, an alert to the user, or combinations thereof.

20. The method of claim 15, wherein the one or more feedback actions are provided to the user via changes in a real or virtual environment of the user, changes in notifications to a caregiver, via pharmacological changes, via an environmental property, or combinations thereof.

21. The method of claim 1, wherein detecting the oximetry parameters of the user is performed to monitor a neurological function of the user associated with one or more of trauma, a disease, an injury, or combinations thereof.

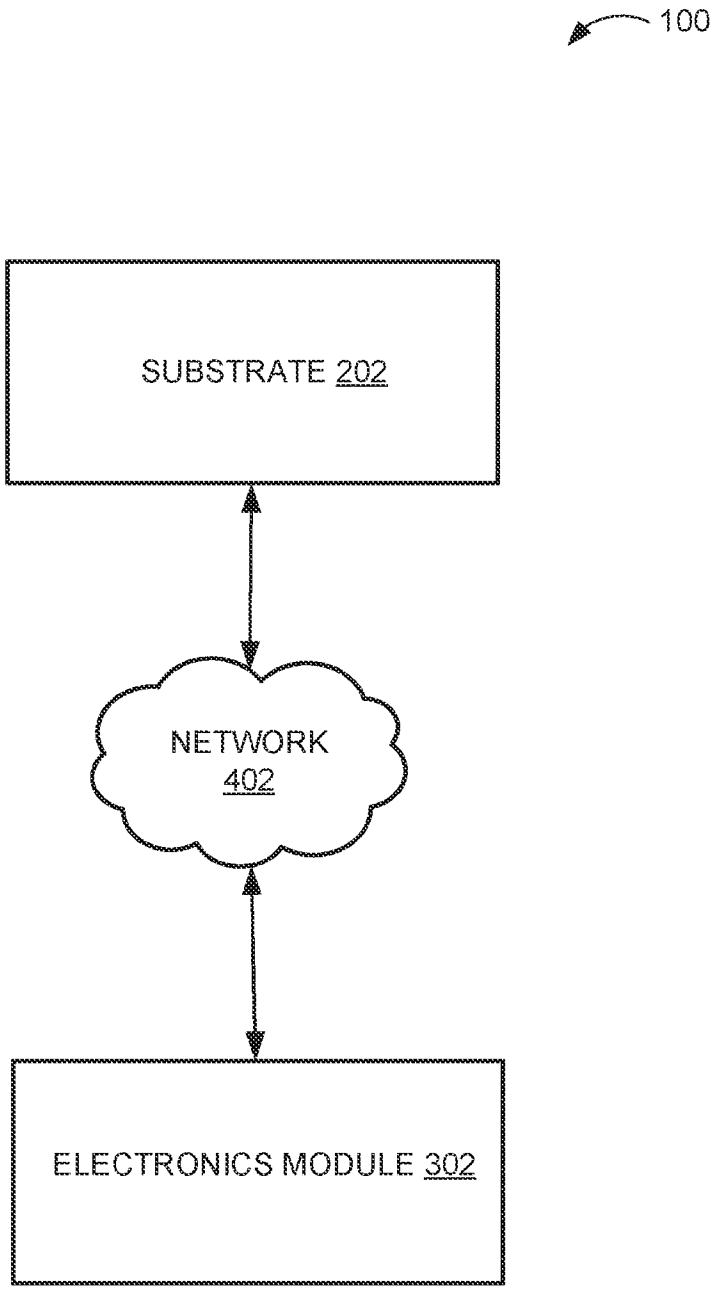


FIG. 1

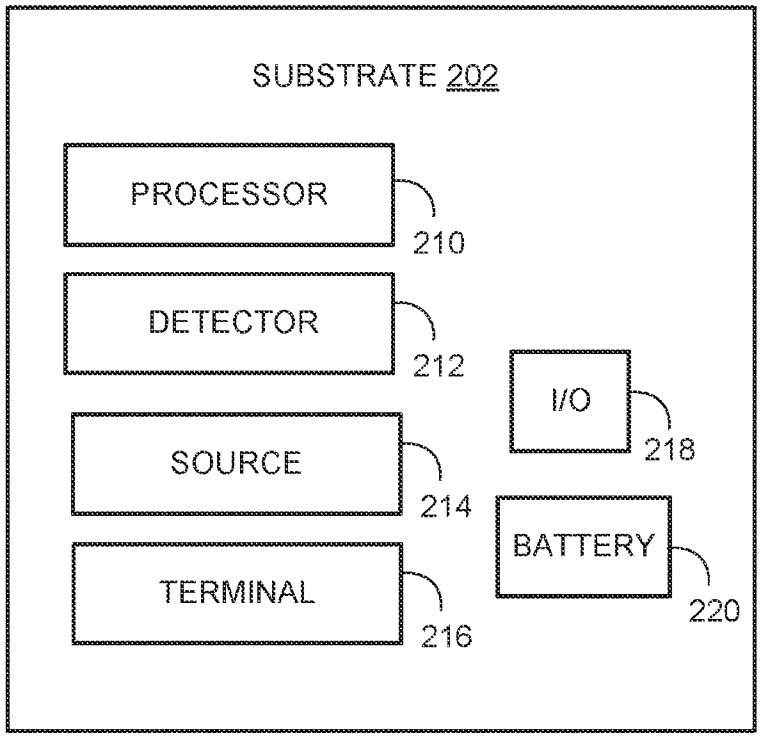

SUBSTRATE 202
PROCESSOR
210
DETECTOR
212
I/O
218
SOURCE
214
BATTERY
220
TERMINAL
216

FIG. 2

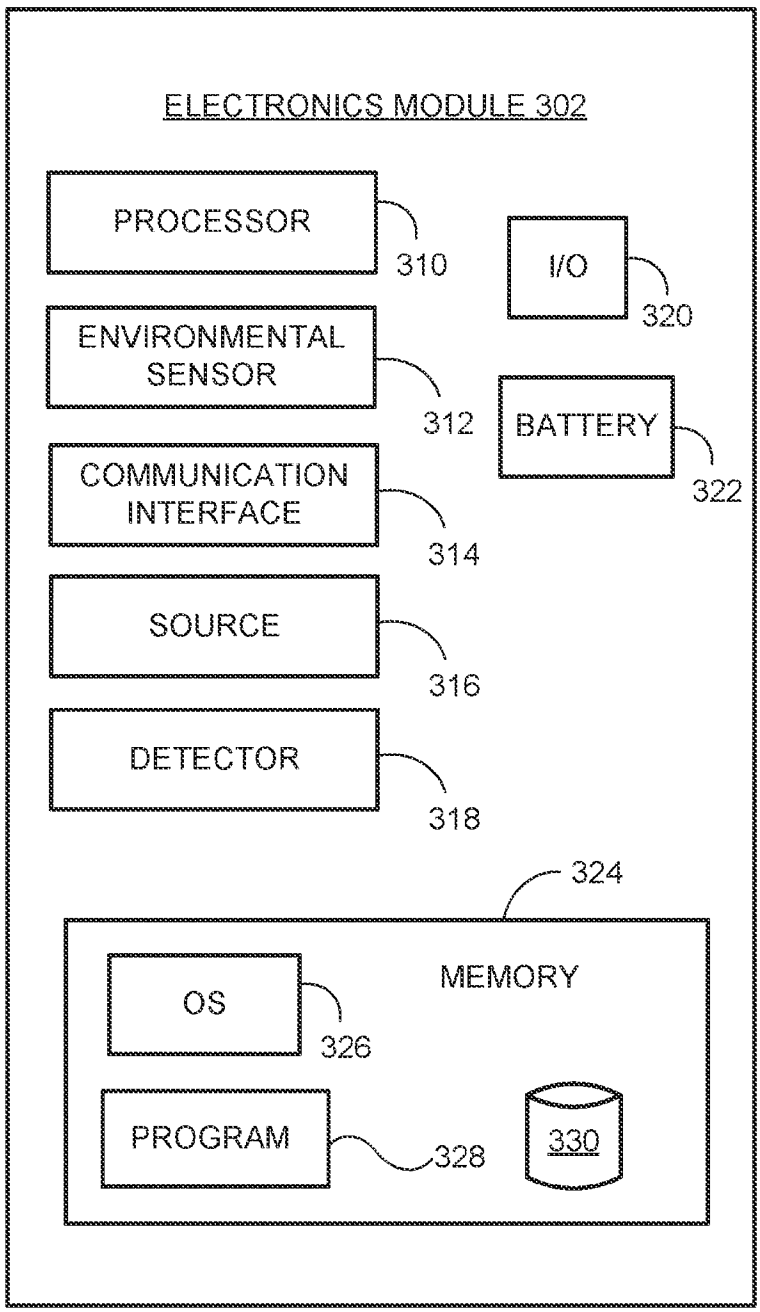
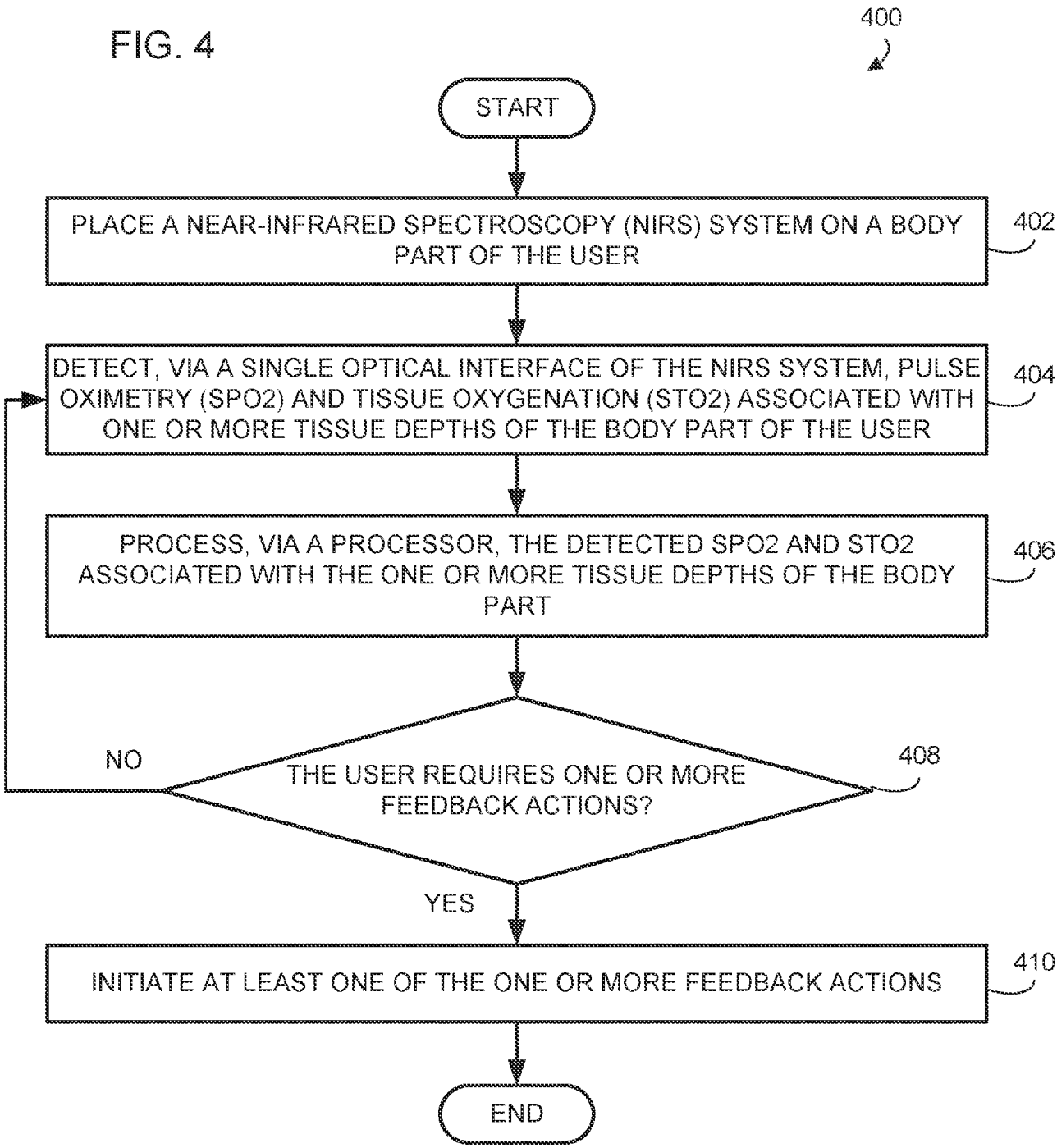

ELECTRONICS MODULE 302
PROCESSOR
310
I/O
320
ENVIRONMENTAL SENSOR
312
BATTERY
322
COMMUNICATION INTERFACE
314
SOURCE
316
DETECTOR
318
324
MEMORY
OS
326
PROGRAM
328
330

FIG. 3

FIG. 4


400
START
PLACE A NEAR-INFRARED SPECTROSCOPY (NIRS) SYSTEM ON A BODY PART OF THE USER
402
DETECT, VIA A SINGLE OPTICAL INTERFACE OF THE NIRS SYSTEM, PULSE OXIMETRY (SPO2) AND TISSUE OXYGENATION (STO2) ASSOCIATED WITH ONE OR MORE TISSUE DEPTHS OF THE BODY PART OF THE USER
404
PROCESS, VIA A PROCESSOR, THE DETECTED SPO2 AND STO2 ASSOCIATED WITH THE ONE OR MORE TISSUE DEPTHS OF THE BODY PART
406
THE USER REQUIRES ONE OR MORE FEEDBACK ACTIONS?
408
NO
YES
INITIATE AT LEAST ONE OF THE ONE OR MORE FEEDBACK ACTIONS
410
END

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/031626

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61B 5/1455*** (2024.01); ***A61B 5/0205*** (2024.01)

CPC: ***A61B 5/14552; A61B 5/0075; A61B 5/0205; A61B 5/6802***

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2021/0244365 A1 (SPECTRONIX INC.) 12 August 2021 (12.08.2021)	
X	entire document	1-6, 8, 12-14, 21
Y	entire document	7, 9-11
	US 2023/0095948 A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA et al.) 30 March 2023 (30.03.2023)	
Y	entire document	7
	US 6,859,658 B1 (KRUG) 22 February 2005 (22.02.2005)	
Y	entire document	9-11
	US 2022/0361774 A1 (RAYDIANT OXIMETRY, INC.) 17 November 2022 (17.11.2022)	
A	entire document	1-14, 21
	US 2023/0133795 A1 (TEXAS A&M UNIVERSITY) 04 May 2023 (04.05.2023)	
A	entire document	1-14, 21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 September 2024 (02.09.2024)	**28 October 2024 (28.10.2024)**

Name and mailing address of the ISA/US	Authorized officer
COMMISSIONER FOR PATENTS **MAIL STOP PCT, ATTN: ISA/US** **P.O. Box 1450** **Alexandria, VA 22313-1450 UNITED STATES OF AMERICA**	**TAINA MATOS**
Facsimile No. **571-273-8300**	Telephone No. **571-272-4300**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/031626

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

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

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

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

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-14, 21**

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/031626

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

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

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-14 and 21, is drawn to a method of detecting oximetry parameters of a user, the method comprising: placing a miniaturized, ingress-protected, crush-resistant, wireless, autonomous, and self-contained near-infrared spectroscopy (NIRS) monitoring wearable system on a body part of the user.

Group II, claims 15-20, is drawn to a method of detecting oximetry parameters of a user, the method comprising: processing, via a processor, the detected SpO2 and StO2 associated with the one or more tissue depths of the body part.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: placing a miniaturized, ingress-protected, crush-resistant, wireless, autonomous, and self-contained near-infrared spectroscopy (NIRS) monitoring wearable system on a body part of the user as claimed therein is not present in the invention of Group II. The special technical feature of the Group II invention: ; processing, via a processor, the detected SpO2 and StO2 associated with the one or more tissue depths of the body part; determining, based on the processed SpO2 and StO2, whether the user requires one or more feedback actions; and responsive to determining the user requires the one or more feedback actions, initiating at least one of the one or more feedback actions as claimed therein is not present in the invention of Group I.

Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of a method of detecting oximetry parameters of a user, the method comprising: placing a near-infrared spectroscopy (NIRS) system on a body part of the user; detecting, via a single optical interface of the NIRS system, pulse oximetry (SpO2) and tissue oxygenation (StO2) associated with the body part of the user, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2022/0361774 to Raydiant Oximetry, Inc. teaches a method of detecting oximetry parameters of a user, the method comprising: placing a near-infrared spectroscopy (NIRS) system on a body part of the user; detecting, via a single optical interface of the NIRS system, pulse oximetry (SpO2) and tissue oxygenation (StO2) associated with the body part of the user (Additionally, or alternatively, uterine contractions may also be measured via near infrared spectroscopy using, for example, light received/detected by detector 160 because uterine contractions, which are muscle contractions, are oscillations of the uterine muscle between a contracted state and a relaxed state. Oxygen consumption of the uterine muscle during both of these stages is different and these differences may be detectable using NIRS, para. 0067. Measurements and/or signals from NIRS adult hemoglobin probe 125, pulse oximetry probe 130, Doppler and/or ultrasound probe 135, and/or uterine contraction measurement device 140 may be communicated to receiver 145 for communication to computer 150 and display on display device 155, para. 0068).

Since none of the special technical features of the Group I or II inventions are found in more than one of the inventions, unity of invention is lacking.