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PATENT APPLIC	CATION	First Named Inv	entor	Stever	Francis LeBoeuf	
TRANSMIT	FAL	Title		Wearable L	ight-Guiding Bands and Patches f	
(Only for new nonprovisional applications	under 37 CFR 1.53(b))	Express Mail Lab	bel No.			
APPLICATION ELE See MPEP chapter 600 concerning utility pat		ADDRESS	TO:		ommissioner for Patents P.O. Box 1450 xandria, VA 22313-1450	
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Apple Inc. APL1002 U.S. Patent No. 8,886,269

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Application De	to Sheet 27 CED 4 70	Attorney Docket Number	9653-7TSCT			
Application Data Sheet 37 CFR 1.76		Application Number				
Title of Invention	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING					
bibliographic data arran This document may be	nged in a format specified by the Un	ited States Patent and Trademark C mitted to the Office in electronic fo	being submitted. The following form contains the Office as outlined in 37 CFR 1.76. rmat using the Electronic Filing System (EFS) or the			

document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

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

Inventor Information:

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Legal	Name) 										
Prefix	Giv	Given Name			Middle Name			Family	Name		Suffix	
	Stev	/en			Francis				LeBoeuf			
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Invent	Inventor 2											
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City		Knightdale					St	ate/Prov	/ince	NC		
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Annli	ination	Data Sh		4 76	Attorney	Docket	Number	9653-7T	SCT	
Арри	Application Data Sheet 37 CFR 1.76				Application Number					
Title of Invention WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING								MONITORING		
City	Raleigh			Province	NC	Country of Residence			US	
Mailing	Address	s of Invent	tor:			<u></u>				
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Application Information:

Title of the Invention	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING				
Attorney Docket Number	9653-7TSCT Small Entity Status Claimed				
Application Type	Nonprovisional				
Subject Matter	Utility				
Total Number of Drawing	Sheets (if any)	Suggested Figure for Publication (if any)			
Filing By Reference :	L				

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

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

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

Publication Information:

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

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

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Application Da	ata Sheet 37 CFR 1.76	Attorney Docket Number	9653-7TSCT			
Application Da		Application Number				
Title of Invention	WEARABLE LIGHT-GUIDING	RABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING				

Representative Information:

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

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Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	12691388	2010-01-21
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12691388	Claims benefit of provisional	61208567	2009-02-25
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12691388	Claims benefit of provisional	61208574	2009-02-25
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12691388	Claims benefit of provisional	61212444	2009-04-13
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Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
12691388	Claims benefit of provisional	61274191	2009-08-14

Foreign Priority Information:

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Application Da	ta Shoot 37 CED 1 76	Attorney Docket Number	9653-7TSCT
Application Data Sheet 37 CFR 1.76		Application Number	
Title of Invention	WEARABLE LIGHT-GUIDING	BANDS AND PATCHES FOR	PHYSIOLOGICAL MONITORING

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

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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.

Authorization to Permit Access:

Authorization to Permit Access to the Instant Application by the Participating Offices

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	9653-7TSCT
		Application Number	
Title of Invention	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING		PHYSIOLOGICAL MONITORING

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

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

Applicant 1

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	O Logal Parragantativo under 35 U.S.C. 117	

Assignee					
O Person to whom the inve	entor is obligated to assign.	O Person who sh	O Person who shows sufficient proprietary interest		
If applicant is the legal re	presentative, indicate the authority	to file the patent applica	tion, the inventor is:		
		<u> </u>			
Name of the Deceased o	r Legally Incapacitated Inventor :				
If the Applicant is an Or	ganization check here.				
Organization Name	Organization Name Valencell, Inc.				
Mailing Address Information For Applicant:					
Address 1 2800-154 Sumner Blvd.					
Address 2					
City	Raleigh	State/Province	NC		
Country US		Postal Code	27616		
Phone Number		Fax Number			

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	9653-7TSCT
		Application Number	
Title of Invention	WEARABLE LIGHT-GUIDING	BANDS AND PATCHES FOR	PHYSIOLOGICAL MONITORING
Email Address			

Assignee Information including Non-Applicant Assignee Information:

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

Assignee 1

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

If the Assignee or Non-Applicant Assignee is an Organization check here.					
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Address 2	Address 2				
City		State/F	Province		
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Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications.					
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First Name	Needham J.	Last Name	Boddie, II	Registration Number	40519
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Application Data Sheet 37 CFR 1.76		Attorney Docket Number	9653-7TSCT
		Application Number	
Title of Invention	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING		PHYSIOLOGICAL MONITORING

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.**

WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

RELATED APPLICATIONS

This application is a continuation application of pending U.S. Patent Application Serial No. 12/691,388, filed January 21, 2010, which claims the benefit of and priority to U.S. Provisional Patent Application No. 61/208,567 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/212,444 filed 4/13/2009, and U.S. Provisional Patent Application No. 61/274,191 filed 8/14/2009, the disclosures of which are incorporated herein by reference as if set forth in their entireties.

FIELD OF THE INVENTION

The present invention relates generally to headsets and, more particularly, to headset earbuds.

BACKGROUND OF THE INVENTION

 There is growing market demand for personal health and environmental monitors, for example, for gauging overall health and metabolism during exercise, athletic training, dieting, daily life activities, sickness, and physical therapy. However, traditional health monitors and environmental monitors may be bulky, rigid, and uncomfortable – generally not suitable for use
 during daily physical activity. There is also growing interest in generating and comparing health and environmental exposure statistics of the general public and particular demographic groups. For example, collective statistics may enable the healthcare industry and medical community to direct healthcare resources to where they are most highly valued. However, methods of collecting these

25 statistics may be expensive and laborious, often utilizing human-based recording/analysis steps at multiple sites.

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As such, improved ways of collecting, storing and analyzing physiological information are needed. In addition, improved ways of seamlessly extracting physiological information from a person during everyday life activities, especially during high activity levels, may be important for enhancing fitness training and healthcare quality, promoting and facilitating prevention, and reducing healthcare costs.

SUMMARY

It should be appreciated that this Summary is provided to introduce a selection of concepts in a simplified form, the concepts being further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of this disclosure, nor is it intended to limit the scope of the invention.

According to some embodiments of the present invention, a headset configured to be attached to the ear of a person includes a base, an earbud housing extending outwardly from the base that is configured to be positioned within an ear of a subject, and a cover surrounding the earbud housing. The base includes a speaker, an optical emitter, and an optical detector. The cover includes light transmissive material that is in optical

- 20 communication with the optical emitter and the optical detector and serves as a light guide to deliver light from the optical emitter into the ear canal of the subject wearing the headset at one or more predetermined locations and to collect light external to the earbud housing and deliver the collected light to the optical detector. The optical emitter, via the light-guiding cover, directs optical energy
- towards a particular region of ear and the optical detector detects secondary optical energy emanating from the ear region. In some embodiments, the optical detector may include an optical filter configured to pass secondary optical energy at selective wavelengths. In some embodiments, the light transmissive material of the cover may be configured, for example via the use of cladding and/or light
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reflective material, such that the cover serves as a light guide that is coupled in parallel to the optical emitter and detector. In some embodiments, the light transmissive material of the cover may be configured, for example via the use of cladding and/or light reflective material, such that the cover serves as a light guide that is coupled perpendicular to the optical emitter and detector.

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In some embodiments, the headset may include various electronic components secured to the base. For example, the headset may include one or more environmental sensors configured to detect and/or measure environmental conditions in a vicinity of the headset. The headset may include a signal

- 5 processor configured to receive and process signals produced by the optical detector. For example, in some embodiments, a signal processor may be configured to extract secondary optical energy and remove optical noise or environmental noise. The headset may include a signal processor configured to receive and process signals produced by the one or more environmental
- sensors. In addition, the headset may include a transmitter configured to transmit signals processed by the signal processor to a remote device in real time. Headsets according to embodiments of the present invention may utilize, for example, Bluetooth®, Wi-Fi, ZigBee, or other wireless transmitters.

In some embodiments, a housing is secured to and overlies the base so as to enclose and protect the speaker, optical emitter and optical detector, as well as other electronic components secured to the base (e.g., sensors, processor, transmitter etc.).

The earbud housing is in acoustical communication with the speaker and has at least one aperture through which sound from the speaker can pass. The light-guiding cover surrounding the earbud housing also includes at least one aperture through which sound from the speaker can pass. The cover may be formed from a soft, resilient material, such as silicone which deforms when inserted within an ear canal of a subject. In some embodiments, the cover includes an alignment member that facilitates alignment of the earbud housing within an ear canal of a subject.

Light directed into the ear of a subject from a light emitter and the subsequent collection of light at a light detector, according to embodiments of the present invention, may be utilized for detecting and/or measuring, among other things, body temperature, skin temperature, blood gas levels, muscle tension, heart rate, blood flow, cardiopulmonary functions, etc.

In some embodiments of the present invention, the light-guiding cover may include a lens that is in optical communication with the optical emitter and/or optical detector. The lens may be configured to focus light emitted by the optical emitter and/or to focus collected light toward the optical detector. In some

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embodiments, multiple lenses may be incorporated into a light-guiding cover.

In some embodiments, the light-guiding cover may include a light diffusion region in optical communication with the light transmissive material that diffuses light emitted by the optical detector.

In some embodiments, the light-guiding cover may include a luminescence-generating region, such as a phosphor-containing region, that is in optical communication with the light transmissive material. The luminescencegenerating region may be embedded within the light-guiding cover and/or on a surface of the light-guiding cover. The luminescence-generating region is

configured to receive light emitted by the optical emitter and convert at least a portion of the received light to light having a different wavelength from that of the received light.

In some embodiments, the light-guiding cover includes one or more grooves formed therein. Each groove is configured to direct external light to the optical detector.

In some embodiments, the light transmissive material of the lightguiding cover is configured to direct light from the optical emitter to a plurality of locations at an outer surface of the cover for delivery into an ear canal of a subject.

In some embodiments, the light transmissive material of the lightguiding cover is a translucent material or includes translucent material in selected locations.

In some embodiments, a light reflective material is on at least a portion of one or both of the inner and outer surfaces of the light-guiding cover.

According to some embodiments of the present invention, a lightguiding earbud for a headset includes light transmissive material that is in optical communication with an optical emitter and optical detector associated with the headset. The light transmissive material is configured to deliver light from the optical emitter into the ear canal of a subject at one or more predetermined

30 locations and to collect light external to the earbud housing and deliver the collected light to the optical detector. In some embodiments, the light emitter and light detector may be integral with the earbud. For example, in some embodiments, a flexible optical emitter is incorporated within the earbud and is in optical communication with the light transmissive material.

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In some embodiments, an earbud includes at least one lens in optical communication with the light transmissive material. Each lens may be configured to focus light from the optical emitter onto one or more predetermined locations in the ear of a subject and/or to focus collected external light onto the optical detector

In some embodiments of the present invention, an earbud may include luminescent material. Luminescent light is generated from optical excitation of the luminescent material by an optical emitter.

In some embodiments of the present invention, an earbud may
integrate a sensor module containing a plurality of sensor elements for
measuring physiological information and at least one noise source for measuring
noise information. A "noise source", as used herein, refers to a sensor, such as
an optical sensor, inertial sensor, electrically conductive sensor, capacitive
sensor, inductive sensor, etc., and derives it name from the fact that it is a
source of input to a filter, such as an adaptive filter described below.

The physiological sensors of the sensor module may generate a signal that includes physiological information plus noise information. The noise may be removed by combining the physiological information and noise information from the sensor module with noise information from the noise source of the sensor module via an electronic filtering method, such as a signal processing technique. Specific examples of such signal processing techniques include FIR (Finite Impulse Response), IIR (Infinite Impulse Response), informatics, machine learning, and adaptive filter methods. The output of the adaptive filter may be a physiological signal that is wholly or partially free of noise. In some embodiments, motion-related noise from a subject activity such as running may be removed from the physiological plus noise signal generated

by a photoplethysmography (PPG) sensor for measuring blood constituent levels or blood flow properties, such as blood oxygen level, VO₂, or heart rate.

In some embodiments of the present invention, the noise source input of an adaptive filter may include a "blocked channel" of optical energy, an inertial sensor, or environmental energy. In some embodiments, the environmental energy may be unwanted ambient optical noise.

In some embodiments of the present invention, a

processor/multiplexor processes physiological signals and noise signals into a

motion-related information.

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data string. This data string may contain information relating to physiological information and motion-related information. The processing method may include signal processing techniques such as pre-adaptive signal conditioning, adaptive filtering, and parameter extraction.

In some embodiments, an earbud includes one or more sensor modules that includes one or more sensors for sensing physiological information and environmental information, such as noise, for example. As such, the earbud may function as a physiological monitor as well as an environmental monitor. In some embodiments, the earbud may include a microprocessor that is in

electrical communication with the sensor module(s). For example, a microprocessor incorporated into an earbud may be configured to execute an adaptive filter algorithm to remove noise from at least one signal generated by a sensor module in the earbud. A microprocessor may also be configured to process information from the one or more sensors to generate a digital output
 string, wherein the digital output string includes a plurality of physiological and

Physiological sensors that may be incorporated into headsets and/or earbuds, according to some embodiments of the present invention, may be configured to detect and/or measure one or more of the following types of physiological information: heart rate, pulse rate, breathing rate, blood flow, VO₂, VO₂max, heartbeat signatures, cardio-pulmonary health, organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood metabolite levels or ratios, blood pH level, physical and/or psychological stress levels and/or stress level indicators, drug

- dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body strain, neurological functioning, brain activity, brain waves, blood pressure, cranial pressure, hydration level, auscultatory information, auscultatory signals associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye
- 30 muscle movement, blood volume, inhaled and/or exhaled breath volume, 30 physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body, anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or

thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice

characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, stem cell regeneration response, etc.

Environmental sensors that may be incorporated into headsets and/or earbuds, according to some embodiments of the present invention, may be configured to detect and/or measure one or more of the following types of environmental information: climate, humidity, temperature, pressure, barometric pressure, soot density, airborne particle density, airborne particle size, airborne

- particle shape, airborne particle identity, volatile organic chemicals (VOCs), hydrocarbons, polycyclic aromatic hydrocarbons (PAHs), carcinogens, toxins, electromagnetic energy, optical radiation, X-rays, gamma rays, microwave radiation, terahertz radiation, ultraviolet radiation, infrared radiation, radio waves, atomic energy alpha particles, atomic energy beta-particles, gravity, light
- intensity, light frequency, light flicker, light phase, ozone, carbon monoxide, carbon dioxide, nitrous oxide, sulfides, airborne pollution, foreign material in the air, viruses, bacteria, signatures from chemical weapons, wind, air turbulence, sound and/or acoustical energy, ultrasonic energy, noise pollution, human voices, animal sounds, diseases expelled from others, exhaled breath and/or
- breath constituents of others, toxins from others, pheromones from others, industrial and/or transportation sounds, allergens, animal hair, pollen, exhaust from engines, vapors and/or fumes, fuel, signatures for mineral deposits and/or oil deposits, snow, rain, thermal energy, hot surfaces, hot gases, solar energy, hail, ice, vibrations, traffic, the number of people in a vicinity of the person,
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coughing and/or sneezing sounds from people in the vicinity of the person, loudness and/or pitch from those speaking in the vicinity of the person.

According to some embodiments of the present invention, earbuds for headsets may include a chipset having at least one sensor element, noise source element, signal processor, input/output line, digital control, and power

regulator.

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Light-guiding earbuds according to the various embodiments of the present invention may be utilized with mono headsets (i.e., headsets having one earbud) as well as stereo headsets (i.e., headsets having two earbuds).

Additionally, the light-guiding region of earbuds, according to embodiments of the present invention, may be integrated not only into an earbud cover and earbud housing, but also into each or all components of an earbud. Moreover, light-guiding earbuds according to the various embodiments of the present invention may be utilized with hearing aids, body jewelry, or any other
attachment that can be placed near the head region, such as eye glasses or shades, a headband, a cap, helmet, visor, or the like.

According to some embodiments of the present invention, a monitoring device includes a circular band capable of encircling a finger of a subject, and a base having an optical emitter and an optical detector attached to the circular band. The circular band includes light transmissive material in optical communication with the optical emitter and optical detector that is configured to deliver light from the optical emitter to one or more portions of the finger of the subject and to collect light from one or more portions of the finger of the subject and deliver the collected light to the optical detector. In some embodiments, the circular band includes first and second concentric body portions.

In some embodiments, the circular band includes a lens region in optical communication with the optical emitter that focuses light emitted by the optical emitter and/or that collects light reflected from a finger. In some embodiments the circular band includes a phosphor-containing region in optical communication with the light transmissive material, wherein the phosphorcontaining region receives light emitted by the optical emitter and converts at least a portion of the received light to light having a different wavelength from the received light.

In some embodiments, the light transmissive material of the circular band has an outer surface and an inner surface, and a cladding material, such as light reflective material, is on (or near) at least a portion of one or both of the inner and outer surfaces.

In some embodiments, the base includes one or more of the following: a signal processor configured to receive and process signals produced

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by the optical detector, a transmitter configured to transmit signals processed by the signal processor to a remote device.

According to some embodiments of the present invention, a monitoring device configured to be attached to the body of a subject includes a base having an optical emitter and an optical detector, and light transmissive material attached to the base. The light transmissive material is in optical communication with the optical emitter and optical detector and is configured to deliver light from the optical emitter to one or more portions of the body of the subject and to collect light from one or more portions of the body of the subject and deliver the collected light to the optical detector. The light transmissive 10

material may include adhesive material in one or more locations that is configured to adhesively secure the device to the body of the subject.

In some embodiments, an outer body portion is attached to the base and to the light transmissive material. The outer body portion may include adhesive material in one or more locations that is configured to adhesively secure the device to the body of the subject.

In some embodiments, the light transmissive material includes a lens region that is in optical communication with the optical emitter and that focuses light emitted by the optical emitter and/or that collects light reflected from a finger. In some embodiments, the light transmissive material includes a phosphor-containing region that receives light emitted by the optical emitter and converts at least a portion of the received light to light having a different wavelength from the received light. In some embodiments, the light transmissive material has an outer surface and an inner surface, and a light reflective material is disposed on or near at least a portion of one or both of the inner and outer

surfaces.

In some embodiments, the base includes one or more of the following: a signal processor configured to receive and process signals produced by the optical detector, a transmitter configured to transmit signals processed by the signal processor to a remote device.

It is noted that aspects of the invention described with respect to one embodiment may be incorporated in a different embodiment although not specifically described relative thereto. That is, all embodiments and/or features of any embodiment can be combined in any way and/or combination. Applicant

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reserves the right to change any originally filed claim or file any new claim accordingly, including the right to be able to amend any originally filed claim to depend from and/or incorporate any feature of any other claim although not originally claimed in that manner. These and other objects and/or aspects of the present invention are explained in detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which form a part of the specification, illustrate various embodiments of the present invention. The drawings and description together serve to fully explain embodiments of the present invention.

Fig. 1 is an exploded perspective view of a headset with a lightguiding earbud, according to some embodiments of the present invention.

Fig. 2 is a perspective view of a stereo headset incorporating lightguiding earbuds, according to some embodiments of the present invention.

Fig. 3 is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Figs. 4A-4D are side section views of light-guiding earbuds for a headset, according to some embodiments of the present invention.

Fig. 5 is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 6 is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 7A is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 7B is a perspective view of a flexible optical emitter utilized in the earbud of Fig. 7A, according to some embodiments of the present invention.

Fig. 8A is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 8B is a cross-sectional view of the earbud of Fig. 8A taken 30 along lines 8B-8B.

Fig. 8C is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 8D is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

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Fig. 9A is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 9B is a cross-sectional view of the earbud of Fig. 9A taken along lines 9B-9B.

Fig. 9C illustrates luminescent particles within the earbud cover of Figs. 9A-9B, according to some embodiments of the present invention.

Fig. 9D is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 9E is a cross-sectional view of the earbud of Fig. 9D taken along lines 9E-9E. 10

Fig. 10 illustrates various anatomy of a human ear.

Fig. 11A is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.

Fig. 11B is a cross-sectional view of the earbud of Fig. 11A taken along lines 11B-11B. 15

Figs. 12A-12B illustrate respective opposite sides of a sensor module that may be located near the periphery of an earbud, according to some embodiments of the present invention.

Fig. 13 illustrates an adaptive filter and noise source for removing noise from a noisy physiological signal, according to some embodiments of the 20 present invention.

Figs. 14A-14D are respective graphs of time-dependent data collected from a light-guiding earbud worn by a person, according to some embodiments of the present invention.

Fig. 15 is a graph of processed physiological signal data from a headset having one or more light-guiding earbuds, according to some embodiments of the present invention.

Fig. 16 is a flow chart of operations for extracting physiological information from headset sensor signals, according to some embodiments of the present invention.

Fig. 17 is a block diagram that illustrates sensor signals being processed into a digital data string including activity data and physiological data, according to some embodiments of the present invention.

> Fig. 18 illustrates a digital data string, according to some 11

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embodiments of the present invention.

Fig. 19 illustrates the optical interaction between the sensor module of Figs. 12A-12B and the skin of a subject.

Fig. 20 illustrates a chipset for use in a headset, according to some embodiments of the present invention.

Fig. 21 illustrates a chipset for use in a stereo headset, according to some embodiments of the present invention.

Fig. 22A is a top plan view of a monitoring device configured to be attached to finger of a subject, according to some embodiments of the present invention.

Fig. 22B is a cross-sectional view of the monitoring device of Fig. 22A taken along lines 22B-22B.

Fig. 23 is a side view of a monitoring device configured to be attached to the body of a subject, according to some embodiments of the present invention.

DETAILED DESCRIPTION

The present invention will now be described more fully hereinafter with reference to the accompanying figures, in which embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Like numbers refer to like elements throughout. In the figures, certain layers, components or features may be exaggerated for clarity, and broken lines illustrate optional features or operations unless specified otherwise. In addition, the sequence of operations (or steps) is not limited to the order presented in the figures and/or claims unless specifically indicated otherwise. Features described with respect to one figure or embodiment can be associated with another embodiment or figure although not specifically described or shown as such.

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It will be understood that when a feature or element is referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will

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also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or

element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that
references to a structure or feature that is disposed "adjacent" another feature

The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. As used herein, the singular forms "a", "an" and "the" are intended to include the

- plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or
- 20 groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items.

may have portions that overlap or underlie the adjacent feature.

Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the

exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless

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specifically indicated otherwise.

It will be understood that although the terms first and second are used herein to describe various features/elements, these features/elements should not be limited by these terms. These terms are only used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention. Like numbers refer to like elements throughout.

Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning

in the context of the specification and relevant art and should not be interpreted in an idealized or overly formal sense unless expressly so defined herein. Wellknown functions or constructions may not be described in detail for brevity and/or clarity.

The term "headset" includes any type of device or earpiece that may be attached to or near the ear (or ears) of a user and may have various configurations, without limitation. Headsets incorporating light-guiding earbuds as described herein may include mono headsets (one earbud) and stereo headsets (two earbuds), earbuds, hearing aids, ear jewelry, face masks, headbands, and the like.

The term "real-time" is used to describe a process of sensing, processing, or transmitting information in a time frame which is equal to or shorter than the minimum timescale at which the information is needed. For example, the real-time monitoring of pulse rate may result in a single average pulse-rate measurement every minute, averaged over 30 seconds, because an instantaneous pulse rate is often useless to the end user. Typically, averaged physiological and environmental information is more relevant than instantaneous changes. Thus, in the context of the present invention, signals may sometimes be processed over several seconds, or even minutes, in order to generate a "real-time" response.

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The term "monitoring" refers to the act of measuring, quantifying, qualifying, estimating, sensing, calculating, interpolating, extrapolating, inferring, deducing, or any combination of these actions. More generally, "monitoring" refers to a way of getting information via one or more sensing elements. For example, "blood health monitoring" includes monitoring blood gas levels, blood hydration, and metabolite/electrolyte levels.

The term "physiological" refers to matter or energy of or from the body of a creature (*e.g.*, humans, animals, etc.). In embodiments of the present invention, the term "physiological" is intended to be used broadly, covering both physical and psychological matter and energy of or from the body of a creature. However, in some cases, the term "psychological" is called-out separately to emphasize aspects of physiology that are more closely tied to conscious or subconscious brain activity rather than the activity of other organs, tissues, or cells.

The term "body" refers to the body of a subject (human or animal) that may wear a headset incorporating one or more light-guiding earbuds, according to embodiments of the present invention.

In the following figures, various headsets and light-guiding earbuds for use with headsets will be illustrated and described for attachment to the ear of the human body. However, it is to be understood that embodiments of the present invention are not limited to those worn by humans.

The ear is an ideal location for wearable health and environmental monitors. The ear is a relatively immobile platform that does not obstruct a person's movement or vision. Headsets located at an ear have, for example, access to the inner-ear canal and tympanic membrane (for measuring core body temperature), muscle tissue (for monitoring muscle tension), the pinna and

earlobe (for monitoring blood gas levels), the region behind the ear (for measuring skin temperature and galvanic skin response), and the internal carotid artery (for measuring cardiopulmonary functioning), etc. The ear is also at or

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near the point of exposure to: environmental breathable toxicants of interest (volatile organic compounds, pollution, etc.; noise pollution experienced by the ear; and lighting conditions for the eye. Furthermore, as the ear canal is naturally designed for transmitting acoustical energy, the ear provides a good location for monitoring internal sounds, such as heartbeat, breathing rate, and mouth motion.

Wireless, Bluetooth®-enabled, and/or other personal communication headsets may be configured to incorporate physiological and/or environmental sensors, according to some embodiments of the present invention. As a specific example, Bluetooth® headsets are typically lightweight,

- unobtrusive devices that have become widely accepted socially. Moreover,
 Bluetooth® headsets are cost effective, easy to use, and are often worn by users
 for most of their waking hours while attending or waiting for cell phone calls.
 Bluetooth® headsets configured according to embodiments of the present
 invention are advantageous because they provide a function for the user beyond
- health monitoring, such as personal communication and multimedia applications, thereby encouraging user compliance. Exemplary physiological and environmental sensors that may be incorporated into a Bluetooth® or other type of headsets include, but are not limited to accelerometers, auscultatory sensors, pressure sensors, humidity sensors, color sensors, light intensity sensors,
- 15 pressure sensors, etc.

Headsets, both mono (single earbud) and stereo (dual earbuds), incorporating low-profile sensors and other electronics, according to embodiments of the present invention, offer a platform for performing near-realtime personal health and environmental monitoring in wearable, socially

- acceptable devices. The capability to unobtrusively monitor an individual's physiology and/or environment, combined with improved user compliance, is expected to have significant impact on future planned health and environmental exposure studies. This is especially true for those that seek to link environmental stressors with personal stress level indicators. The large scale commercial
- availability of this low-cost device can enable cost-effective large scale studies. The combination of monitored data with user location via GPS data can make on-going geographic studies possible, including the tracking of infection over large geographic areas. The commercial application of the proposed platform encourages individual-driven health maintenance and promotes a healthier lifeatule through proper calorie inteke and eversion

30 lifestyle through proper caloric intake and exercise.

Accordingly, some embodiments of the present invention combine a personal communications headset device with one or more physiological and/or environmental sensors. Other embodiments may combine physiological and/or environmental sensors into a headset device.

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Optical coupling into the blood vessels of the ear may vary between individuals. As used herein, the term "coupling" refers to the interaction or communication between excitation light entering a region and the region itself. For example, one form of optical coupling may be the interaction between

- 5 excitation light generated from within a light-guiding earbud and the blood vessels of the ear. In one embodiment, this interaction may involve excitation light entering the ear region and scattering from a blood vessel in the ear such that the intensity of scattered light is proportional to blood flow within the blood vessel. Another form of optical coupling may be the interaction between
- excitation light generated by an optical emitter within an earbud and the lightguiding region of the earbud. Thus, an earbud with integrated light-guiding capabilities, wherein light can be guided to multiple and/or select regions along the earbud, can assure that each individual wearing the earbud will generate an optical signal related to blood flow through the blood vessels. Optical coupling of
- light to a particular ear region of one person may not yield photoplethysmographic signals for each person. Therefore, coupling light to multiple regions may assure that at least one blood-vessel-rich region will be interrogated for each person wearing the light-guiding earbud. Coupling multiple regions of the ear to light may also be accomplished by diffusing light from a light source within the earbud.

Embodiments of the present invention are not limited to headsets that communicate wirelessly. In some embodiments of the present invention, headsets configured to monitor an individual's physiology and/or environment may be wired to a device that stores and/or processes data. In some embodiments, this information may be stored on the headset itself. Furthermore, embodiments of the present invention are not limited to earbuds. In some embodiments, the light-guiding structure may be molded around another part of the body, such as a digit, finger, toe, limb, around the nose or earlobe, or the like. In other embodiments, the light-guiding structure may be integrated into a patch, such as a bandage that sticks on a person's body.

Referring to Fig. 1, a headset 10 according to some embodiments of the present invention is illustrated. The illustrated headset 10 includes a base 12, a headset housing 14, an earbud housing 16, and a cover 18 that surrounds the earbud housing 16. The base 12 includes a main circuit board 20 that

supports and/or is connected to various electronic components. In the illustrated embodiment, a speaker 22, optical emitter 24, optical detectors 26, and thermopile 28 (described below) are mounted onto a secondary circuit board 32 which is secured to the main circuit board 20. The earbud housing surrounds the

speaker 22, optical emitter 24, optical detectors 26, and thermopile 28.
 Collectively, the earbud housing 16, cover 18, and various electronic components (e.g., speaker 22, optical emitter 24, optical detectors 26, thermopile 28) located within the earbud housing 16 of the illustrated headset 10 may be referred to as an earbud 30. The headset housing 14 is secured to the

base 12 and is configured to enclose and protect the various electronic components mounted to the base (e.g., main circuit board 20 and components secured thereto, etc.) from ambient interference (air, humidity, particulates, electromagnetic interference, etc).

Each optical detector 26 may be a photodiode, photodetector, phototransistor, thyristor, solid state device, optical chipset, or the like. The optical emitter 24 may be a light-emitting diode (LED), laser diode (LD), compact incandescent bulb, micro-plasma emitter, IR blackbody source, or the like. The speaker 22 may be a compact speaker, such as an inductive speaker, piezoelectric speaker, electrostatic speaker, or the like. One or more

20 microphones, such as electrets, MEMS, acoustic transducers, or the like, may also be located within the headset housing or earbud housing to pick up speech, physiological sounds, and/or environmental sounds.

The main circuit board 20 and secondary circuit board 32 may also support one or more sensor modules (not shown) that contain various

- 25 physiological and/or environmental sensors. For example, a sensor module, such as sensor module 70 illustrated in Figs. 12A-12B, may be attached to the circuit boards 20, 32. The circuit boards 20, 32 also may include at least one signal processor (not shown), at least one wireless module (not shown) for communicating with a remote device, and/or at least one memory storage device
- 30 (not shown). An exemplary wireless module may include a wireless chip, antenna, or RFID tag. In some embodiments, the wireless module may include a low-range wireless chip or chipset, such as a Bluetooth® or ZigBee chip. These electronic components may be located on the main circuit board 20, or on another circuit board, such as the secondary circuit board 32, attached to the

main circuit board.

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Secondary circuit board 32 may also include a temperature sensor, such as a thermopile 28 mounted thereto. The thermopile 28 is oriented so as to point towards the tympanic membrane within the ear of a subject wearing the headset 10 through the acoustic orifices 34a, 34b in the earbud housing 16 and cover 18, respectively. The secondary circuit board 32 may be in electrical contact with the main circuit board 20 via soldering, connectors, wiring, or the like. A battery 36, such as a lithium polymer battery or other portable battery, may be mounted to the main circuit board 20 and may be charged via a USB charge port 38. Although not shown in Fig. 1, an ear hook may be attached to the base 12 or housing 14 to help stabilize the earbud 30 and headset 10 worn

by a subject and such that the earbud 30 is consistently placed at the same location within the ear canal of a subject.

In the illustrated embodiment, the earbud housing 16 is in acoustical communication with the speaker 22 and includes an aperture 34a through which sound from the speaker 22 can pass. However, additional apertures may also be utilized. The cover 18 also includes at least one aperture 34b through which sound from the speaker 22 can pass. The thermopile 28 is used as a heat sensor and measures thermal radiation from the ear of a subject via the acoustic apertures 34a, 34b. Additional or other sensors may be in the location of the thermopile 28, aligned towards the tympanic membrane, to sense other forms of energy, such as acoustic, mechanical, chemical, optical, or nuclear energy from the tympanic membrane region. For example, a photodetector may replace the thermopile 28 to measure light scattering off the

25 tympanic membrane.

The cover 18 includes light transmissive material in a portion 19 thereof that is referred to as a light-guiding region. The light transmissive material in light-guiding region 19 is in optical communication with the optical emitter 24 and detectors 26. The light transmissive material in light-guiding

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region 19 is configured to deliver light from the optical emitter 24 into an ear canal of the subject at one or more predetermined locations and to collect light external to the earbud 30 and deliver the collected light to the optical detectors 26. As such, the earbud 30 of the illustrated headset 10 is referred to as a "light-guiding" earbud 30.

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In some embodiments, the light transmissive material in the lightguiding region 19 may include a lens (e.g., lens 18L illustrated in Fig. 6). The lens 18L is in optical communication with the optical emitter 24 and/or with the optical detectors 26. For example, a lens 18L may be configured to focus light emitted by the optical emitter 24 onto one or more portions of an ear and/or to focus collected light on the light detectors 26. Lenses are described below with respect to Figs. 5-6.

In some embodiments, the earbud cover 18 may integrate a transparent light-guiding layer, wherein air is utilized as a cladding layer. For example, the earbud cover 18 may include an optically transparent silicone molded layer, and the earbud housing 16 may be removed such that a cladding layer is air. In some embodiments, the earbud housing 16 may be closed, and the light-guiding region 19 may be integrated within the cover 18 or between the housing 16 and cover 18.

The illustrated cover 18 of Fig. 1 includes an alignment member 40 (also referred to as a stabilization arm) that facilitates alignment of the earbud 30 within an ear canal of a subject. The alignment member 40 may facilitate stable measurements of optical scattered light from the ear region, which can be important for PPG measurements and tympanic temperature measurements.

In some embodiments, a light-guiding cover 18 is formed from a soft, resilient material, such as silicone, which deforms when inserted within an ear canal of a subject. However, various materials may be utilized for lightguiding covers 18 and for serving as light guides depending on the type of earbud desired for a particular use case, according to embodiments of the

present invention. For example, in some embodiments, a light-guiding cover 18 25 may be formed from a substantially rigid material such that the light-guiding earbud 30 is substantially rigid. For example, for a running use case, the runner may wish to have firm but soft earbuds, such that the earbud may deform to some extent when inserted into the ear. In such case, the light-guiding region may be silicone or other soft material and the outer cladding may be air, a

polymer, plastic, or a soft material having a lower index of refraction than silicone.

Fig. 2 illustrates a stereo headset 100 that utilizes two light-guiding earbuds 130, according to some embodiments of the present invention. The

headset 100 also includes various sensor elements 132 located at several regions in the stereo headset 100. A benefit of the stereo headset 100 may be that the total number of sensors measuring the ear region may be doubled; alternatively, the sensors in each earbud may be halved. Another benefit of the

stereo headset is that it may enable stereo music during daily activities. Another benefit of the stereo headset is that asymmetric physiological differences can be detected in the user by measuring each side of the user in real-time. For example, differences in blood flow between right and left sides of a user may be detected, indicating changes in right/left brain activity, the onset of a stroke,
localized inflammation, or the like.

Light-guiding earbuds according to various embodiments of the present invention will now be described with respect to Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B. Referring initially to Figs. 3-4, a light-guiding earbud 30 includes a base 50, an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear E of a subject, and a cover 18 that surrounds the earbud housing 16. The earbud housing 16 is in acoustical communication with a speaker 22 and includes at least one aperture 34a through which sound from the speaker 22 can pass. The cover 18 includes at least one aperture 34b through which sound from the speaker 22 can pass, and includes light transmissive material in optical communication with an optical

emitter 24 and detector 26.

The cover 18 includes cladding material 21 on an inner surface 18b thereof and on an outer surface 18a thereof, as illustrated. An end portion 18f of the cover outer surface 18a does not have cladding material. As such, the cover 18 serves as a light guide that delivers light from the optical emitter 24 through the end portion 18f and into the ear canal C of a subject at one or more predetermined locations and that collects light external to the earbud housing 16 and delivers the collected light to the optical detector 26. In the various embodiments described herein, the terms light guide and cover are intended to be interchangeable. However, it should be noted that, in other embodiments, the

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The base 50 in all of the earbud embodiments (Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B) described herein may include any combination of a printed circuit board, electrical connectors, and housing

earbud housing 16 may also serve as a light guide without the need for cover 18.

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component for a headset. For example, the base 50 in Figs. 3-6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B, may include, for example, the base 12 of the headset 10 of Fig. 1, the main circuit board 20 of the headset 10 of Fig. 1, the housing 14 of the headset 10 of Fig. 1, or may be a combination of the base 12, main circuit board 20, and/or housing 14 of the headset 10 of Fig. 1.

The optical emitter 24 generates inspection light 111 and the lightguiding region 19 of the light guide 18 directs the inspection light 111 towards an ear region. This light is called inspection light because it interrogates the surface of the ear, penetrates the skin of the ear, and generates a scattered light

response 110 which may effectively inspect blood vessels within the ear region. The optical detector 26 detects scattered light 110 from an ear region and the light-guiding region 19 of the light guide 18 guides the light to the optical detector 26 through the light-guiding region 19, as illustrated.

In the embodiment of Fig. 3, the light-guiding earbud 30 is configured for optical coupling that is parallel to the light guide (i.e., cover 18). The optical detector 26 and optical emitter 24 are configured to detect and generate light substantially parallel to the light-guiding region 19 of the light guide 18. For example, the light guide 18 defines an axial direction A₁. The optical emitter 24 and optical detector 26 are each oriented such that their respective primary emitting and detecting planes P₁, P₂ are each facing a respective direction A₃, A₂ that is substantially parallel with direction A₁.

The light guiding region 19 of the light guide 18 in the illustrated embodiment of Fig. 3 is defined by cladding material 21 that helps confine light within the light guiding region 19. The cladding material 21 may be reflective material in some embodiments. In other embodiments, the cladding material may be optically transparent or mostly transparent with a lower index of refraction than the light transmissive material of the cover 18. The cladding 21 may be a layer of material applied to one or more portions of the inner and/or outer surfaces 18a, 18b of the light guide 18. In some embodiments, the outer surface

16a of the earbud housing 16 may serve as cladding that confines light within the light-guiding region 19. In some embodiments, the light transmissive material of the light guide 18 may be composed of a material having a higher index of refraction than the cladding material 21. In some embodiments, air may serve as a cladding layer.

In the embodiment of Fig. 4A, the light-guiding earbud 30 is configured for optical coupling that is substantially perpendicular to the light guide (i.e., cover 18). The optical detector 26 and optical emitter 24 are configured to detect and generate light substantially perpendicular to the lightguiding region 19 of the light guide 18. For example, the light guide 18 defines

⁵ guiding region 19 of the light guide 18. For example, the light guide 18 defines an axial direction A₁. The optical emitter 24 and optical detector 26 are each oriented such that their respective primary emitting and detecting planes P₁, P₂ are each facing a respective direction A₃, A₂ that is substantially perpendicular to direction A₁. The orientation of the optical emitter 24 and optical detector 26 in

Fig. 4A may be convenient for manufacturing purposes, where side-emitting LEDs and side-detecting photodetectors can couple directly to the light-guiding region 19 for generating light 111 and detecting light 110. This may relax size constraints for an earbud 30 because the dimensions of the light-guiding region 19 may be independent of the optical emitter 24 and optical detector 26.

Fig. 4B illustrates the light-guiding earbud 30 of Fig. 4A modified such that the earbud cover 18 and cladding material 21 are elongated to reach deeper within the ear canal C of a subject, and closer to the tympanic membrane, for example. In the illustrated embodiment of Fig. 4B, there are no apertures in the housing 16 or cover 18. Acoustic energy 44 from/to the
speaker/microphone passes through the material of the cover 18 and housing 16. The illustrated elongated configuration serves as both an optical light-guiding region and an acoustic wave-guiding region.

Fig. 4C illustrates the light-guiding earbud 30 of Fig. 4A modified such that the earbud cover 18 and cladding material 21 are elongated to reach deeper within the ear canal C of a subject, and closer to the tympanic membrane, for example. In the illustrated embodiment of Fig. 4C, apertures 34a, 34b in the housing 16 and cover 18 are provided. As such, the optical lightguiding region 19 and the acoustic wave-guiding region 54 are isolated from each other. The light-guiding region 19 may be a light transmissive material,

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such as a dielectric material, and the acoustic wave-guiding region 54 may be air or another material, and the separation between these regions may be defined by at least part of the cladding material 21. Embodiments of the present invention may include multiple openings 34a, 34b in the housing 16 and cover 18. The separation between the light-guiding region 19 and the acoustic wave-

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guiding region 54 may be defined by other structures composed of a variety of possible materials. Specific examples of these materials include plastic molding, metals, polymeric structures, composite structures, or the like.

Fig. 4D illustrates the light-guiding earbud 30 of Fig. 4A modified
such that the earbud cover 18 and cladding material 21 are elongated to reach deeper within the ear canal C of a subject, and closer to the tympanic membrane, for example. In the illustrated embodiment of Fig. 4D, the area within the housing 16 may be air, silicone, plastic, or any material capable of passing sound. As such, at opening 34b, an interface exists between the material of the
light-guiding region 19 and the material within the housing 16. In some embodiments, the light-guiding region 19 and the region within the housing 16

light-guiding region 19 and the material within the housing 16. In some embodiments, the light-guiding region 19 and the region within the housing 16 may both be air. In other embodiments, the light-guiding region 19 and the region within the housing 16 may be formed from the same or different materials. In some embodiments, the region within the housing 16 may be formed from an optical wave guiding material identical or similar to the material in the light

optical wave guiding material identical or similar to the material in the lightguiding region 19.

In the embodiments of Figs. 4B-4D, the optical energy 110 coming from the ear may include optical wavelengths, such as IR wavelengths, emitting from the tympanic membrane due to black body radiation. If the optical detector 26 is configured to measure this black body radiation, then the earbud can be used to measure tympanic temperature, blood analyte levels, neurological, electrical activity, or metabolic activity of the earbud wearer.

Referring to Fig. 5, a light-guiding earbud 30 is configured for optical coupling that is parallel to the light guide (i.e., cover 18) as in the embodiment of Fig. 3. However, the embodiment of Fig. 5 does not include a separate earbud housing. Instead, the light guide 18 serves the function of the earbud housing. In addition, the light guide 18 includes multiple windows 18w formed in the cladding material 21 on the outer surface 18a of the cover and through which light 111 emitted by the light emitter 24 passes and multiple

windows 18w through which scattered light 110 passes into the light guide 18 to be directed to the light detector 26. These openings 18w may extend circumferentially around the light guide 18 or may partially extend circumferentially around portions of the light guide 18. In some embodiments of this invention, the earbud housing and light guide 18 may be separated, as

shown in other figures.

In addition, the illustrated light guide 18 of Fig. 5 is surrounded by a layer 29 of light transmissive material. One or more lenses 29L are formed in this layer 29 and are in optical communication with respective windows 18w in the

light guide 18. In the illustrated embodiment, a lens 29L is in optical communication with a respective window 18w through which emitted light 111 passes, and a respective window 18w through which scattered light 110 passes. Lenses 29L are configured to focus inspection light 111 onto a particular region of the ear. Lenses 29L are configured to help collect scattered light 110 and

direct the scattered light 110 into the light guiding region 19. In some embodiments, these lenses 29L may be a molded part of the light guide 18. The illustrated location of lenses 29L in Fig. 5 is non-limiting, and the lenses 29L may be located wherever optical coupling between the earbud and ear is desired. Though convex lens embodiments are shown in Fig. 5, this is not meant to limit

embodiments of the present invention. Depending on the desired optical coupling and configuration of the earbud against the ear, a variety of lens types and shapes may be useful, such as convex, positive or negative meniscus, planoconvex, planoconcave, biconvex, biconcave, converging, diverging, and the like.

Referring now to Fig. 6, a light guiding earbud 30, according to some embodiments of the present invention, includes a base 50, an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear E of a subject, and a cover 18 of light transmissive material surrounding the earbud housing 16 that forms a light-guiding region 19. The earbud housing 16 is in acoustical communication with a speaker 22 and includes at least one aperture 34a through which sound from the speaker 22 can pass. The earbud housing 16 encloses the speaker 22, an optical emitter 24 and an optical detector 26 as illustrated. An additional light detector 26 is located on the base 50 but is not surrounded by the earbud housing 16.

The earbud housing 16 is formed of a cladding material. The cladding material may be reflective material in some embodiments. In other embodiments, the cladding material may be optically transparent or mostly transparent with a lower index of refraction than the light transmissive material of the cover 18. In some embodiments, the earbud housing 16 may be replaced by

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air, such that the cladding region is air. Air may have a smaller index of refraction than that of the cover 18, supporting light transmission along the cover 18. In other embodiments, a cladding region exists between the earbud housing 16 and the light-guiding region 19. In another embodiment, a cladding region exists covering the outside of light-guiding region 19, with the exception of regions surrounding the lens regions 18L.

A plurality of windows 16w are formed in the earbud housing 16 at selected locations to permit light emitted by the light emitter 24 to pass therethrough. In some embodiments, the earbud housing 16 may have translucent or transparent material that serves the function of one or more windows 16w. The cover 18 includes a plurality of lenses 18L that are in optical communication with respective windows 16w in the earbud housing 16. These lenses 18L are configured to focus light 111 passing through a respective window 16w towards a particular region of the ear of a subject, and to help collect scattered light 110 and direct the scattered light 110 into the earbud housing 16 towards the light detector 26.

The earbud 30 of Fig. 6, via the locations of windows 16w, produces isotropic optical coupling, such that the light generated by the optical emitter 24 is roughly identical in all directions with respect to the earbud housing 16. The inspection light 111 generated by the optical emitter 24 passes isotropically into the light guiding region 19 through the windows 16w.

A benefit of light guiding earbud 30 of Fig. 6 is that manufacturing may not require alignment of the light-guiding region 19 with respect to the optical emitter 24 and detector 26. This may be in part because the optical energy density generated/detected by the optical emitter/detector may be the same, or relatively uniform, within the earbud housing 16 regardless of alignment of the light guide 18 with respect to the earbud housing 16 or regardless of alignment between the optical emitters/detectors and the earbud housing 16. This effect may be similar to that observed in "integrating spheres" commonly

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used for quantifying the lumen output of an optical source. Namely, because the light from the optical emitter 24 may be substantially isotropic and not focused, there is less restriction on the alignment of the earbud housing and earbud cover with respect to the optical emitter 24 or optical detector 26.

Referring now to Figs. 7A-7B, a light guiding earbud 30, according 26

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to some embodiments of the present invention, includes a base 50, and an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear E of a subject. The earbud housing 16 is formed from translucent material such that light can pass therethrough and forms a light-

- 5 guiding region 19. The earbud housing 16 is in acoustical communication with a speaker 22 and includes at least one aperture 34a through which sound from the speaker 22 can pass. A pair of optical detectors 26 are secured to the base 50 but are not surrounded by the earbud housing 16, as illustrated.
- The earbud housing 16 includes a flexible optical emitter 24 integrally formed within the housing 16, as illustrated. The optical emitter 24 is flexible such that it may be positioned around the earbud in an earbud formfactor. The flexible optical emitter 24 is configured to be conformable to an earbud shape and configuration. The flexible optical emitter 24 may be in, near, or part of the earbud housing 16, cladding material 21, or housing 16. In some embodiments, the flexible optical emitter 24 may be part of a flexible optical circuit inserted into an earbud 30.

The optical detectors 26 positioned outside the earbud housing 16 of the earbud 30 of Figs. 7A-7B collect scattered light from an ear originating from inspection light 111 generated by the flexible optical emitter 24. The flexible optical emitter 24 may be mounted to the earbud base 50 through one or more electrical connectors 24a. In some embodiments, these may be soldered, wired, or detachable connectors. In some embodiments, the flexible optical emitter 24 may include a flexible optical detector. In some embodiments, the flexible optical emitter 24 may be part of a flexible optical circuit comprising the form-factor of 24

- shown in Figs. 7A-7B, where the flexible optical circuit may include one or more optical emitters and detectors as well as amplifiers, microprocessors, wireless circuitry, and signal conditioning electronics. In some embodiments, the flexible optical circuit may include a complete chipset for physiological and environmental detection and for wired/wireless transfer of data to a remote
- 30 location. For example, these flexible devices may include an organic LED (OLED) and an organic optical detector circuit. This embodiment may be useful for generating a diffuse light beam towards the ear region and for detecting a diffuse optical scatter response from the ear region. In some embodiments, the emitter and detector on the flexible optical emitter 24 may be a traditional light-

emitting diode (LED) and photodetector (PD) integrated onto a flexible printed circuit board. In other embodiments, transparent solid state optical emitters, detectors, or switches may be used. For example, an electrically controlled liquid crystal matrix may be embedded within an earbud, covering the flexible optical emitter 24. This may allow localized control of light flow to selected areas from/to

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emitter 24. This may allow localized control of light flow to selected areas from/t the earbud going towards/away-from the ear. Additionally, this may allow localized control of light wavelength to selected areas.

Referring now to Figs. 8A-8B, a light guiding earbud 30, according to some embodiments of the present invention, includes a base 50, an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear of a subject, and a cover 18 that surrounds the earbud housing 16. The earbud housing 16 is in acoustical communication with a speaker 22 and includes at least one aperture 34a through which sound from the speaker 22 can pass. The cover 18 includes at least one aperture 34b through

which sound from the speaker 22 can pass. The cover 18 includes a cladding material 21 on the outer surface 18a thereof, except at end portion 18f, as illustrated. In the illustrated embodiment, there is no cladding material on the cover inner surface 18b. The housing 16 is in contact with the cover inner surface 18b and serves as a cladding layer to define the light guiding region 19.

The cover 18 with the illustrated cladding material 18c serves as a light guide that delivers light from the optical emitters 24 into an ear canal of a subject through cover end portion 18f. The cover 18 also collects light through end portion 18f and delivers the collected light to the optical detectors 26. Various configurations and arrangements of optical emitters and detectors may be utilized in accordance with embodiments of the present invention.

In the illustrated embodiment of Figs. 8A-8B, to reduce the risk of the inspection light 111 interrogating and saturating the optical detectors 26, a bottom portion 16a of the earbud housing 16 includes a light blocking region that blocks light from passing therethrough. This light blocking region 16a may be a black-painted region, an optically opaque region, or a material or structure that blocks light transmission. The illustrated configuration of the earbud housing 16 and bottom portion 16a may help confine inspection light 111 generated by the optical emitters 24 within the light-guiding layer (i.e., 19), guiding this light towards the ear region through the end portion 18f of the earbud 30.

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In some embodiments, as illustrated in Fig. 8C, the earbud housing 16 may be at least partially reflective to scatter light within the cavity defined by the earbud housing 16. In such case, the optical energy 111 may exit the earbud 30 through apertures 34a, 34b in the housing 16 and cover 18. An advantage of this configuration is that light 111 can be focused on a particular region of the ear where a particular physiological activity may be located. Also, this configuration may reduce unwanted optical signals from regions that may not be relevant to the physiological activity of interest. Although Fig. 8C shows the apertures 34a, 34b positioned toward the tympanic membrane, the apertures 34a, 34b may be located at one or more other locations about the earbud 30. For example, an aperture may be formed in the housing 16 and cover 18 at the location where the earbud 30 contacts the antitragus of an ear to allow optical energy 111 to interrogate the antitragus region of the ear.

In some embodiments, as illustrated in Fig. 8D, the earbud housing 15 16 may contain a material that reflects one or more wavelengths of light and transmits one or more wavelengths of light. For example, the earbud housing 16 may be comprised of a polymer, plastic, glass, composite material, or resin that reflects visible wavelengths and transmits IR wavelengths. Exemplary materials include color absorbing materials, such as organic dyes, found in photographic

film. Alternatively, the earbud housing 16 may include an optical filter region, such as a Bragg filter or other optical filter layer deposited on one or more sides of the housing region. If an optical detector 26' is configured to measure visible wavelengths only, then the optical energy detected by optical detector 26' may consist primarily of optical energy scattered from the earbud housing 16, and the optical energy detected by the optical detectors 26 may consist of optical energy scattered from the earbud housing 16, and the optical energy detected by the optical detectors 26 may consist of optical energy scattered from the ear region. This configuration may be useful because the signal from the optical detector 26' may represent motion noise which may be removed from the signal derived from the optical detectors 26, which may contain physiological information and motion noise.

Referring now to Figs. 9A-9B, a light guiding earbud 30, according to some embodiments of the present invention, includes a base 50, an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear of a subject, and a cover 18 surrounding the earbud housing 16. The earbud housing 16 is in acoustical communication with a

speaker 22 and includes at least one aperture 34a through which sound from the speaker 22 can pass. The cover 18 includes at least one aperture 34b through which sound from the speaker 22 can pass. A pair of optical emitters 24 are secured to the base 50 and are surrounded by the earbud housing 16, as

5 illustrated. An optical detector 26 is secured to the base 50 and is not surrounded by the earbud housing 16, as illustrated. The cover 18 serves as a light guide that delivers light from the optical emitters 24 into an ear canal of a subject.

The light-guiding region 19 of the cover 18 is designed to diffuse light and/or to generate luminescence. In this embodiment, the light-guiding region 19 includes at least one optical scatter or luminescence region. The optical scatter or luminescence region may be located anywhere within the earbud in the optical path of the optical emitters 24, but preferably within or about the cladding layer itself. When inspection light 111 generated by the

- optical emitters 24 is scattered or by an optical scatter region, this light may form a more diffuse optical beam 111a that is more uniform across the earbud 30 than the inspection light 111 generated by the optical emitters 24. This diffused beam, having an intensity distribution being less sensitive to motion of the ear, may be useful in alleviating motion artifacts in the scattered light coming from the ear,
- such that the scattered light coming from the ear, measured by the optical detector 26, is more indicative of blood flow changes within blood vessels and less indicative of mouth movements and body motion. The optical scatter region within the light-guiding region 19 may be at least partially comprised of impurities or morphological differences within the light-guiding region. An example of such
- ²⁵ impurities may include point defects, volume defects, native defects, metallics, polymers, microspheres, phosphors, luminescent particles, air pockets, particles, particulate matter, and the like. An example of morphological differences may include density variations, roughness, air pockets, stoichiometry variations, and the like. As a specific example, the light-guiding region 19 may comprise a
- transparent material, such as glass, a polymer, or silicone, and a luminescent impurity, such as a phosphor or luminescent polymer or molecule, may be integrated within the light-guiding region. This configuration may generate luminescence within the light-guiding region 19 in response to optical excitation from the optical emitters 24. In other embodiments, nanoscale fluctuations or

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impurities may be used to diffuse or manipulate light through the earbud. Examples of nanoscale fluctuations or impurities may include quantum dots, rods, wires, doughnuts, or the like.

Fig. 9C illustrates an exemplary homogeneous distribution of
luminescent particles 44, such as phosphors, embedded within the earbud cover
18, according to some embodiments of the present invention. Figs. 9D-9E
illustrate an exemplary distribution of luminescent particles 44, such as
phosphors, where the particles are distributed near one or more surfaces of the
earbud cover 18, according to some embodiments of the present invention.

In another embodiment, an optical scatter or luminescent region may be at least partially located in a separate region from the light-guiding region 19, such as a coating, that may be in physical contact with the light-guiding region 19.

In another embodiment, the optical scatter region or luminescent region may include multiple layers of light-guiding material having at least one dissimilar optical property, such as a dissimilar index of refraction, transparency, reflectivity, or the like. In another embodiment, the optical scatter region may include one or more patterned regions having at least one dissimilar optical property.

In another embodiment, the optical scatter or luminescent region may be distributed at select locations throughout the earbud.

Fig. 10 illustrates relevant anatomy of a human ear E. Blood vessels are located across the ear, but it has been discovered that photoplethysmography (PPG) signals are the strongest near the antitragus,
tragus, lobule, and portions of the acoustic meatus, and the ear canal. The antitragus is a particularly attractive location for photoplethysmography because a strong PPG signal can be derived with minimal motion artifacts associated with running and mouth motion.

Referring now to Figs. 11A-11B, a light guiding earbud 30, according to some embodiments of the present invention, includes a base 50, an earbud housing 16 extending outwardly from the base 50 that is configured to be positioned within an ear of a subject, and a cover 18 surrounding the earbud housing 16. The earbud housing 16 is in acoustical communication with a speaker 22 and includes at least one aperture 34a through which sound from the

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speaker 22 can pass. The cover 18 includes at least one aperture 34b through which sound from the speaker 22 can pass. The cover 18 serves as a light guide for directing light into an ear of a subject and defines a light-guiding region 19. The illustrated earbud 30 is configured to focus light towards the antitragus of the

ear of a human. In the illustrated embodiment, there is no cladding material on the outer surface 18a or inner surface 18b of the cover 18. Air serves as a cladding layer at the outer surface 18a and the housing 16 serves as a cladding layer at the inner surface 18b. Air may serve as a sufficient cladding layer due to the index of refraction difference between air and the light guiding layer. Namely, the index of refraction of the light-guiding layer 19 may be more than that of air.

A sensor module 70 is located near the earbud periphery, as illustrated. This sensor module 70 is shown in more detail in Figs. 12a-12B, and is described below. Three benefits of locating the sensor module 70 near the periphery of the light-guiding earbud 30 are: 1) PPG signals near the antitragus

- are less corrupted by motion artifacts than are PPG signals in other bloodvessel-rich regions of the ear; 2) the sensor module 70 may be designed somewhat independently of the earbud 30, liberating earbud comfort maximization from PPG signal maximization; and 3) because design constraints may be liberated, sensors need not be located in the acoustic cavity (i.e., within
- the earbud housing 16), allowing sound to pass through the acoustic orifices 34a, 34b with minimal interference. In this embodiment, it may be beneficial to incorporate lenses within the cover 18, similar to the lenses 18L of Fig. 6. It may be beneficial to extend the light-guiding region 19 of the cover 18 near the location where the earbud 30 rests near the antitragus. This light-guide
- extension 19a serves as an additional light-coupling region and may improve optical coupling from the light-guiding region 19 to an ear region and/or improve optical coupling from an ear region to the light-guiding region 19, including the antitragus and portions of the acoustic meatus. This is because this extended light-guiding region 19a may provide skin contact between the light guiding layer
- 19 and the skin, providing better optomechanical stability and optical coupling. In this embodiment, light may couple into the extended light-guiding region 19a, from an optical emitter 24, and into the ear region. Similarly, light may couple from the ear region, into the extended light-guiding region 19a, and to the optical detector 26. This extended light-guiding region 19a may appear as a bulb or lens

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near the bottom of the earbud cover 18.

Figs. 12A-12B illustrate respective opposite sides of a sensor module 70 that may be located near the periphery of an earbud 30, for example as illustrated in Figs. 11A-11B, according to some embodiments of the present invention. Sensor module 70 may include a number of electronic components capable of converting various forms of energy into an electrical signal and digitizing the signal. For example, the sensor module 70 may include lightemitting diodes, optical sensors, accelerometers, capacitive sensors, inertial sensors, mechanical sensors, electromagnetic sensors, thermal sensors, nuclear radiation sensors, biological sensors, and the like. In some embodiments, the optical emitters of this invention may be a combination of side emitting, edge

optical emitters of this invention may be a combination of side-emitting, edgeemitting, or surface-emitting light-emitting diodes (LEDs) or laser diodes (LDs).

In the illustrated embodiment of Figs. 12A-12B, the sensor module 70 includes two sets of optical emitters 24a, 24b. The first set of optical emitters 24a may be side-emitters (or edge-emitters) that are located at the top of the module 70 and direct light towards the earbud tip (e.g., cover end portion 18f, Fig. 8A) and towards the acoustic meatus and/or ear canal of the ear. The second set of optical emitters 24b may be located near the middle of the module 70 and may direct light in a beam that is largely perpendicular to that of the sideemitters 24a. In this particular embodiment, a single optical emitter 24b is shown mounted on a circuit board 70c such that this optical emitter 24b directs light towards the antitragus, which is located largely perpendicular to the acoustic meatus.

The optical energy generated by these optical emitters 24a, 24b may be scattered by blood vessels in the ear. This scattered light may be at least partially captured by the optical detectors 26. This light may be digitized by an optical detector 26 itself or with other circuitry on the sensor module circuit board 70c. The light-guiding design of the aforementioned light-guiding earbuds 30 may direct light towards each of these detectors 26. For example, this may be accomplished via the light-guiding earbud 30, wherein a lens (e.g., 18L, Fig. 6) facilitates inspection light coupling from the optical emitters 24 into the ear region and facilitates scattered light coupling to the optical detectors 26 from the ear region. Additional sensor components 27a, 27b may be used to measure an orthogonal energy component, facilitate sensor analysis, and thus help generate

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physiological assessments. For example, sensor components 27a, 27b may be thermal sensors for measuring the temperature of the inner ear (using the thermal sensors 27a facing the ear region) with respect to the outer ear (using the thermal sensor 27b facing away from the ear region). By subtracting the two

measured digitized temperatures from these two sensors 27a, 27b, an indication of heat flow from the ear can be generated. This temperature differential may be mathematically related to metabolic rate. For example, this temperature differential may be directly proportional metabolic rate. These temperature sensors may include thermistors, thermopiles, thermocouples, solid state
 sensors, or the like. They may be designed to measure thermal conduction,

convection, radiation, or a combination of these temperature components.

The earbud-facing side (Fig. 12B) of the sensor module 70 may include sensors that do not need to be located on the antitragus-facing side of the sensor module. For example, one or more inertial sensors 27c may be located on the earbud-facing side (Fig. 12B) of the sensor module 70. In a particular embodiment, the inertial sensor 27c may be a 3-axis accelerometer, and because this sensor does not need to optically couple with the ear region, a better use of sensor real estate may be to locate this sensor on the earbudfacing side of the sensor module 70. Additional optical emitters 24a, 24b may be

- located on the earbud-facing side to facilitate an optical noise reference. Namely, as the person wearing the earbud module 30 moves around, the interrogation light generated by the optical emitters 24a, 24b may be scattered off the earbud and be detected by optical detectors 27d. This scattered light intensity, phase, and/or frequency due to body motion may be proportional to the motion-related
- component of the scattered light intensity from the ear region. The motionrelated component is the component due to the physical motion of the ear and not the component related to blood flow. Thus, the optical scatter signal collected by the detectors 27d may provide a suitable noise reference for an adaptive filter to remove motion artifacts from the scattered light from the ear region,
- 30 generating an output signal that is primarily related to blood flow (which may be the desired signal). In the same token, the scattered light reaching the optical detectors 27d may be used to generate a measure of activity. The intensity, phase, and frequency of this scattered light may be related to physical activity. Sinusoidal variations of the heart rate waveform may be counted digitally, by

optical wavelengths.

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identifying and counting crests and peaks in the waveform, to generate an effective step count. Embodiments of the present invention, however, are not limited to the illustrated location of components in the sensor module 70. Various types and orientations of components may be utilized without limitation.

Fig. 19 illustrates the optical interaction between the sensor module 70 of Figs. 12A-12B and the skin of a subject. The sensor module 70 is shown in a reflective pulse oximetry setup 80 where reflected wavelengths 110 are measured, as opposed to measuring transmitted wavelengths. The optical emitter and optical detector wavelengths for pulse oximetry and

photoplethysmography may include ultraviolet, visible, and infrared wavelengths.
 In the illustrated embodiment, an optical source-detector assembly 71 is
 integrated into sensor module 70 to generate optical wavelengths 111 and
 monitor the resulting scattered optical energy 110. The optical source-detector
 assembly 71 contains one or more optical sources emitting one or more optical
 wavelengths, as well as one or more optical detectors detecting one or more

The epidermis 90, dermis 91, and subcutaneous 92 layers of skin tissue are shown in Fig. 19 for reference. The scattered optical energy 110 may be modulated in intensity by changes in blood flow in the blood vessels, changes in physical motion of the body, respiration, heart rate, and other physiological changes. In some cases, the scattered optical energy may be luminescent energy from the skin, blood, blood analytes, drugs, or other materials in the body.

As previously described, the optical scatter signal collected by the detectors 27d may provide a suitable noise reference for an adaptive filter to remove motion artifacts from the scattered light from the ear region, generating an output signal that is primarily related to blood flow (which may be the desired signal). This is because light detected by these detectors would come from light that has not been scattered by a physiological region but rather light that has been scattered from a region of the associated earpiece that may move along with the ear. Thus, the scattered light reaching the optical detectors 27d may be used to generate a measure of activity.

Fig. 13 illustrates the basic configuration of an adaptive noise cancellation scheme 200 for extracting a physiological signal from noise. The

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two types of sensor inputs are represented by the terms "Channel A" and "Channel B". Channel A refers to inputs from sensors that collect physiological information plus noise information, and Channel B refers to inputs from sensors that collect primarily (or substantially) noise information. Channel B information is

- passed through an electronic filter 203 whose properties are updated adaptively and dynamically. The filter 203 properties are updated to minimize the difference between Channel A and the post-processed Channel B, denoted as B[^]. In this way, noise is removed from Channel A and Channel C contains predominantly physiological information from which parameters such as blood flow, heart rate,
- 10 blood analyte levels, breathing rate or volume, blood oxygen levels, and the like may be calculated. It is important to note that the Channel A information can still be useful despite the presence of noise, and the noise information may still be utilized for the computation of relevant parameters. For instance, the residual noise information in Channel A may be extracted by a parameter estimator 201

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and the output in Channel D may be one or more activity assessments or the like. Similarly, the raw noise channel, Channel B, may be post-processed by a parameter estimator 205 to extract activity assessments for Channel E. Activity assessments may include exertion, activity level, distance traveled, speed, step count, pace, limb motion, poise, performance of an activity, mastication rate, intensity, or volume, and the like. The noise cancellation scheme 200 may be integrated into the firmware of a microprocessor or the like.

Although the embodiment of Fig. 13 for cancelling motion noise has been presented for an earbud configuration, this does not limit the invention to earbuds. An element of the adaptive noise cancellation scheme 200 for cancelling motion noise with an optical noise source may be that the optical detectors (such as 27d) are configured such that they do not receive scattered light from a physiological region while the detectors are simultaneously receiving scattered light from a region that is moving in synchronization with the physiological region. Even the slightest physiological signal existing in the optical

noise reference of Channel B may prevent the adaptive filter from working properly such that the physiological signal may inadvertently be removed altogether by the filter 203. Furthermore, although the noise source Channel B is described as an optical noise source, other forms of energy may be used in this invention. Namely, any inertial sensor input may constitute the input for Channel

B. More specifically, a sensor for measuring changes in capacitance along the earbud with respect to the ear may provide an inertial noise reference without also measuring physiological information. Similarly, an accelerometer may provide an inertial noise reference without also measuring physiological

- information. An inductive sensor may also provide an inertial noise reference without also measuring physiological information. For each noise source, a defining element may be that the noise source may be configured to measure physical motion only (or mostly) and not physiological information (such as blood flow, blood oxygen, blood pressure, and the like). The utility of an optical noise
- source is that because the optical signal Channel A and the optical noise Channel B have the same linearity response, the adaptive filter scheme 200 may be more effective than the case where the signal and noise channels operate via different forms of sensed energy. For example, the response linearity characteristics of an accelerometer sensor in response to inertial changes may not be the same as the response linearity characteristics of an optical sensor.

The adaptive noise cancellation scheme 200 for cancelling motion noise with an optical source (specifically an infrared LED) has been demonstrated in the laboratory, with a human wearing a light-guiding earbud while resting, jogging, and running over a treadmill, and various data summaries 300a-300d are presented in Figs. 14A-14D. The data was recorded by a chip and memory card embedded in an earbud 30, having electrical connectivity with the sensor module 70 within the earbud 30. The raw signal in low motion 300a and raw signal in high motion 300c may be equated with the signal of Channel A of Fig. 13. Similarly, the "blocked channel" in low motion 300b and "blocked channel" in high motion 300d may be equated with Channel B of Fig. 13. In this experiment, the "block channel" consisted of an optical noise source, wherein the optical noise source included an optical emitter-detector module such as 70

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covered by black tape to prevent light from the emitter (such as 24a and 24b) from reaching the ear. Thus, scatter from the black tape was scattered back to the emitter-detector module through the silicone and sensed as motion noise by the detectors (such as 26 and 27d). In a sense, for this configuration, the optical channel to the human ear is "blocked", hence the term "blocked channel". The

emitter-detector module was covered with a layer of clear silicone that was then

of Figs. 12A-12B. However, instead of being exposed to the ear, the optical

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purpose of the clear silicone below the black tape was to: 1) provide an unobstructed, transparent optical scatter path for the IR light and 2) provide motion sensitivity similar to that of human skin, as silicone has a vibration response that may be similar to that of human skin.

Figs. 14A-14D show that the raw signal in low motion 300a indicates blood flow pulses which can be translated as heart rate. This is because each blood flow pulse represents one heart beat. However, the raw signal in high motion 300c indicates measured mostly physical activity. This is evident by the fact that the high motion signal 300c matches the corresponding blocked channel signal 300d, and the blocked channel in high motion 300d was found to have a substantially identical beat profile with the measured steps/second of the runner.

Fig. 15 is a graph of processed physiological signal data from a headset having one or more light-guiding earbuds 30, according to some
embodiments of the present invention. Specifically, Fig. 15 shows the analysis results 400 of the data summaries 300a-300d presented in Figs. 14A-14D of blood flow (y-axis) versus time (x-axis) following two data processing sequences to extract heart rate. One sequence incorporated the adaptive filtering process 200 of Fig. 13 as well as a beat finder processing step. The second sequence

incorporated the beat finder processing step without the adaptive filtering process 200 of Fig. 13. The beat finder process counts each heart beat by monitoring the peaks and valleys of each pulse, such as the peaks and valleys shown in the graph 300a of Fig. 14A. As shown in Fig. 15, the beat finder was effective at measuring heart rate during resting and jogging. However, the beat finder alone was not sufficient for monitoring heart rate during running. This is because at high motion, the signal 300d (Fig. 14D) associated with footsteps is

strong enough to overwhelm the smaller signal associated with heart rate, and so the motion-related contribution dominated the overall signal 300d. Thus, the beat finder cannot distinguish heart beats from footsteps. By employing the

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adaptive filtering process 200 (Fig. 13) before the beat finder process, the footstep motion artifacts during running were effectively removed from the sensor signal (Channel A of Fig. 13) such that the output signal (Channel C of Fig. 13) contained blood flow information with minimal motion artifacts. Thus, this output signal contained blood flow pulse signals that could then be "counted" by

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the beat finder to generate an accurate heart rate assessment.

In the specific analysis results 400 of Fig. 15, a beat finder was employed, following the adaptive filter process 200 of Fig. 13, to count heart beats. A more general method 500 for extracting physiological information from sensor signals in the midst of noise is illustrated in Fig. 16. The first block (block 510) represents the pre-adaptive signal conditioning stage. This process may utilize a combination of filters to remove frequency bands outside the range of interest. For example, a combination of band-pass, low-pass, and/or high-pass filters (such as digital filters) may be used. The second block (block 520)

represents an adaptive filtering process such as the process 200 described in Fig. 13. This process may utilize the pre-conditioned signals from block 510 as inputs into an adaptive filter that reduces motion or environmental artifacts and noise in the primary data channel. The third block (block 530) represents the parameter extraction stage. This process may utilize a combination of signal

conditioning filters in addition to peak finding (such as beat finding) algorithms to calculate properties of interest (e.g. heart rate, blood flow, heart rate variability, respiration rate, blood gas/analyte level, and the like). The method 500 of Fig. 16 may be encoded in the firmware of a microprocessor (or similar electronics) to facilitate real-time processing of physiological information.

Fig. 17 is a block diagram that illustrates sensor signals being processed into a digital data string including activity data and physiological data using the method 500 of Fig. 16, according to some embodiments of the present invention. Optical detectors 26 and optical emitters 24 may include digitizing circuitry such that they may be connected serially to a digital bus 600. Data from the detectors 26 may be processed by a processor/multiplexer 602 to generate multiple data outputs 604 in a serial format at the output 606 of the processor 602. In some embodiments, the processing methods may involve one or more of the methods described in Figs. 13, 14A-14D, 15 and 16. The multiple data outputs 604 may be generated by the processor/multiplexer 602 by time division multiplexing or the like. The processor 602 may execute one or more serial

multiplexing or the like. The processor 602 may execute one or more serial processing methods, wherein the outputs of a plurality of processing steps may provide information that is fed into the multiplexed data outputs 604.

The multiplexed data outputs 604 may be a serial data string of activity and physiological information 700 (Fig. 18) parsed out specifically such

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that an application-specific interface (API) can utilize the data as required for a particular application. The applications may use this data to generate high-level assessments, such as overall fitness or overall health. Furthermore, the individual data elements of the data string can be used to facilitate better

- assessments of other individual data elements of the data string. As a specific 5 example, the Blood Flow data string may contain information on the first and second derivatives of each blood pulse. This information may be processed from a PPG signal by running the adaptively filtered heart rate signal through a slopefinder algorithm (such as a differentiator circuit). In another example, the filtered PPG signal may be run through an integration circuit to estimate blood volume 10
 - over each blood pulse. This information may then be used to assess blood pressure and blood oxygen levels more accurately than a direct measurement of blood pressure or blood oxygen levels.
- In some embodiments of the invention, new methods of generating physiological assessment algorithms are enabled. These new methods may be 15 achieved by measuring each data output of the data output string 604 in real time while an earbud user is also wearing one or more benchmark sensors. Principal component analysis, multiple linear regression, or other statistical or machine learning techniques can then be used to generate statistical
- relationships between the data outputs 604 and high level assessments 20 measured simultaneously by the benchmark sensors. These benchmark sensors may measure aerobic fitness level, VO₂max, blood pressure, blood analyte levels, and the like. The relationships between the earbud sensor and benchmark sensor readings may be translated as algorithms embedded in the
- earbud, wherein each algorithm generates at least one assessment for the 25 earbud user. In some cases, Bland-Altman plots of the earbud-derived assessment value versus the benchmark value may be used to judge the effectiveness of the algorithm, and this information may then feedback into improving the said earbud-derived assessment algorithm. Examples of these
- assessments may include aerobic fitness level, VO₂max, blood pressure, blood 30 analyte levels (such as blood glucose, oxygen, carbon monoxide, etc.), and the like.

In some cases, it may be important to remove the effects of ambient optical noise from the physiological signal of a light-guiding earbud 30.

In such cases, one or more optical detectors 26 may be configured to measure outdoor or ambient lighting, and this information may be fed back into the processor 602 (Fig. 17) to extract external optical noise from the physiological signal. For example, some optical detectors may be configured to measure light

- from the ear, whereas others may be configured to measure light from the ambient environment, such as sunlight, room light, headlights, or the like. This may be achieved by directing the optical detectors towards and away from the ear, respectively. In a specific example, the ambient light reaching the optical detectors 26 may generate an undesirable sinusoidal response on an optical
- detector that is configured to measure light from the ear. This undesirable sinusoidal noise response may be generated as an earbud user moves their head from side to side while running. Thus, Channel A of the adaptive filter 200 (Fig. 13) may include physiological information plus undesired ambient optical noise information. To remove this noise from the final output Channel C, the
- output of the optical detector configured to measure ambient optical noise may be an input (Channel B of Fig. 13) into the adaptive filter 200. In this way, ambient noise from Channel A may be removed to generate a mostly physiological signal in Channel C.
- The optical detectors 26 and emitters 24 may be of multiple 20 wavelengths, with the goal of providing specialized physiological information for each wavelength. Referring to Fig. 19, for example, violet or UV light may be used to measure motion-related aspects of the ear, as violet and UV light may not penetrate greatly through the skin of the ear. Green, red, and IR wavelengths may have deeper penetration and provide information on the blood vessels and 25 blood analyte levels. Blue wavelengths may be particularly useful for gauging changes in the size of the blood vessels.

Embodiments of the present invention may be more generally applied to non-optical or mix-optical configurations. For example, one or more of the detectors 26 and emitters 24 may be mechanical, acoustical, electrical,

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gravimetric, or nuclear detectors and emitters, all providing physiological information to the processor 602 (Fig. 17). For example, an accelerometer or capacitor may be used as a detector 26 for the noise reference (Channel B) input of an adaptive filter running in real-time on the processor 602.

Referring to Fig. 20, a chipset 800 for use in light-guiding earbuds 41

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30, according to some embodiments of the present invention, may include optical emitters, optical detectors, mechanical, acoustical, electrical, gravimetric, nuclear detectors, additional sensors, signal processing, power regulation, digital control, and input/output lines. The chipset 800 may include firmware for signal

- extraction and for generating physiological assessments from information derived from the sensors and noise sources. One benefit of the chipset configuration is that the chipset 800 may be fully or partially integrated and hence compact and scalable to a wide range of products. To be integrated with a light-guiding earbud 30, the chipset 800 may be aligned such that the sensor
- region has an exposed window to a subject's ear. For example, the chipset 800 may be attached to the earbud base 50 or an earbud sensor module 70 and aligned line-of-sight through an acoustic orifice of an earbud and/or through a transparent end portion of an earbud 30 (e.g., through end portion 18f of the earbud 30 of Figs. 8A-8B or 18w of Figs. 4 & 5).
- A specific embodiment of a chipset 800 for a stereo headset,
 according to some embodiments of the present invention, is illustrated in Fig. 21.
 This stereo chipset 800 may be integrated into an electronic module that may be
 attached to a printed circuit board. In another configuration, this stereo chipset
 800 may be integrated into 3 modules, wherein the right and left earbud sensors
 comprise two separate modules, embedded in right and left earbuds
 respectively, and wherein the remaining circuit elements comprise the main

According to other embodiments of the present invention, monitoring devices with light-guiding regions may be configured to be attached to earlobes, fingers, toes, other digits, etc. For example, Figs. 22A-22B illustrate a monitoring device 70 that is configured to fit over a finger F, for example, as a finger ring, according to some embodiments of the present invention. The illustrated monitoring device 70 includes a generally circular band capable of encircling a finger F of a subject, with a cylindrical outer body portion 72 and a generally cylindrical inner body portion 74 secured together in concentric relationship. The outer body portion may be formed from virtually any type of material and may have an ornamental configuration. In some embodiments, the outer body portion 72 may include a flex circuit containing various electronic

components, such as a microprocessor, D/A converter, power source, power 42

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regulator, and the like. However, in some embodiments, the outer body portion 72 may not be required and the circular band of the monitoring device 70 includes only the inner body portion 74 secured to the base 50 (described below).

A base 50 is secured to the inner and outer body portions 74, 72 of the illustrated embodiment and may be similar to the base 50 described above with respect to Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B. The base 50 provides support for one or more sensors. In the illustrated embodiment, the base 50 supports an optical emitter 24, an optical detector 26, and an optical noise detector 26'.

The inner body portion 74 includes light transmissive material similar to that of the cover 18 described above with respect to Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B. In some embodiments, the inner body portion 74 is formed from a soft, resilient material, such as silicone, which deforms when a finger of a subject is inserted therethrough. However, various types of light transmissive materials may be utilized, without limitation.

A layer of cladding material 21 is applied to (or near) the outer surface 74a of the inner body portion 74 and a layer of cladding material 21 is applied to (or near) the inner surface 74b of the inner body portion 74, as illustrated, to define a light-guiding region 19. As such, the inner body portion 74 serves as a light guide that delivers light from the optical emitter 24 to the finger F of a subject at one or more predetermined locations and that collects light from the finger F and delivers the collected light to the optical detectors 26, 26'. In some embodiments, the cladding material 21 may be embedded within the inner body portion 74 adjacent to the outer surface 74a and inner surface 74b. In some embodiments, the outer body portion 72 may serve as a cladding layer adjacent to the inner body portion outer surface 74a.

In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger F. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of a finger F and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows 74w may include optical

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filters to selectively pass one or more optical wavelengths and reflect and/or absorb other optical wavelengths.

In the illustrated embodiment, the light-guiding region 19 includes light blocking members 80 that isolate light emitter 24 and light detector 26 from each other. In some embodiments, only a single light blocking member 80 may be utilized. For example, a single light blocking member 80 may be positioned between the light emitter 24 and light detector 26. By adding an additional blocking member 80, as illustrated, the only light reaching the optical detector 26 may be light passing through at least one portion of the finger.

In some embodiments, multiple light emitters 24 may be utilized. For example, light emitters of different wavelengths may be utilized. In some embodiments, multiple light detectors may be utilized that are configured to measure light at different wavelengths (e.g., light detectors 26 and 26' may be configured to measure light at different wavelengths). In this way, either optical

- detector may be configured to measure light mostly due to motion (such as finger motion) or to measure light mostly due to physiological processes and motion. For example, if the windows 74w incorporate IR-pass filters, visible light will not pass through the windows 74w and the light will be scattered to the photodetectors 26 and 26'. Or, if the two illustrated blocking regions 80 are in
- place, and if photodetector 26' is configured to measure only visible light and photodetector 26 is configured to measure only IR light, then only the photodetector 26' will detect scattered visible light. As this visible scattered light cannot reach the finger, the scatter intensity measured by optical detector 26' may be indicative of motion and not physiological activity.

Referring now to Fig. 23, a monitoring device 70', according to some embodiments of the present invention, may be configured to be attached to a body of a subject as a bandage or "band-aid". The illustrated monitoring device 70' includes an outer layer or body portion 72 and an inner layer or body portion 74 secured together, as illustrated. The outer body portion may be

formed from virtually any type of material and may have an ornamental configuration. In some embodiments, the outer body portion 72 may include a flex circuit containing various electronic components, such as a microprocessor, D/A converter, power source, power regulator, and the like. However, in some embodiments, the outer body portion 72 may not be required and the monitoring

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device 70' includes only the inner body portion 74 secured to the base 50 (described below).

A base 50 is secured to the inner and outer body portions 74, 72 and may be similar to the base 50 described above with respect to Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B. The base 50 provides support for one or more sensors. In the illustrated embodiment, the base 50 supports an optical emitter 24, an optical detector 26, and an optical noise detector 26'.

The inner body portion 74 is formed of light transmissive material similar to that of the cover 18 described above with respect to Figs. 3, 4A-4D, 5, 6, 7A-7B, 8A-8D, 9A-9B, and 11A-11B. In some embodiments, the inner body portion 74 is formed from a soft, resilient material, such as silicone, which deforms when the device is attached to the body of a subject. However, various types of light transmissive materials may be utilized, without limitation.

A layer of cladding material 21 is applied to (or near) the outer surface 74a of the inner body portion 74 and a layer of cladding material 21 is applied to (or near) the inner surface 74b of the inner body portion 74, as illustrated, to define a light-guiding region 19. As such, the inner body portion 74 serves as a light guide that delivers light from the optical emitter 24 to the body of a subject at one or more predetermined locations and that collects light from the body and delivers the collected light to the optical detectors 26, 26'. In some embodiments, the cladding material 21 may be embedded within the inner body portion 74 adjacent to the outer surface 74a and inner surface 74b. In some embodiments, the outer body portion 72 may serve as a cladding layer adjacent to the inner body portion outer surface 74a.

In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the body of a subject. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of the body of a subject and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows 74w may include optical filters to selectively pass one or more optical wavelengths and reflect and/or absorb other optical wavelengths.

In the illustrated embodiment, the light-guiding region 19 includes a 45

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light blocking member 80 that isolates light emitter 24 and light detector 26 from each other. In some embodiments, multiple light emitters 24 may be utilized. For example, light emitters of different wavelengths may be utilized. In some embodiments, multiple light detectors may be utilized that are configured to measure light at different wavelengths (e.g., light detectors 26 and 26' may be

configured to measure light at different wavelengths).

The illustrated monitoring device 70' may be removably attached to the body of a subject via adhesive on one or more portions of the device 70'. In some embodiments, adhesive may be on the inner body portion 74. In

embodiments where the outer body portion is utilized, the adhesive may be on the outer body portion 74. In some embodiments, the illustrated device 70' may be removably attached to the body of a subject via tape or other known devices.

The foregoing is illustrative of the present invention and is not to be construed as limiting thereof. Although a few exemplary embodiments of this

invention have been described, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the claims. The invention is defined by the

20 following claims, with equivalents of the claims to be included therein.

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THAT WHICH IS CLAIMED IS:

1. A monitoring device, comprising:

a band capable of encircling a portion of the body of a subject; and an optical emitter and an optical detector attached to the band; wherein the band comprises light transmissive material in optical communication with the optical emitter and optical detector that is configured to deliver light from the optical emitter to one or more locations of the body of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector.

2. The monitoring device of Claim 1, wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit.

15 3. The monitoring device of Claim 1, wherein the band comprises first and second concentric body portions.

 The monitoring device of Claim 1, wherein the band comprises a lens region in optical communication with the optical emitter that
 focuses light emitted by the optical emitter and/or that collects light reflected from the body.

5. The monitoring device of Claim 1, wherein the band comprises a phosphor-containing region in optical communication with the light transmissive material, wherein the phosphor-containing region receives light emitted by the optical emitter and converts at least a portion of the received light to light having a different wavelength from the received light.

6. The monitoring device of Claim 1, wherein the band has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

7. The monitoring device of Claim 6, further comprising a signal processor, and wherein at least a portion of light reflected by the light 47

reflection material and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector.

5 8. The monitoring device of Claim 1, further comprising a signal processor configured to receive and process signals produced by the optical detector.

9. The monitoring device of Claim 1, further comprising a
 transmitter configured to transmit signals processed by the signal processor to a remote device.

The monitoring device of Claim 1, further comprising light
 blocking material positioned between the optical emitter and detector such that
 the optical emitter and detector are not in direct optical communication with each other.

11. The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength.

12. The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

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13. The monitoring device of Claim 12, further comprising a signal processor, and wherein at least a portion of light blocked by the optical filter and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector.

14. The monitoring device of Claim 1, further comprising one or more of the following: an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear

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radiation sensor, a biological sensor.

15. The monitoring device of Claim 1, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processer is configured to process signals from the at least one accelerometer and optical detector to attenuate motion noise from optical signals produced by the optical detector.

16. The monitoring device of Claim 1, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processor is configured to process signals from the at least one accelerometer and optical detector to measure or detect physiological information.

17. The monitoring device of Claim 16, wherein the physiological information comprises at least one of the following: heart rate, pulse rate, breathing rate, blood flow, VO₂, VO_{2max}, heartbeat signatures, cardio-pulmonary health, organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood
 metabolite levels or ratios, blood pH level, physical and/or psychological stress levels and/or stress level indicators, drug dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body

associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye muscle movement, blood volume, inhaled and/or exhaled breath volume, physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body,

strain, neurological functioning, brain activity, brain waves, blood pressure, cranial pressure, hydration level, auscultatory information, auscultatory signals

anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice

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characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, and stem cell regeneration response.

18. A monitoring device configured to be attached to the body of a subject, comprising:

a base comprising an optical emitter and an optical detector; and light transmissive material attached to the base, wherein the light transmissive material is in optical communication with the optical emitter and optical detector, and configured to deliver light from the optical emitter to one or more portions of the body of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector, and wherein at least one portion of the monitoring device comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

19. The monitoring device of Claim 18, further comprising an outer body portion attached to the base and to the light transmissive material, wherein the outer body portion comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

20. The monitoring device of Claim 18, wherein the light transmissive material comprises a lens region in optical communication with the optical emitter that focuses light emitted by the optical emitter and/or that collects light reflected from the body.

21. The monitoring device of Claim 18, wherein the light transmissive material comprises a phosphor-containing region that receives light emitted by the optical emitter and converts at least a portion of the received light to light having at least one different wavelength from the received light.

22. The monitoring device of Claim 18, wherein the light 50

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transmissive material has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

5 23. The monitoring device of Claim 18, wherein at least a portion of the reflected light detected by at least one optical detector is processed as a motion noise reference for attenuating motion noise from the optical detector signal.

10 24. The monitoring device of Claim 18, wherein the monitoring device further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

25. The monitoring device of Claim 24, wherein at least a
 portion of the light not passed by the optical filter detected by at least one optical detector is processed as a motion noise reference for attenuating motion noise from the optical detector signal.

26. The monitoring device of Claim 18, wherein the base
 comprises a signal processor configured to receive and process signals
 produced by the optical detector.

27. The monitoring device of Claim 18, wherein the base
 comprises a transmitter configured to transmit signals processed by the signal
 processor to a remote device.

28. The monitoring device of Claim 18, further comprising light blocking material positioned between the optical emitter and detector such that the optical emitter and detector are not in direct optical communication with each other.

29. The monitoring device of Claim 18, further comprising one or more of the following: an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a

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nuclear radiation sensor, a biological sensor.

30. The monitoring device of Claim 18, further comprising at least one accelerometer and at least one signal processor, wherein the at least
one signal processer is configured to process signals from the at least one accelerometer and optical detector to attenuate motion noise from optical signals produced by the optical detector.

31. The monitoring device of Claim 18, further comprising at
 least one accelerometer and at least one signal processor, wherein the at least one signal processor is configured to process signals from the at least one accelerometer and optical detector to measure or detect physiological information.

32. The monitoring device of Claim 31, wherein the physiological information comprises at least one of the following: heart rate, pulse rate, breathing rate, blood flow, VO₂, VO_{2max}, heartbeat signatures, cardio-pulmonary health, organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood
metabolite levels or ratios, blood pH level, physical and/or psychological stress level and/or stress level indicators, drug dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body strain, neurological functioning, brain activity, brain waves, blood pressure,

associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye muscle movement, blood volume, inhaled and/or exhaled breath volume, physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body,

cranial pressure, hydration level, auscultatory information, auscultatory signals

anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice

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characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, and stem cell regeneration response.

ABSTRACT OF THE DISCLOSURE

A monitoring device includes a band capable of encircling a portion of the body of a subject, and an optical emitter and detector attached to the band. The band includes comprises light transmissive material in optical communication with the optical emitter and optical detector and is configured to deliver light from the optical emitter to one or more locations of the body of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector. The monitoring device may include a signal processor configured to receive and process signals produced by the optical detector, a transmitter configured to transmit signals processed by the signal processor to a remote device, and/or an optical filter.

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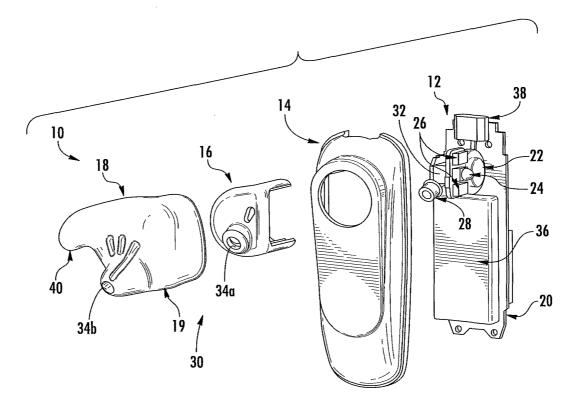
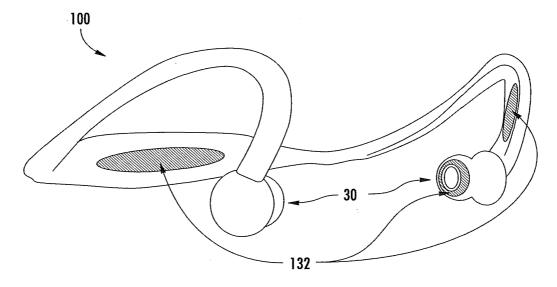


FIG. 1





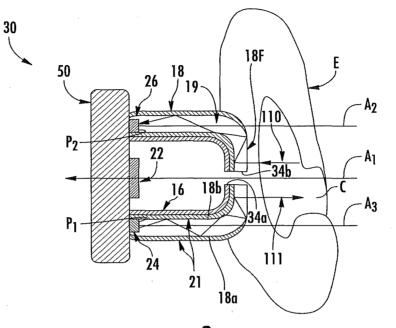
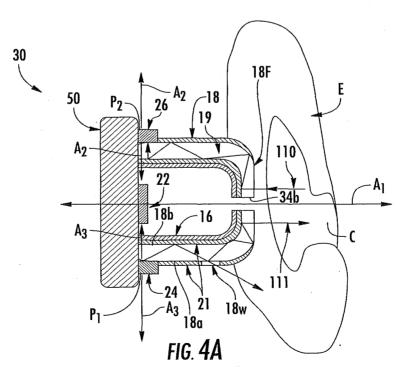
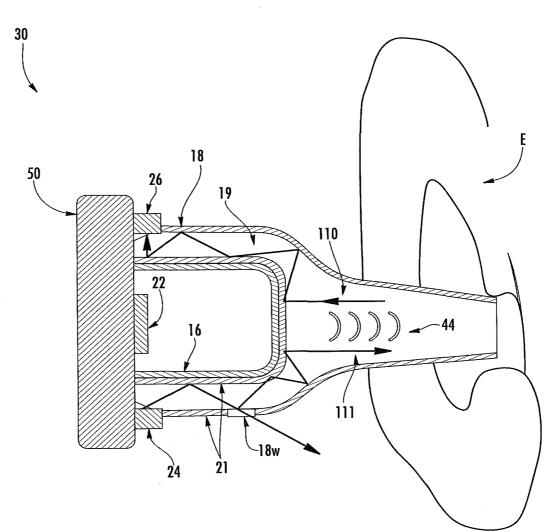


FIG. **3**

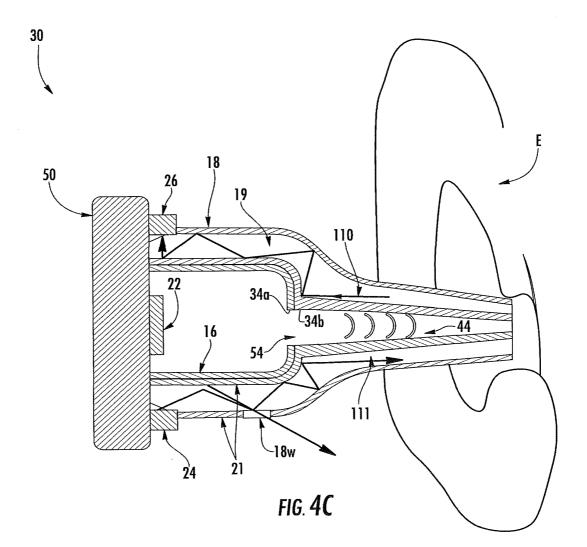


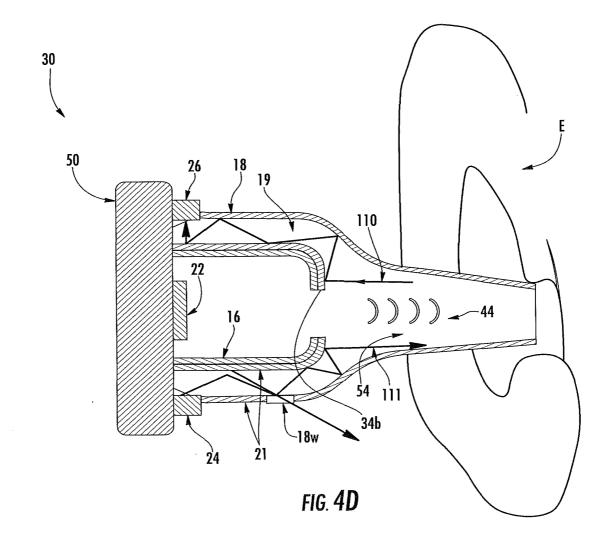
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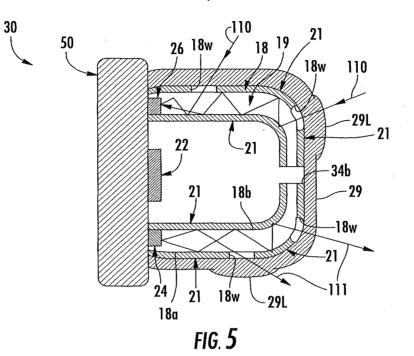
FITBIT, Ex. 1002

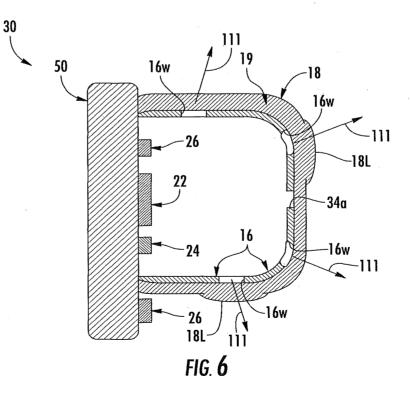




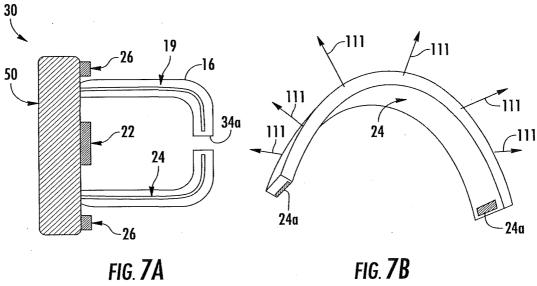




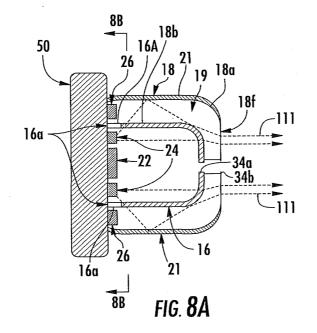


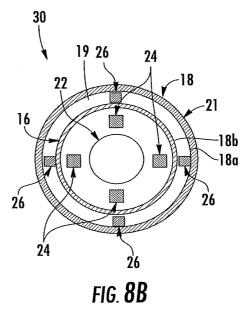


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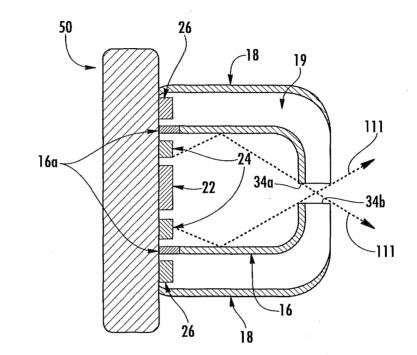
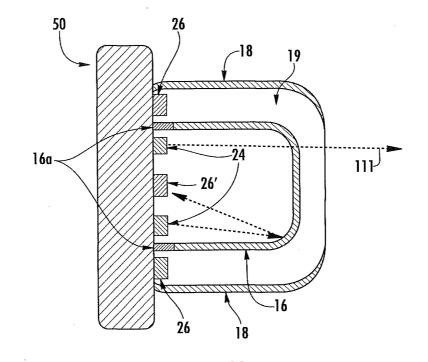
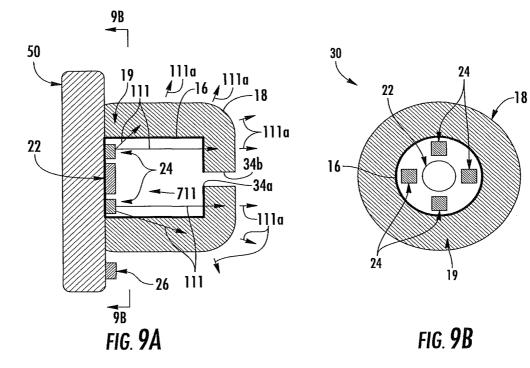
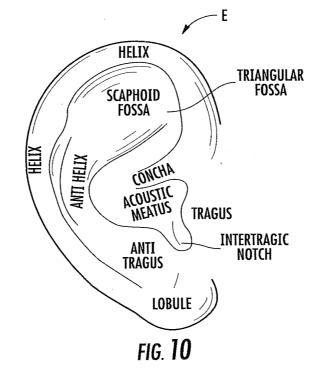


FIG. **8C**









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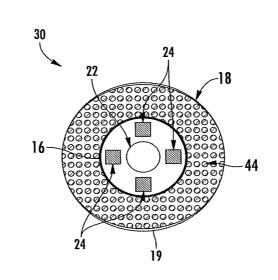
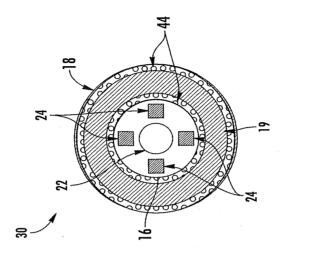
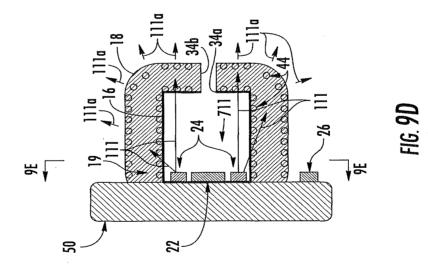


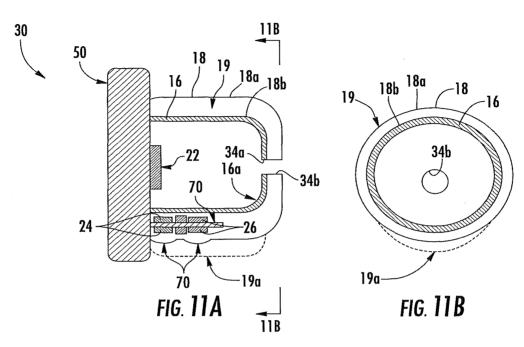
FIG. **9C**

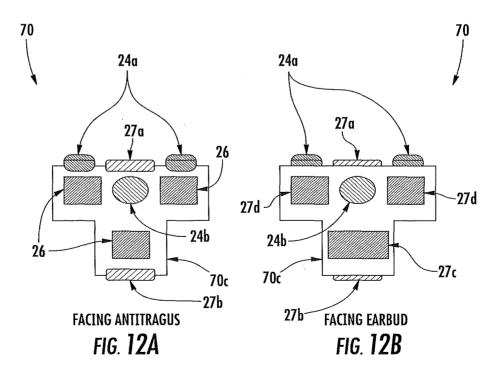


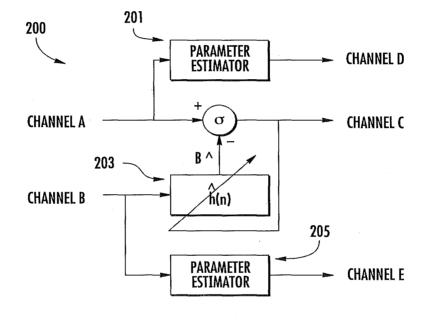




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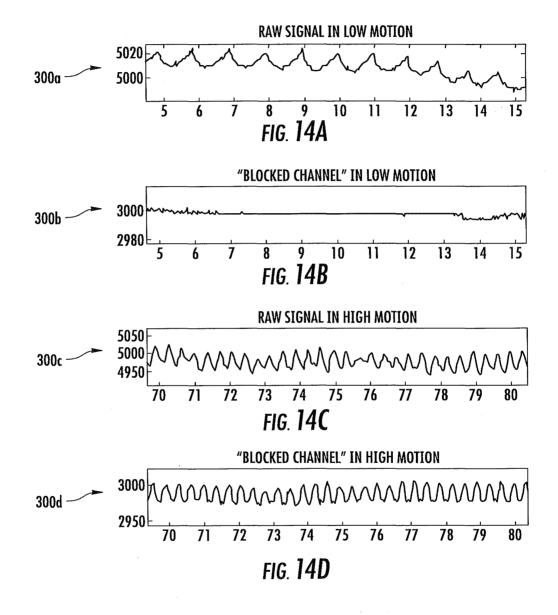








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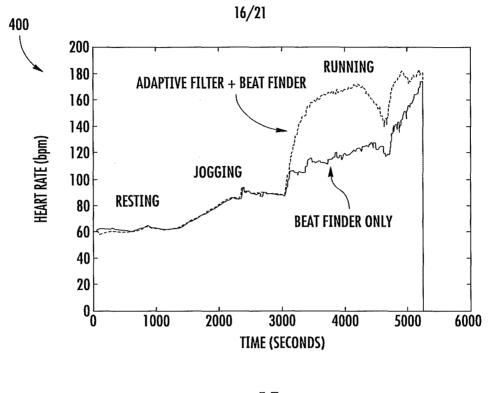
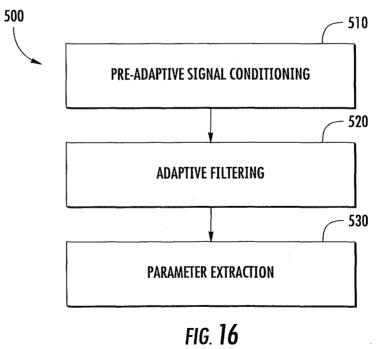
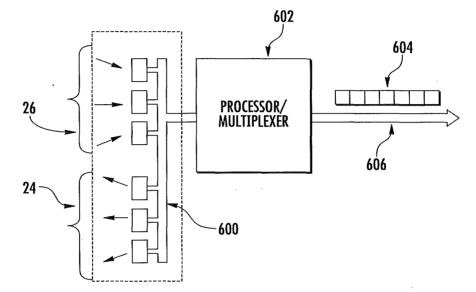


FIG. 15









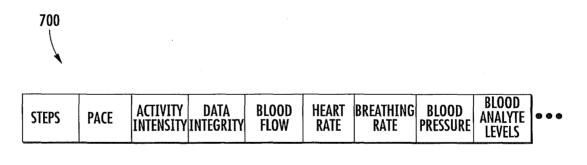
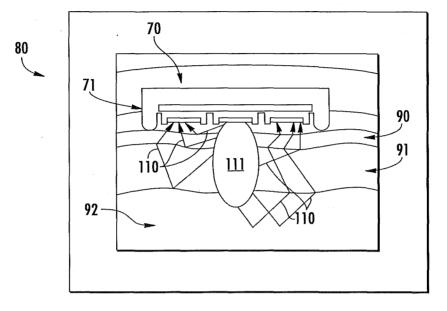


FIG. **18**

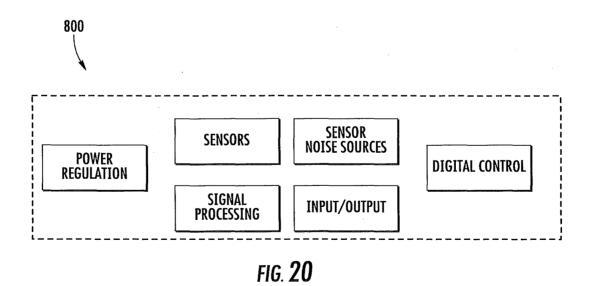
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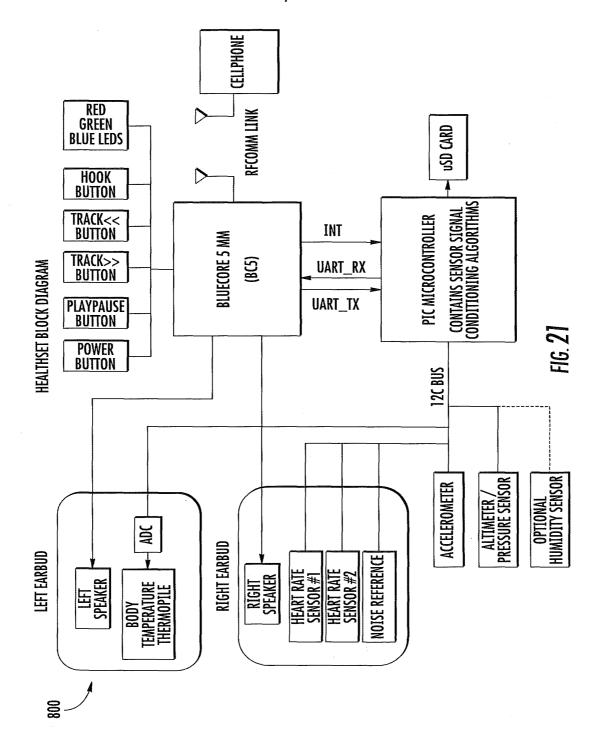
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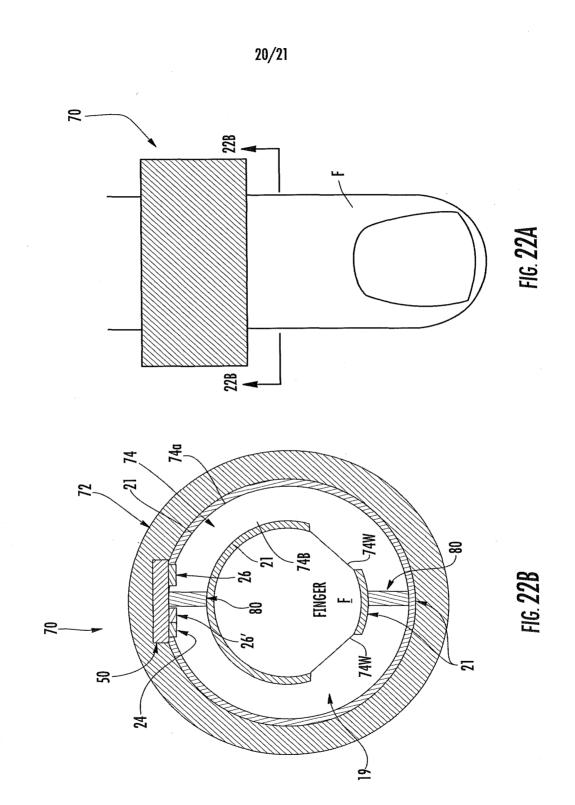












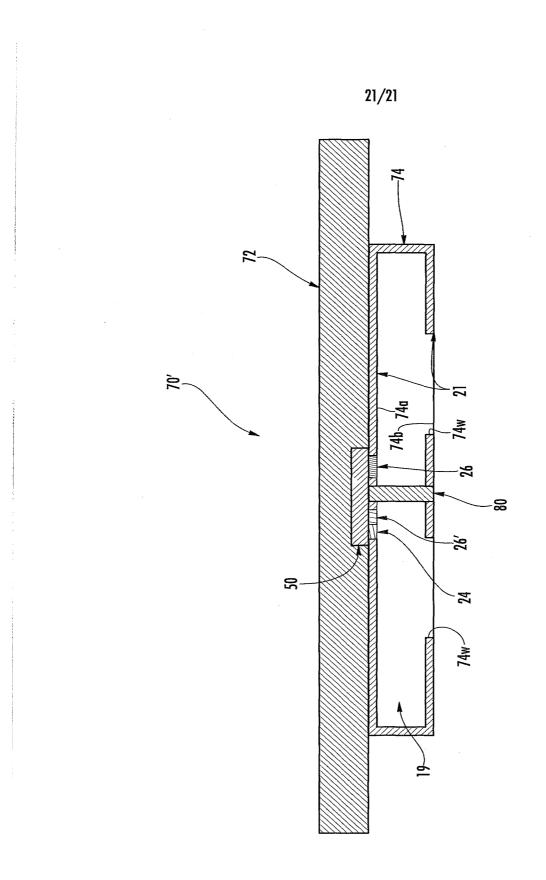


FIG. 23

Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.

Serial No.: To Be Assigned Filed: Concurrently Herewith

For: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Date: February 19, 2014

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT COVER LETTER

Sir:

Attached is an Information Disclosure Statement listing of documents previously of record in parent Application No. <u>12/691,388</u>, filed <u>January 21, 2010</u>. As the benefit of this application is claimed under 35 U.S.C. § 120, no copies need to be furnished in accordance with 37 C.F.R. § 1.98(d); however, copies will be furnished on request.

- In accordance with 37 CFR 1.97(b), the information disclosure statement is being filed:
 - (1) within three months of the filing date of a national application other than a continued prosecution application under (1.53)
 - □ (2) within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - \square (3) before the mailing of a first Office Action on the merits; or
 - (4) before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

In accordance with **37 CFR 1.97(c)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(b) above, but before the mailing date of any of a final action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by <u>one</u> of the following:

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

□ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; <u>or</u>

(2) The fee set forth in 1.17(p);

In accordance with **37 CFR 1.97(d)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(c) above, but on or before payment of the issue fee, and is accompanied by **both** of the following:

In re: LeBoeuf et al. Application No.: To Be Assigned Filing Date: Concurrently Herewith Page 2 of 2

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; <u>or</u>

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; and

(2) The fee set forth in §1.17(p);

In accordance with **37 CFR 1.97(g)**, the information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with **37 CFR 1.97(h)**, the information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b).

The Director is hereby authorized to charge the fee specified in 37 C.F.R. § 1.17(p), and any fee deficiency or credit any overpayment, to Deposit Account No. 50-0220; <u>or</u>

No fee is believed due. However, the Director is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

Book I

Needham J. Boddie, II Registration No. 40,519 Attorney for Applicant

Customer Number 20792

Myers Bigel Sibley & Sajovec, P.A. P.O. Box 37428, Raleigh, NC 27627 919-854-1400 919-854-1401 (Fax)

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on **February 19, 2014.**

Name: Gwen R. Bailey

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INFORMATION DISCLOSURE			RE	Filing Date	Concurrently Herewith		
STATE	STATEMENT BY APPLICANT			First Named Inventor	Steven Francis LeBeouf		
				Art Unit			
(use as	many sheets	as necessary)	Examiner Name			
Sheet	A1	of	A2	Attorney Docket Number	9653-7TSCT		

				U.S. PATENT DOC			
Examiner Initials*	No		Document Number Imber-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Whe Relevant Passages or Releva Figures Appear	
	1.	US-	2013/0131519	05-2013	LeBoeuf et al.		
	2.	US-	2012/0197093	08-2012	LeBoeuf et al.		
	3.	US-	2011/0105869 A1	05-2011	Wilson et al.		
	4.	US-	2009/0287067 A1	11-2009	Dorogusker et al.		
	5.	US-	2009/0270698 A1	10-2009	Shioi et al.		
	6.	US-	2009/0105556 A1	04-2009	Fricke et al.		
	7.	US-	2009/0054752 A1	02-2009	Jonnalagadda et al.		
	8.	US-	2009/0030350 A1	01-29-2009	Yang et al.		
	9.	US-	2008/0177162 A1	07-2008	Bae et al.		
	10	US-	2008/0165017 A1	07-2008	Schwartz		
	11	US-	2008/0096726 A1	04-2008	Riley et al.		
	12	US-	2008/0076972 A1	03-2008	Dorogusker et al.		
	13	US-	2006/0009685	01-12-2006	Finarov et al.		
	14	US-	2005/0228299	10-13-2005	Banet		
	15	US-	2005/0209516	09-22-2005	Fraden		
	16	US-	2005/0177034 A1	08-2005	Beaumont		
	17	US-	8,512,242 B2	08-2013	LeBoeuf et al.		
	18	US-	8,251,903 B2	08-2012	LeBoeuf et al.		
	19	US-	8,055,319 B2	11-2011	Oh et al.		
	20	US-	7,209,775 B2	04-2007	Bae et al.		
	21.		6,859,658 B1	02-2005	Krug		
	22	US-	6,808,473 B2	10-2004	Hisano et al.		
	23.	US-	6,371,925 B1	04-2002	Imai et al.		
	24.	US-	6,783,501 B2	08-31-2001	Takahashi et al.		
	25	US-	6,080,110 A	06-2000	Thorgersen		
	26	US-	6,078,829 A	06-2000	Uchida et al.		

	FOREIGN PATENT DOCUMENTS									
Examiner Initials*	Cite No.	Foreign Patent Document Country Code, Number, Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т				
	27	WO 2013/038296 A1	03-21-2013	KONINKLIJKE PHILIPS ELECTRONICS N.V.						
	28	JP 2007-185348	07-26-2007	OLYMPUS CORP						
	29	JP 2001-025462	01-30-2001	DENSO CORP						

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Sheet	Á2	of	A2	Attorney Docket Number	9653-7TSCT		

30	JP 2000-116611	04-25-2000	KOWA SPINNING CO LTD; KOWA CO	
31	JP 9-299342	11-25-1997	IKYO KK	
32	JP 9-253062	09-30-1997	IKYO KK	
33	JP 7-241279	09-19-1995	NIPPON KODEN CORP	

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	34.	FITRAINER "The Only Trainer You Need"; <u>http://itami.com;</u> Downloaded 2/26/2010; ©2008 FiTriainer™; 2 pages				

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First Named Inver	ntor	Steven Francis LeBoeuf						
Title		WEARABLE LIGHT-GUIDING BANDS A PHYSIOLOGICAL MONITORING	AND PATCHE	SFOR				
Art Unit								
Examiner Name			a na manakadan kina Sini M <u>anagang an</u> a dan					
Attorney Docket N	lumber	9653-7TSCT						
SIGNATU	RE of A	oplicant or Patent Practitioner						
Signature		ngBodd: "	Date (Optional)	February 19, 2014				
Name	Needha	m J. Boddie, II	Registration Number	40,519				
Title (if Applicant is a juristic entity)			L					
Applicant Name (if Applicant is a j		uristic entity)						
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Name	Todd Ackman
Title	Vice President of Finance, Valencell, Inc.
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Filing Date:						
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING					
First Named Inventor/Applicant Name:	Ste	ven Francis LeBoeu	ıf			
Filer:	Needham J. Boddie/Gwen Bailey					
Attorney Docket Number:	965	3-7TSCT				
Filed as Large Entity						
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:	1					
Utility application filing		1011	1	280	280	
Utility Search Fee		1111	1	600	600	
Utility Examination Fee		1311	1	720	720	
Pages:	1					
Claims:						
Claims in Excess of 20		1202	12	80	960	
Miscellaneous-Filing:						
Petition:						

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
	Tot	al in USD	(\$)	2560

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EFS ID:	18245028
Application Number:	14184364
International Application Number:	
Confirmation Number:	1023
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Gwen Bailey
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT
Receipt Date:	19-FEB-2014
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1	Transmittal of New Application	9653-7TSCT_ApplicationTrans	143976	no	1	
		mittal.pdf	86efa7c18c14708c7048c5f97f89931a4c09c 5a4	110		
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2	Application Data Sheet	9653-7TSCT_ADS.pdf	833009	no	7	
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	Specificat	ion	1	46		
	Claims	47	53			
	Abstrac	t	54	54		
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4	Drawings-only black and white line	9653-7TSCT_Drawings.pdf	1310589	no	21	
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5		9653-7TSCT_IDS.pdf	420471	yes	4	
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7	Fee Worksheet (SB06)	fee-info.pdf	37033	no	2
Information:					1
Warnings:					
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6	Power of Attorney	9653-7TSCT_POA.pdf	331403	no	2

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

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

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New International Application Filed with the USPTO as a Receiving Office

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

United States Patent and Trademark Office Sales Receipt for Accounting Date: 03/07/2014

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf, *et al.* Serial No.: 14/184,364 Filed: February 19, 2014

For: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Date: February 21, 2014

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

PRELIMINARY AMENDMENT

Please enter the following Preliminary Amendment before examining the present application. Applicants provide the present Amendment pursuant to the rules stated in revised 37 C.F.R. 1.121 that became effective on July 30, 2003. In re: LeBoeuf, *et al.* Page 2 of 9

In the Specification:

On page 1, please replace the paragraph beginning at line 10 with the following:

-- FIELD OF THE INVENTION

The present invention relates generally to headsets physiological monitoring and, more particularly, to headset earbuds physiological monitoring devices. --

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In the Claims:

(Original) A monitoring device, comprising:
 a band capable of encircling a portion of the body of a subject; and
 an optical emitter and an optical detector attached to the band;

wherein the band comprises light transmissive material in optical communication with the optical emitter and optical detector that is configured to deliver light from the optical emitter to one or more locations of the body of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector.

2. (Original) The monitoring device of Claim 1, wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit.

3. (Original) The monitoring device of Claim 1, wherein the band comprises first and second concentric body portions.

4. (Original) The monitoring device of Claim 1, wherein the band comprises a lens region in optical communication with the optical emitter that focuses light emitted by the optical emitter and/or that collects light reflected from the body.

5. (Original) The monitoring device of Claim 1, wherein the band comprises a phosphor-containing region in optical communication with the light transmissive material, wherein the phosphor-containing region receives light emitted by the optical emitter and converts at least a portion of the received light to light having a different wavelength from the received light.

6. (Original) The monitoring device of Claim 1, wherein the band has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

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7. (Original) The monitoring device of Claim 6, further comprising a signal processor, and wherein at least a portion of light reflected by the light reflection material and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector.

8. (Original) The monitoring device of Claim 1, further comprising a signal processor configured to receive and process signals produced by the optical detector.

9. (Original) The monitoring device of Claim 1, further comprising a transmitter configured to transmit signals processed by the signal processor to a remote device.

10. (Original) The monitoring device of Claim 1, further comprising light blocking material positioned between the optical emitter and detector such that the optical emitter and detector are not in direct optical communication with each other.

11. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength.

12. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

13. (Original) The monitoring device of Claim 12, further comprising a signal processor, and wherein at least a portion of light blocked by the optical filter and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector.

14. (Original) The monitoring device of Claim 1, further comprising one or more of the following: an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor.

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15. (Original) The monitoring device of Claim 1, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processer is configured to process signals from the at least one accelerometer and optical detector to attenuate motion noise from optical signals produced by the optical detector.

16. (Original) The monitoring device of Claim 1, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processor is configured to process signals from the at least one accelerometer and optical detector to measure or detect physiological information.

17. (Original) The monitoring device of Claim 16, wherein the physiological information comprises at least one of the following: heart rate, pulse rate, breathing rate, blood flow, VO₂, VO_{2max}, heartbeat signatures, cardio-pulmonary health, organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood metabolite levels or ratios, blood pH level, physical and/or psychological stress levels and/or stress level indicators, drug dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body strain, neurological functioning, brain activity, brain waves, blood pressure, cranial pressure, hydration level, auscultatory information, auscultatory signals associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye muscle movement, blood volume, inhaled and/or exhaled breath volume, physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body, anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones,

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internal body sounds, digestive system functioning, cellular regeneration response, healing response, and stem cell regeneration response.

18. (Original) A monitoring device configured to be attached to the body of a subject, comprising:

a base comprising an optical emitter and an optical detector; and

light transmissive material attached to the base, wherein the light transmissive material is in optical communication with the optical emitter and optical detector, and configured to deliver light from the optical emitter to one or more portions of the body of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector, and wherein at least one portion of the monitoring device comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

19. (Original) The monitoring device of Claim 18, further comprising an outer body portion attached to the base and to the light transmissive material, wherein the outer body portion comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

20. (Original) The monitoring device of Claim 18, wherein the light transmissive material comprises a lens region in optical communication with the optical emitter that focuses light emitted by the optical emitter and/or that collects light reflected from the body.

21. (Original) The monitoring device of Claim 18, wherein the light transmissive material comprises a phosphor-containing region that receives light emitted by the optical emitter and converts at least a portion of the received light to light having at least one different wavelength from the received light.

22. (Original) The monitoring device of Claim 18, wherein the light transmissive material has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

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23. (Original) The monitoring device of Claim 18, wherein at least a portion of the reflected light detected by at least one optical detector is processed as a motion noise reference for attenuating motion noise from the optical detector signal.

24. (Original) The monitoring device of Claim 18, wherein the monitoring device further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

25. (Original) The monitoring device of Claim 24, wherein at least a portion of the light not passed by the optical filter detected by at least one optical detector is processed as a motion noise reference for attenuating motion noise from the optical detector signal.

26. (Original) The monitoring device of Claim 18, wherein the base comprises a signal processor configured to receive and process signals produced by the optical detector.

27. (Original) The monitoring device of Claim 18, wherein the base comprises a transmitter configured to transmit signals processed by the signal processor to a remote device.

28. (Original) The monitoring device of Claim 18, further comprising light blocking material positioned between the optical emitter and detector such that the optical emitter and detector are not in direct optical communication with each other.

29. (Original) The monitoring device of Claim 18, further comprising one or more of the following: an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor.

30. (Original) The monitoring device of Claim 18, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processer is configured to process signals from the at least one accelerometer and optical detector to attenuate motion noise from optical signals produced by the optical detector.

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31. (Original) The monitoring device of Claim 18, further comprising at least one accelerometer and at least one signal processor, wherein the at least one signal processor is configured to process signals from the at least one accelerometer and optical detector to measure or detect physiological information.

32. (Original) The monitoring device of Claim 31, wherein the physiological information comprises at least one of the following: heart rate, pulse rate, breathing rate, blood flow, VO₂, VO_{2max}, heartbeat signatures, cardio-pulmonary health, organ health, metabolism, electrolyte type and/or concentration, physical activity, caloric intake, caloric metabolism, blood metabolite levels or ratios, blood pH level, physical and/or psychological stress levels and/or stress level indicators, drug dosage and/or dosimetry, physiological drug reactions, drug chemistry, biochemistry, position and/or balance, body strain, neurological functioning, brain activity, brain waves, blood pressure, cranial pressure, hydration level, auscultatory information, auscultatory signals associated with pregnancy, physiological response to infection, skin and/or core body temperature, eye muscle movement, blood volume, inhaled and/or exhaled breath volume, physical exertion, exhaled breath physical and/or chemical composition, the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body, anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, and stem cell regeneration response.

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REMARKS

Applicants have amended the Field of the Invention section of the application, as indicated above, to more accurately describe the field of the claimed invention. Entry of this Preliminary Amendment, examination of the application, and allowance of the application, including Claims 1-32 are respectfully requested.

Respectfully submitted,

ng Bodeli I

Needham J. Boddie, II Attorney for Applicants Registration No. 40,519

USPTO Customer No. 20792 Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, North Carolina 27627 Telephone: (919) 854-1400 Facsimile: (919) 854-1401 Doc. No. 1473300

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R.K Gwen R. Bailey

Electronic Acl	knowledgement Receipt
EFS ID:	18267696
Application Number:	14184364
International Application Number:	
Confirmation Number:	1023
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Gwen Bailey
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT
Receipt Date:	21-FEB-2014
Filing Date:	
Time Stamp:	15:18:49
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted wi	th Payment	no	no				
File Listin	g:						
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)		
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	Multipart Description/PDF files in .zip description						
	Document Description	Start	End				
	Preliminary Amendment	1	1				
	Specification	2	2				
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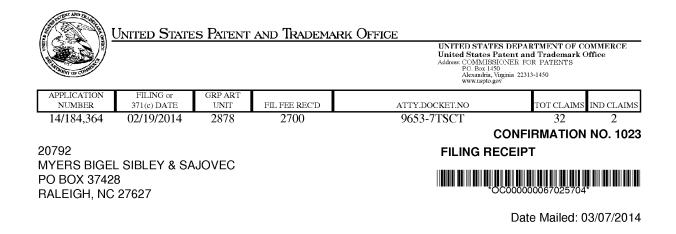
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	PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875								tion or Docket Num 4,364	ber
	APPLICATION AS FILED - PART I (Column 1) (Column 2) SMALL ENTITY						OR	OTHER SMALL		
	FOR	NUMBE	R FILED	NUMBE	R EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
	IC FEE FR 1.16(a), (b), or (c))	N	/A	N	I/A	N/A		1	N/A	280
SEA	RCH FEE FR 1.16(k), (i), or (m))		/A	N	J/A	N/A		1	N/A	600
EXA	MINATION FEE FR 1.16(o), (p), or (q))	N	/A	N	J/A	N/A		1	N/A	720
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		(Column 1) CLAIMS		(Column 2) HIGHEST	(Column 3)	SMALL	ENTITY	OR	OTHER SMALL	
NT A		REMAINING AFTER AMENDMENT		NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
MEI	Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
AM	Application Size Fe	e (37 CFR 1.16(s))			•					
	FIRST PRESENT	TION OF MULTIPL	E DEPEND	DENT CLAIM (37 C	FR 1.16(j))			OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
		(Column 1) CLAIMS		(Column 2) HIGHEST	(Column 3)		1	-		
NT B		AFTER AMENDMENT		NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
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AMENDMENT	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
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	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	
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Inventor(s)

Steven Francis LeBoeuf, Raleigh, NC;
Jesse Berkley Tucker, Knightdale, NC;
Michael Edward Aumer, Raleigh, NC;
Applicant(s)
Valencell, Inc., Raleigh, NC
Assignment For Published Patent Application
Valencell, Inc., Raleigh, NC
Power of Attorney: The patent practitioners associated with Customer Number 20792

Domestic Priority data as claimed by applicant

This application is a CON of $12/691,388\ 01/21/2010$ which claims benefit of $61/208,567\ 02/25/2009$ and claims benefit of $61/208,574\ 02/25/2009$ and claims benefit of $61/212,444\ 04/13/2009$ and claims benefit of $61/274,191\ 08/14/2009$

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <u>http://www.uspto.gov</u> 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.

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page 1 of 3

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/184,364**

Projected Publication Date: 06/19/2014

Non-Publication Request: No

Early Publication Request: No Title

WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Preliminary Class

250

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

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Date Mailed: 03/07/2014

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):
 Steven Francis LeBoeuf
 Lesse Berkley Typicar

Jesse Berkley Tucker Michael Edward Aumer

page 1 of 1

UNITED STATES PATENT AND TRADEMARK OFFICE United States Patent and Tradem Address. COMMISSIONER FOR PATEN P. Box 1430 Alexandra, Virginia 22313-1450 www.uspb.gov				
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE	
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	
			CONFIRMATION NO. 1023	
20792		POA ACCI	EPTANCE LETTER	
MYERS BIGEL SIBLEY &	SAJOVEC			
PO BOX 37428			CC000000067022970*	
RALEIGH, NC 27627		-(JC00000067022970"	

Date Mailed: 03/07/2014

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/19/2014.

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

/dnguyen/

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

page 1 of 1

				Complete if Known		
				Application Number	14/184,364	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	February 19, 2014			
		First Named Inventor	Steven Francis LeBoeuf			
		Art Unit	2878			
(use as i	many sheets	as necessary	<i>י</i>)	Examiner Name		
Sheet	B1	of	B1	Attorney Docket Number	9653-7TSCT	

				U.S. PATENT DOC	UMENTS	
Examiner Cite		Document Number		Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.	Nu	nber-Kind Code (if known)		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	1.	US-	2010/0217103 A1	08-26-2010	Abdul-Hafiz et al.	· · · · · · · · · · · · · · · · · · ·
	2.	US-	2004/0054291 A1	03-18-2004	Schultz et al.	
	3.	US-	2004/0034293 A1	02-19-2004	Kimball	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document Country Code, Number, Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т		
		Kilowity						

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	Т			
	4.	Notification of Transmittal of The International Search Report and The Written Opinion of the International Searching Authority, or the Declaration corresponding to International Application No. PCT/US2013/070271; Date of Mailing: February 26, 2014; International Search Report; Written Opinion of the International Searching Authority; 13 pages				

Examiner		Date			
Signature		Considered			
*EXAMINED: Initial if reference considered whether or not citation is in conformance with MDED 600. Draw line through citation if not					

*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.

PCT/US2013	/070271
101/004013	/0/04/1

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY	03-04-1	4 14:03 RCV	D			
To: MYERS BIGEL SIBLEY & SAJOVEC, P.A.	РСТ	COF				
P.O. BOX 37428 RALEIGH NC 27627 USA	NOTIFICATION OF TRANSM THE INTERNATIONAL SEARCH THE WRITTEN OPINION OF THE I SEARCHING AUTHORITY, OR THI	I REPORT AND NTERNATIONAL				
	(PCT Rule 44.1)					
	Date of mailing (day/month/year) 26 February 2014 (26.02	2.2014)				
Applicant's or agent's file reference 9653-71P-WO	FOR FURTHER ACTION See paragraph	s 1 and 4 below				
International application No. PCT/US2013/070271	International filing date (day/month/year) 15 November 2013 (15	.11.2013)				
Applicant VALENCELL, INC.						
 The applicant is hereby notified that the international s Authority have been established and are transmitted he Filing of amendments and statement under Article The applicant is entitled, if he so wishes, to amend the When? The time limit for filing such amendments i international search report. Where? Directly to the International Bureau of WI 1211 Geneva 20, Switzerland, Facsimile No For more detailed instructions, see PCT Applicant 	rewith. 19: claims of the international application (see Rule is normally two months from the date of transmi IPO, 34 chemin des Colombettes o.: +41 22 338 82 70	46): DO(ttal of the By	жетер 80 3/4			
 The applicant is hereby notified that no international s Article 17(2)(a) to that effect and the written opinion or 	earch report will be established and that the decla	aration under FC				
3. With regard to any protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.						
no decision has been made yet on the protest; the 4. Reminders		trensversation and a				
The applicant may submit comments on an informal basis Authority to the International Bureau. The International F Offices unless an international preliminary examination r expiration of 30 months from the priority date, these comm	Bureau will send a copy of such comments to report has been or is to be established. Follow	o all designated wing the				
Shortly after the expiration of 18 months from the priorid International Bureau. If the applicant wishes to avoid or p international application, or of the priority claim, must rea- technical preparations for international publication (Rules	ostpone publication, a notice of withdrawal ch the International Bureau before the comp	of the				
Within 19 months from the priority date, but only in resp preliminary examination must be filed if the applicant wis months from the priority date (in some Offices even later) priority date, perform the prescribed acts for entry into the In respect of other designated Offices, the time limit of 30 within 19months.	shes to postpone the entry into the national p); otherwise, the applicant must, within 20 n national phase before those designated Offic	bhase until 30 aonths from the ces.				
For details about the applicable time limits, Office by Of PCT Applicant's Guide, National Chapters.	fice, see www.wipo.int/pct/en/texts/time_lin	nits.html and the				
Name and mailing address of the ISA/KR International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Métropolitan City, 302-701,	Authorized officer COMMISSIONER					
Republic of Korea Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8754	FUSEBORS				
Earm $PCT/IS \lambda/220$ (July 2010)						

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* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for six months(expire date : **2014.08.27**) from the date of mailing of the international search report.

http://www.kipo.go.kr/en/ => PCT Services => PCT Services

ID : PCT international application number PW : **UPLA5Y5H**

Inquiries related to PCT International Search Report or Written Opinion prepared by KIPO as an International Searching Authority can be answered not only by KIPO but also through IPKC (Intellectual Property Korea Center), located in Vienna, VA, which functions as a PCT Help Desk for PCT applicants.

Homepage: http://www.ipkcenter.com

Email: ipkc@ipkcenter.com

Notes to Form PCT/ISA/220 (July 2010)

PCT/US2013/070271

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 9653-7IP-WO	FOR FURTHER ACTION as well a	see Form PCT/ISA/220 is, where applicable, item 5 below.					
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)					
PCT/US2013/070271	PCT/US2013/070271 15 November 2013 (15.11.2013) 14 December 2012 (14.12.2012)						
Applicant VALENCELL, INC.							
This International search report has been prep to Article 18. A copy is being transmitted to t This international search report consists of a t		y and is transmitted to the applicant according					
·	ppy of each prior art document cited in this rep	ort.					
	ternational search was carried out on the basi ion in the language in which it was filed	s of :					
a translation of the intern translation furnished for	national application into the purposes of international search (Rules 12.	, which is the language of a $3(a)$ and $23.1(b)$)					
	t has been established taking into account the r s Authority under Rule 91 (Rule 43.6 <i>bis</i> (a)).	rectification of an obvious mistake					
c. With regard to any nucleotide	and/or amino acid sequence disclosed in the	international application, see Box No. I.					
2. Certain claims were found ur	searchable (See Box No. II)						
3. Unity of invention is lacking ((See Box No. III)						
4. With regard to the title,		· · · · · · · · · · · ·					
the text is approved as submitte	ed by the applicant.						
the text has been established by	v this Authority to read as follows:						
	ed by the applicant. ccording to Rule 38.2, by this Authority as it a the date of mailing of this international search re						
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b. none of the figures is to be pub	lished with the abstract.						

Form PCT/ISA/210 (first sheet) (July 2009)

	INTERNATIONAL SEARCH REPORT		International application No. PCT/US2013/070271	
A. CL	ASSIFICATION OF SUBJECT MATTER			
H04R 1/1	0(2006.01)i			
According to	o International Patent Classification (IPC) or to both natio	nal classification and IPC		
B. FIE	ELDS SEARCHED	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	
	locumentation searched (classification system followed by ; A61B 5/1455; A61B 5/00	classification symbols)		
Korean util	tion searched other than minimum documentation to the e lity models and applications for utility models tility models and applications for utility models	xtent that such documents are	included in the fields searched	
	lata base consulted during the international search (name of SS(KIPO internal) & Keywords: PPG. emitter, detector, s		cable, search terms used)	
			; ;	
C. DOCI	UMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where app	propriate, of the relevant passa	nges Relevant to claim No.	
X	US 2005-0209516 A1 (JACOB FRADEN) 22 Septemb See paragraphs [0056]-[0061]; and figures 7,		1-19,21-32	
Y	See paragraphis (0000) (0001), and rightes 7,	10.	20	
Y	US 6078829 A (SHINJ1 UCHIDA et al.) 20 June See column 5, lines 29-42; and figure 2.	20		
A		US 2010-0217103 A1 (YASSIR ABDUL-HAFIZ et al.) 26 August 2010 See claims 1-2; paragraphs [0056]-[0064]; and figures 9A-9B, 16. US 2004-0034293 A1 (VICTOR E. KIMBALL) 19 February 2004 See claims 1-7; paragraphs [0047]-[0049]; and figures 5B, 8.		
A				
A	US 2004-0054291 A1 (CHRISTIAN SCHULZ et al.) See paragraphs [0036]-[0043]; and figures 4-		1-32	
			- 16 - L	
Furtl	her documents are listed in the continuation of Box C.	See patent fam	ily annex.	
 * Special categories of cited documents: * A " document defining the general state of the art which is not considered to be of particular relevance * "T" later document published after the international filing date or particular relevance; the claimed invention * "T" later document published after the international filing date or particular relevance; the claimed invention * "T" later document published after the international filing date or particular relevance; the claimed invention can considered novel or cannot be considered to involve an invertion can considered novel or cannot be considered to involve an invertion can considered novel or cannot be considered to involve an invertion can considered novel or particular relevance; the claimed invention can considered to involve an invertion can be ing obvious to a person skilled in the art * "P" document published prior to the international filing date but later than the priority date claimed 				
Date of the a	actual completion of the international search	Date of mailing of the inter		
	25 February 2014 (25.02.2014)	· · · · · · · · · · · · · · · · · · ·	y 2014 (26.02.2014)	
Name and r	mailing address of the ISA/KR International Application Division Korcan Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea	Authorized officer KIM, Sung Gon		
Facsimile N	No. +82-42-472-7140	Telephone No. +82-42-48	1-8746	

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No. PCT/US2013/070271

-Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005-0209516 A1	22/09/2005	None	
US 6078829 A	20/06/2000	None	
US 2010-0217103 A1	26/08/2010	US 8588880 B2 WO 2011-102846 A2	19/11/2013 25/08/2011
US 2004-0034293 A1	19/02/2004	AU 2003-262620 A1 EP 1545308 A1 JP 2005-535408 A US 6879850 B2 WO 2004-016170 A1	03/03/2004 29/06/2005 24/11/2005 12/04/2005 26/02/2004
US 2004-0054291 A1	18/03/2004	US 7341559 B2	11/03/2008

Form PCT/ISA/210 (patent family annex) (July 2009)

PCT/US2013/070271

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:			DAT	
MYERS BIGEL SIBLEY & SAJOVEC, P.A. P.O. BOX 37428 RALEIGH NC 27627 USA		PCI		
		WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)		
		Date of mailing (day/month/year)	26 February 2014 (26.02.2014)	
Applicant's or agent's file reference 9653-71P-WO		FOR FURTHER	ACTION See paragraph 2 below	
PCT/US2013/070271	International filing date (15 November 2013 (15.11.2013)	Priority date(<i>day/month/year</i>) 14 December 2012 (14.12.2012)	
International Patent Classification (IPC) o H04R 1/10(2006.01)i Applicant VALENCELL, INC,	r both national classificat	tion and IPC		
 Box No. IV Lack of unity o Box No. V Reasoned staten citations and exp Box No. VI Certain docume Box No. VII Certain defects Box No. VIII Certain observational FURTHER ACTION If a demand for international preliminar International Preliminary Examining A other than this one to be the IPEA and opinions of this International Searchin If this opinion is, as provided above, c 	nion ent of opinion with regard of invention nent under Rule 43bis.1(a oblanations supporting suc- onts cited in the international appli- tions on the international ary examination is made, Authority ("IPEA") except the chosen IPEA has not ag Authority will not be so considered to be a written appropriate, with amendin xpiration of 22 months fro	d to novelty, inventiv (i) with regard to not h statement ication application this opinion will be o to that this does not ap ified the Internationa o considered. opinion of the IPEA nents, before the expi	te step and industrial applicability ovelty, inventive step and industrial applicability considered to be a written opinion of the oply where the applicant chooses an Authority al Bureau under Rule 66.1 bis(b) that written , the applicant is invited to submit to the ration of 3 months from the date of mailing whichever expires later.	
Name and mailing address of the ISA/KR International Application Division Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic Facsimile No. +82-42-472-7140		tion of this opinion 2014 (25.02.2014)	Authorized officer KIM, Sung Gon Telephone No. +82-42-481-8746	

Form PCT/ISA/237 (cover sheet) (July 2011)

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International application No. PCT/US2013/070271

ox No. I Basis of thi						
. With regard to the la	inguage, this opinion h	as been establis	hed on the basis of :	•		•
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subsequent	ly to this Authority for	the purposes of	search.			
In addition, in t	he case that more than	one version or c	opy of a sequence list	ing has been filed or fu	rnished, the requ	iired
	the information in the site application as filed,		-	tical to that in the app	lication as filed o	or does
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Form PCT/ISA/237 (Box No. I)(July 2011)

International application No. PCT/US2013/070271

Box No. V Reasoned statement u citations and explanat		43bis.1(a)(i) with regard to novelty, invo rting such statement	entive step or industrial applicability;
1. Statement			
Novelty (N)	Claims	1-32	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-32	
Industrial applicability (IA)	Claims	1-32	YES
	Claims	NONE	NÖ

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2005-0209516 A1 (JACOB FRADEN) 22 September 2005 D2: US 6078829 A (SHINJI UCHIDA et al.) 20 June 2000

1. Novelty and Inventive Step

1,1 Claims [1-15]

1.1.1 Independent Claim [1]

D1, which is considered to be the closest prior art to the subject matter of claim [1], discloses a device for detecting photo-plethysmographic signals from a patient ear canal comprising; an ear plug (64) inserted into an ear canal (4) of ears (60) (see paragraph [0056] and figure 10); and a first LED (71) and light detector (73) (see paragraphs [0057], [0061] and figures 7, 10). Claim [1] differs from D1 in that the at least one light guide is in optical communication with the optical emitter or optical detector, and that the at least one light guide is configured to deliver light from the optical emitter into an ear region of the subject via the distal end or collect light from an ear region of the subject via the distal end and deliver collected light to the optical detector. However, such an additional feature is virtually suggested by the feature of D1 considering that the entire sensing assembly works as follows: a first LED (71) emits light that in the form of a first beam (87) travels through the body of an illuminator (65) which comes in physical contact (120) with the opening of the ear canal and this contact allows light (in the form of a second beam 88) to continue traveling into the biological tissue and be modulated by the oxyhemoglobin and pulsatile blood volume (see paragraph [0061] and figure 10). Accordingly, claim [1] would have been obvious over D1. Therefore, claim [1] lacks an inventive step under PCT Article 33(3).

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Form PCT/ISA/237 (Box No. V) (July 2011)

Supplemental Box

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1.1.2 Dependent Claims [2-15]

The additional feature of claim [2] dependent on claim 1 is identical to the feature of D1 in that an ear plug (64) is inserted into an ear canal (4) of ears (60) (see paragraph [0056] and figure 10).

The additional features of claims [3, 5-6] dependent on claim 1 relate to the material of the at least one light guide. However, such additional features are merely matters of design option when the general knowledge in the relevant field of the art is used.

The additional feature of claim [4] is considered to be a minor difference over the disclosure of D1 that falls under the general knowledge of a person skilled in the art.

The additional feature of claim [7] dependent on claim 1 is identical to the feature of D1 in that shield 66 may be fabricated of any material that is opaque for the used light (see paragraph [0056]).

The additional feature of claim [8] dependent on claim 1 is identical to the feature of D1 in that after installation of a light transmission assembly (63) onto a holder (76), both LEDs can send light through an illuminator (65) (see paragraph [0058]).

The additional feature of claim [9] dependent on claim 1 is identical to the feature of D1 in that a light transmitting assembly (63) may be plugged into a holder (76) so that a butt (85), which is part of an ear plug (64), comes in proximity with an end (74) of a light coupler (72) (see paragraph [0058]).

The additional feature of claim [10] dependent on claim 1 is virtually suggested by the feature of D1 considering that the shield (66) may be fabricated of any material that is opaque for the used light (see paragraph [0056]).

The additional feature of claim [11] dependent on claim 1 is identical to the feature of D1 in a variant of an ear plug (64) with protruding ribs (84) that are pliable, flexible and resilient (see paragraph [0059] and figure 7).

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Supplemental Box

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The additional feature of claim [12] dependent on claim 1 is identical to the feature of D1 in that first and second LEDs (71 and 77) are coupled to a first section (108), while a detector (73) is coupled to a second section (110) by means of the intermediate light conducting rod (106) (see paragraph [0060]).

The additional feature of claim [13] dependent on claim 1 is merely a variation of the feature of D1 in that the modulated light in the form of a receiving light beam (111) passes toward a detector (73) (see paragraph [0060]), and a person skilled in the art would arrive at the claimed invention by general experimentation alone without exercising any ingenuity.

The additional feature of claim [14] dependent on claim 1 is virtually suggested by the feature of D1 considering that it detects the photo-plethysmographic waves of the pulsatile blood at two wavelengths and passes them to a module 27 for the signal processing (see paragraph [0051]).

The additional feature of claim [15] dependent on claim 1 is identical to the feature of D1 in that the light emitting devices (for example, light emitting diodes-LED) are positioned inside a probe (62) (see paragraph [0056] and figure 6).

Accordingly, claims [2-15] would have been obvious over D1. Therefore, claims [2-15] lack an inventive step under PCT Article 33(3).

1.2 Claims [16-22]

1.2.1. Independent Claim [16]

D1, which is considered to be the closest prior art to the subject matter of claim [16], discloses a device for detecting photo-plethysmographic signals from a patient ear canal, comprising: an ear plug (64) inserted into an ear canal (4) of ears (60) (see paragraph [0056] and figure 10); and a first LED (71), a second LED (77) and a light detector (73) (see paragraphs [0057], [0061] and figures 7, 10).

Claim [16] differs from D1 in that the first light guide is in optical communication with the optical emitter and is configured to deliver light from the optical emitter into an ear region of the subject via the first light guide distal end, and that the second light guide is in optical

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communication with the optical detector and is configured to collect light from an ear region of the subject via the second light guide distal end and deliver collected light to the optical detector. However, such additional features are virtually suggested by the feature of D1 considering that the entire sensing assembly works as follows: a first LED (71) emits light that in the form of a first beam (87) travels through the body of an illuminator (65) which comes in physical contact (120) with the opening of the ear canal and this contact allows light (in the form of a second beam 88) to continue traveling into the biological tissue and be modulated by the oxyhemoglobin and pulsatile blood volume (see paragraph [0061] and figure 10). Accordingly, claim [16] would have been obvious over D1. Therefore, claim [16] lacks an inventive step under PCT Article 33(3).

1.2.2 Dependent Claims [17-19, 21-22]

The technical features of claims [17-19, 21-22] are substantially the same as those of claims 2-4, 14-15 respectively. Accordingly, the same reasoning as in claims 2-4, 14-15 applies respectively to claims [17-19, 21-22], and claims [17-19, 21-22] would have been obvious over D1. Therefore, claims [17-19, 21-22] lack an inventive step under PCT Article 33(3).

1.2.3 Dependent Claim [20]

D1 does not disclose that a speaker is disposed within the housing, and that the housing comprises at least one aperture through which sound from the speaker can pass. But D2 discloses that the measuring apparatus for biological information is provided with a speaker (8) as an acoustic oscillator on the side facing the external auditory meatus (see column 5, lines 29-42 and figure 2). Accordingly, claim [20] would have been obvious over D1 in view of D2. Therefore, claim [20] lacks an inventive step under PCT Article 33(3).

1.3 Claims [23-26]

1.3.1 Independent Claim [23]

D1, which is considered to be the closest prior art to the subject matter of claim [23], discloses a device for detecting photo-plethysmographic signals from a patient ear canal,

Continued on The Next Page

International application No. PCT/US2013/070271

Supplemental Box

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comprising: an ear plug (64) inserted into an ear canal (4) of ears (60) (see paragraph [0056] and figure 10); and a first LED (71) and a light detector (73) (see paragraphs [0057], [0061] and figures 7, 10).

Claim [23] differs from D1 in that the light guide is in optical communication with the optical emitter and is configured to deliver light from the optical emitter into an ear region of the subject via the light guide distal end, and that the light guide is in optical communication with the optical detector and is configured to collect light from an ear region of the subject via the light guide distal end and deliver collected light to the optical detector. However, such the features are virtually suggested by the feature of D1 considering that the entire sensing assembly works as follows: a first LED (71) emits light that in form of a first beam (87) travels through the body of an illuminator (65) which comes in physical contact (120) with the opening of the ear canal and this contact allows light (in form of a second beam 88) to continue traveling into the biological tissue and be modulated by the oxyhemoglobin and pulsatile blood volume (see paragraph [0061] and figure 10). Accordingly, claim [23] would have been obvious over D1. Therefore, claim [23] lacks an inventive step under PCT Article 33(3).

1.3.2 Dependent Claims [24-26]

The technical features of claims [24-26] are substantially the same as those of claims 15, 2-3 respectively. Accordingly, the same reasoning as in claims 15, 2-3 applies respectively to claims [24-26], and claims [24-26] would have been obvious over D1. Therefore, claims [24-26] lack an inventive step under PCT Article 33(3).

1.4 Claims [27-32]

1.4.1 Independent Claim [27]

The independent claim [27] relates to a wearable sensor module, but it has the same technical features as those of claim 1 except for the type of invention. Thus, the same reasoning as in claim 1 could be applied to claim [27]. Therefore, claim [27] lacks an inventive step under PCT Article 33(3).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient. Continuation of : Previous Page

1.4.2 Dependent Claims [28-32]

The technical features of claims [28-32] are substantially the same as those of claims 2-3, 7, 10, 15 respectively. Accordingly, the same reasoning as in claims 2-3, 7, 10, 15 applies respectively to claims [28-32], and claims [28-32] would have been obvious over D1. Therefore, claims [28-32] lack an inventive step under PCT Article 33(3).

2. Industrial Applicability

Claims [1-32] are industrially applicable under PCT Article 33(4).

Electronic Acknowledgement Receipt				
EFS ID:	18506615			
Application Number:	14184364			
International Application Number:				
Confirmation Number:	1023			
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING			
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf			
Customer Number:	20792			
Filer:	Needham J. Boddie/Gwen Bailey			
Filer Authorized By:	Needham J. Boddie			
Attorney Docket Number:	9653-7TSCT			
Receipt Date:	18-MAR-2014			
Filing Date:	19-FEB-2014			
Time Stamp:	13:14:55			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted with Payment no		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		9653-7TSCT IDS.pdf	288717	yes	з
		2000 / DOLPAR	2c8db3d983eb9a7fed18c96e59c920c4dff7 cb5f	,	5

	Multipart Description/PDF files in .zip description				
	Document Description		Start	E	nd
	Transmittal	Letter	1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	3	
Warnings:					
Information:					
2	Non Patent Literature	ISR_Feb_26_2014.pdf	1217310	no	13
2	Non ratent Enerature		a401bcbcb0d6212d5458c84004a9ffd91d7 d2677	110	
Warnings:					
Information:					
		Total Files Size (in bytes)	: 15	06027	
characterize Post Card, as <u>New Applica</u> If a new appl 1.53(b)-(d) a Acknowledg	ledgement Receipt evidences receip d by the applicant, and including pay described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> ication is being filed and the applica nd MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filin ge of an International Application ur	ge counts, where applicable. tion includes the necessary o R 1.54) will be issued in due g date of the application.	It serves as evidence components for a filin	of receipt s g date (see	imilar to a 37 CFR
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.					
If a new inter an internatic and of the In	tional Application Filed with the USP mational application is being filed an onal filing date (see PCT Article 11 an ternational Filing Date (Form PCT/RC urity, and the date shown on this Ack on.	nd the international applicat d MPEP 1810), a Notification D/105) will be issued in due c	of the International <i>I</i> ourse, subject to pres	Application criptions co	Number oncerning

Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al. Serial No.: 14/184,364 Filed: February 19, 2014 Confirmation No.: 1023 Group Art Unit: 2878

For: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Date: March 18, 2014

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT COVER LETTER

Sir:

Attached is an Information Disclosure Statement listing of documents, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with 37 C.F.R. § 1.98(a)(2)(ii).

In accordance with **37 CFR 1.97(b)**, the information disclosure statement is being filed:

- (1) within three months of the filing date of a national application other than a continued prosecution application under 1.53(d);
- □ (2) within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- \Box (3) before the mailing of a first Office Action on the merits; or
- (4) before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

In accordance with **37 CFR 1.97(c)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(b) above, but before the mailing date of any of a final action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by **one** of the following:

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; <u>or</u>

□ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; <u>or</u>

(2) The fee set forth in 1.17(p);

In accordance with **37 CFR 1.97(d)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(c) above, but on or before payment of the issue fee, and is accompanied by **both** of the following:

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

In re: LeBoeuf et al. Application No.: 14/184,364 Filing Date: February 19, 2014 Page 2 of 2

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; <u>or</u>

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; and

(2) The fee set forth in 1.17(p);

In accordance with **37 CFR 1.97(g)**, the information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with **37 CFR 1.97(h)**, the information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b).

The Director is hereby authorized to charge the fee specified in 37 C.F.R. § 1.17(p), and any fee deficiency or credit any overpayment, to Deposit Account No. 50-0220; <u>or</u>

No fee is believed due. However, the Director is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

ngBodd: I

Needham J. Boddie, II Registration No. 40,519 Attorney for Applicant

Customer Number 20792 Myers Bigel Sibley & Sajovec, P.A. P.O. Box 37428, Raleigh, NC 27627 919-854-1400 919-854-1401 (Fax)

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on **March 18, 2014.**

R. Bai Im Name: Gwen R. Bailey

Attorney Docket No. 9653-7TSCT Page 1 of 2

DECLARATIO	ON (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)
Invention	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING med inventor, I hereby declare that:
This declaratic is directed to:	•
The above-ide	entified application was made or authorized to be made by me.
I believe that I in the applicat	am the original inventor or an original joint inventor of a claimed invention ion.
	ed and understand the contents of the above-identified specification, claims, as amended by any amendment specifically referred to above.
defined in 37 (information the	the duty to disclose information which is material to patentability as C.F.R. § 1.56, including for continuation-in-part applications, material at became available between the filing date of the prior application and the T international filing date of the continuation-in-part application.
	owledge that any willful false statement made in this declaration is der 18 U.S.C. 1001 by fine or imprisonment of not more than five (5)
LEGAL NAME Signature: Legal Name:	Date: 3/15/2014 Steven Francis LeBoeuf

.

Attorney Docket No. 9653-7TSCT Page 2 of 2

LEGAL NAME OF INVENTOR 2 Signature: Jun Bully turling Date: 3/17/2014	
Legal Name: Jesse Berkley Tucker	
,	
LEGAL NAME OF INVENTOR 3	,
Signature: <u>MM EM (2</u> Date: <u>718/14</u>	
Legal Name: Michael Edward Aumer	

Electronic Acknowledgement Receipt				
EFS ID:	18555784			
Application Number:	14184364			
International Application Number:				
Confirmation Number:	1023			
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING			
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf			
Customer Number:	20792			
Filer:	Needham J. Boddie/Gwen Bailey			
Filer Authorized By:	Needham J. Boddie			
Attorney Docket Number:	9653-7TSCT			
Receipt Date:	23-MAR-2014			
Filing Date:	19-FEB-2014			
Time Stamp:	14:43:19			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted with Payment		no				
File Listing:						
Document Number	Document Description		File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	9	0652 7TCCT Deduction odf	157902	no	2
		9653-7TSCT_Declaration.pdf 4		4555500bc9a096b98940549e19e511aafa7 dc810		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.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023
	7590 04/02/201 L SIBLEY & SAJOVE		EXAM	IINER
PO BOX 37428	6		FULLER, RO	DNEY EVAN
RALEIGH, NC	27627		ART UNIT	PAPER NUMBER
			2852	
			MAIL DATE	DELIVERY MODE
			04/02/2014	PAPER

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.

	Application No. 14/184,364	Applicant(s	
Office Action Summary	Examiner RODNEY FULLER	Art Unit 2852	AIA (First Inventor to File) Status No
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet w	vith the corresponder	nce address
A SHORTENED STATUTORY PERIOD FOR REPL' THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - 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 earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a will apply and will expire SIX (6) MOI , cause the application to become A	reply be timely filed NTHS from the mailing date BANDONED (35 U.S.C. § 13	of this communication. 33).
Status			
 Responsive to communication(s) filed on <u>Febr</u> A declaration(s)/affidavit(s) under 37 CFR 1.1 		<u> </u>	
2a) ☐ This action is FINAL . 2b) ☑ This	action is non-final.		
3) An election was made by the applicant in resp			ing the interview on
 4) Since this application is in condition for allowal closed in accordance with the practice under <i>B</i> 	nce except for formal mat	ters, prosecution as	
Disposition of Claims*			
 5) Claim(s) <u>1-32</u> is/are pending in the application 5a) Of the above claim(s) is/are withdraw 6) Claim(s) is/are allowed. 7) Claim(s) <u>1-32</u> is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/o * If any claims have been determined <u>allowable</u>, you may be eleparticipating intellectual property office for the corresponding a <u>http://www.uspto.gov/patents/init_events/pph/index.jsp</u> or sence Application Papers 10) The specification is objected to by the Examine 11) The drawing(s) filed on <u>February 19, 2014</u> is/are Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 	wn from consideration. r election requirement. igible to benefit from the Pa pplication. For more informa an inquiry to <u>PPHfeedback</u> r. e: a) accepted or b) drawing(s) be held in abeya	tion, please see @uspto.gov.] objected to by the nce. See 37 CFR 1.85	Examiner. 5(a).
Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign Certified copies: a) ☐ All b) ☐ Some** c) ☐ None of the: 1. ☐ Certified copies of the priority documen 2. ☐ Certified copies of the priority documen 3. ☐ Copies of the certified copies of the priority documen 3. ☐ Copies of the certified copies of the priority documen ** See the attached detailed Office action for a list of the certified	ts have been received. ts have been received in prity documents have bee u (PCT Rule 17.2(a)).	Application No.	
Attachment(s)			
1) X Notice of References Cited (PTO-892)		Summary (PTO-413)	
2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SPaper No(s)/Mail Date <u>2/19/2014, 3/18/2014</u> .	BB/08b) Paper No 4) Other:	(s)/Mail Date ·	
U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13) Office Action	Summarv	Part of Paper N	lo./Mail Date 20140327

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

Specification

2. The disclosure is objected to because of the following item(s):

The first paragraph of the Specification (Related Applications) should include the status of the parent application No. 12/691,388, i.e., now U.S. Patent No. 8,700,111.

Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following item(s) must be shown or the feature(s) canceled from the claim(s):

(Note: The embodiments of the claims correspond to Figures 22A, 22B and 23.

- a. (Claim 4): "a lens region"
- b. (Claim 5): "a phosphor-containing region"
- c. (Claim 11): "at least one optical filter"
- d. (Claim 12): "at least one optical filter"

e. (Claim 14): "an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor"

f. (Claim 15): "at least one accelerometer"

- g. (Claim 16): "at least one accelerometer"
- h. (Claim 19): "adhesive in one or more locations"
- i. (Claim 20): "a lens region"
- j. (Claim 21): "a phosphor-containing region"
- k. (Claim 24): "at least one optical filter"
- I. (Claim 25): "the optical filter"

m. (Claim 29): "an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor."

- n. (Claim 30): "at least one accelerometer"
- o. (Claim 31): "at least one accelerometer"

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next

Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17 and 32 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-

AIA), first paragraph, as failing to comply with the enablement requirement. The

claim(s) contains subject matter which was not described in the specification in such a

way as to enable one skilled in the art to which it pertains, or with which it is most nearly

connected, to make and/or use the invention.

Claim 17 depends from claim 16. Claim 32 depends from claim 31.

Claims 16 and 32 sets forth "wherein the at least one signal processor is

configured to process signals from the at least one accelerometer and optical

detector to measure or detect physiological information". There is no description

Page 4

> to enable a signals from an accelerometer and an optical detector to determine the physiological information listed in claims 17 and 32, i.e., brain waves, hunger and/or thirst, voice tone, head tilt, pheromones, stem cell regeneration response, etc.

Claim Rejections - 35 USC § 102

6. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

7. The following is a quotation of the appropriate paragraphs of pre-AIA 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 -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6-10, 14-20, 22, 23 and 26-32 are rejected under pre-AIA 35 U.S.C.
102(b) as being anticipated by Diab, et al. (US 2005/0043600).

Regarding claim 1, Diab discloses "a band (Fig. 29A, ref.# 2005) capable of encircling a portion of the body of a subject (Fig. 29B: finger); and an optical emitter (Fig. 28, ref.# 1074) and an optical detector (Fig. 1074) attached to the band; wherein the band comprises light transmissive material (Fig. 1, ref.# 1076, 1078, 1092, 1094)) in optical communication with the optical emitter (Fig. 29A, ref.# 1074) and optical detector

(Fig. 28, ref.# 1090) that is configured to deliver light from the optical emitter to one or more locations of the body of the subject (Fig. 28, ref.# 2000) and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector (Fig. 28, ref.# 1090)."

Regarding claim 2, Diab discloses "wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit." (paragraph 0004, lines 8-9)

Regarding claim 3, Diab discloses "wherein the band comprises first and second concentric body portions." (Fig. 28, ref.# 1072: top and bottom, 1084: top and bottom; Fig. 29B, ref.# 2015: shows thickness of band)

Regarding claims 4 and 20, Diab discloses "wherein the band comprises a lens region (Fig. 28, ref.# 1076) in optical communication with the optical emitter (Fig. 28, ref.# 1074) that focuses light emitted by the optical emitter and/or that collects light reflected from the body."

Regarding claims 6 and 22, Diab discloses "wherein the band has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces." (paragraph 0162, lines 2-4)

Regarding claims 7 and 23, Diab discloses "a signal processor (Fig. 24, ref.# 620), and wherein at least a portion of light reflected by the light reflection material and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector." (paragraph 0144: motion artifacts)

Regarding claims 8 and 26, Diab discloses "further comprising a signal processor (Fig. 24, ref.# 620) configured to receive and process signals produced by the optical detector (Fig. 24, ref.# 426)."

Regarding claims 9 and 27, Diab discloses "further comprising a transmitter configured to transmit signals processed by the signal processor to a remote device (Fig. 24, ref.# 630)."

Regarding claims 10 and 28, Diab discloses "light blocking material (Fig. 21, material between ref.# 726 and 730) positioned between the optical emitter (Fig. 21, ref.# 730) and detector (Fig. 21, ref.# 726) such that the optical emitter and detector are not in direct optical communication with each other."

Regarding claims 14-17 and 29-32, the Specification and Drawings do not provide support for the limitations of claims. The embodiments of the current application (and independent claims) correspond to Figures 22A, 22B and 23. The limitations of claims 14-17 and 29-32 are not given any patentable weight.

Regarding claim 18, Diab discloses "a base (Fig. 28, ref.# 1072, 1084) comprising an optical emitter (Fig. 28, ref.# 1074) and an optical detector (Fig. 28, ref.# 1090); and light transmissive material (Fig. 28, ref.# 1076, 1078, 1092, 1094) attached to the base, wherein the light transmissive material is in optical communication with the optical emitter and optical detector (See Fig. 28), and configured to deliver light from the optical emitter to one or more portions of the body (Fig. 28, ref.# 2000) of the subject and to collect light from one or more locations of the body of the subject and deliver the collected light to the optical detector (Fig. 28, ref.# 1090), and wherein at least one

portion of the monitoring device comprises adhesive (abstract: adhesive) in one or more

locations that is configured to adhesively secure the device to the body of the subject."

Regarding claim 19, Diab discloses "an outer body portion attached to the base

and to the light transmissive material, wherein the outer body portion comprises

adhesive in one or more locations that is configured to adhesively secure the device to

the body of the subject." (abstract: adhesive; Fig. 29A, ref.# 2005)

Claim Rejections - 35 USC § 103

9. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 5 and 21 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Diab, et al. (US 2005/0043600) in view of Jonnalagadda, et al. (US 2009/0054752)

Regarding claims 5 and 21, Diab does not discloses "wherein the band comprises a phosphor-containing region in optical communication with the light transmissive material, wherein the phosphor-containing region receives light emitted by the optical emitter and converts at least a portion of the received light to light having a different wavelength from the received light." However, the use of a luminescent material (phosphor or polymeric material) as part of the illumination system of a device

Page 8

used in measuring physiologic information was well known in the art at the time the invention was made as evident from the teaching of Jonnalagadda (See Abstract, paragraphs 0030, 0032, 0034, 0036). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Diab by including the structure of claims 5 and 21 (i.e., phosphor containing region) in order to accurately determine a user's pule rate and blood oxygen levels as taught by Jonnalagadda.

11. Claims 11-13, 24 and 25 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Diab, et al. (US 2005/0043600) in view of Rosenthal, et al. (US 5,086,229).

Diab discloses a red and an infrared light source with an electronic band pass filter / sync demodulator to separate out the red and infrared detected signals. However, Diab does not specifically set forth the use of an "optical filter" (i.e., IR filter). Thus, Diab does not teach (Claims 11, 12, and 24) "wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength" or (Claims 13 and 25) "a signal processor, and wherein at least a portion of light blocked by the optical filter and detected by the optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the optical detector." However, the use of optical bandpass filter with a light emitting diode to provide specific wavelength selection was well known in the art at the time the invention was made as evident from the teaching of Rosenthal (See column 5, lines 45-64). Thus, it would have been obvious to one of ordinary skill in the art at the time the

 Application/Control Number: 14/184,364
 Page 10

 Art Unit: 2852
 invention was made to utilize an optical (IR) filter to avoid "laborious characterization

 and sorting" of LEDs in order to provide a specific wavelength selection as taught by

Rosenthal.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. McCombie; Devin et al. US 20100298653 A1
- b. Shaltis; Phillip Andrew et al. US 20100168531 A1
- c. Finarov; Alexander et al. US 20060009685 A1
- d. Chance; Britton US 5596987 A

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RODNEY FULLER whose telephone number is (571)272-2118. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Clayton Laballe can be reached on 571-272-1594. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 14/184,364 Art Unit: 2852

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> /RODNEY FULLER/ Primary Examiner, Art Unit 2852

March 31, 2014

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	APPLICANTS Valencell, Inc., Raleigh, NC, Assignee (with 37 CFR 1.172 Interest);											
Jesse Ber	Steven Francis LeBoeuf, Raleigh, NC; Jesse Berkley Tucker, Knightdale, NC; Michael Edward Aumer, Raleigh, NC;											
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STATEMENT BY APPLICANT		First Named Inventor	Steven Francis LeBeouf				
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	("20050043600"). FN .	US-PGPUB; USPAT; USOCR	OR	OFF	2014/03/31 08:57
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L3	1	1 and "2003"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/03/31 09:26
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L8	0	1 and accelerometer	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2014/03/31 10:00

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L9	1	1 and sensor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/03/31 10:01
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		"6541756"	"6542764"	"6580086"				
		"6584336"	"6597933"	"6606511"				
		"6632181"	"6640116")					
		("6643530"						
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		"6699194"	"6714804"	"6725075"				
1 1		"CTAEOCO"	1					
81 8		10/40000		6//0028	3	3	•	11 ST
		"6745060" "6771994"	"6760607" "6792300"	"6770028" "6813511"				
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EAST Search History (Interference)

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				Complete if Known			
				Application Number	14/184,364		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			RE	Filing Date	February 19, 2014		
			NT	First Named Inventor	Steven Francis LeBoeuf		
• • • • • •		/		Art Unit	2878		
(use as i	(use as many sheets as necessary)		Examiner Name				
Sheet	B1	of	B1	Attorney Docket Number	9653-7TSCT		

				U.S. PATENT DOC	UMENTS	
Examiner Initials*	Cite No.	Nui	Document Number nber-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-	2010/0217103 A1	08-26-2010	Abdul-Hafiz et al.	· · · · · · · · · · · · · · · · · · ·
	2.	US-	2004/0054291 A1	03-18-2004	Schultz et al.	
	3.	US-	2004/0034293 A1	02-19-2004	Kimball	

FOREIGN PATENT DOCUMENTS						
	Cite No.	Foreign Patent Document Country Code, Number, Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7

		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	Т
		Notification of Transmittal of The International Search Report and The Written Opinion of the International Searching Authority, or the Declaration corresponding to International Application No. PCT/US2013/070271; Date of Mailing: February 26, 2014; International Search Report; Written Opinion of the International Searching Authority; 13 pages	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RF/

Examiner Signature	/Rodney Fuller/	Date Considered	03/26/2014
*EVAMINED, Initio	lif reference considered	whether or not ditation is in conformance with MRE	D 600 Drow line through attation if not

*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.

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED				
Symbol	Date	Examiner		

	US CLASSIFICATION SEARCHE	Ð	
Class	Subclass	Date	Examiner
600	310	3/31/2014	/RF/

SEARCH NOTES		
Search Notes	Date	Examiner
600/301, 302, 310, 322, 323, 324 (w/ text search)	3/31/2014	/RF/
East text search history printout	3/31/2014	/RF/

	INTERFERENCE SEARCH		
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/RODNEY FULLER/ Primary Examiner.Art Unit 2852
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Part of Paper No. : 20140327

Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.

Serial No.: 14/184,364

Confirmation No.: 1023

Group Art Unit: 2852

Filed: February 19, 2014

Examiner: Rodney Evan Fuller

For: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Date: June 9, 2014

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

RESPONSE TO OFFICE ACTION OF APRIL 2, 2014

Applicants provide the present Response to address the issues raised in the Office Action (the "Action") mailed April 2, 2014. Applicants provide the present Response pursuant to the rules stated in revised 37 C.F.R. 1.121 that became effective on July 30, 2003.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Amendments to the drawings begin on Page 2 of this paper.

Amendments to the Specification begin on Page 3 of this paper.

Amendments to the claims begin on Page 5 of this paper.

Remarks begin on Page 12 of this paper.

In the Drawings:

The attached replacement sheet 20/21 containing Figs. 22A and 22B replaces the existing sheet 20/21 containing Figs. 22A and 22B of the drawings.

The attached replacement sheet 21/21 containing Fig. 23 replaces the existing sheet containing Fig. 23 of the drawings.

Attachment: Replacement Sheets

In the Specification:

On page 1, line 1, please amend the RELATED APPLICATIONS section as follows:

RELATED APPLICATIONS

This application is a continuation application of pending U.S. Patent Application Serial No. 12/691,388, filed January 21, 2010, now U.S. Patent No. 8,700,111, which claims the benefit of and priority to U.S. Provisional Patent Application No. 61/208,567 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/212,444 filed 4/13/2009, and U.S. Provisional Patent Application No. 61/274,191 filed 8/14/2009, the disclosures of which are incorporated herein by reference as if set forth in their entireties.

Please amend the paragraph beginning on page 43, line 28 of the specification as follows:

-- In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger F. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses $74w_L$ such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of a finger F and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows 74w may include optical filters $74w_F$ to selectively pass one or more optical wavelengths and reflect and/or absorb other optical wavelengths. --

Please amend the paragraph beginning on page 45, line 25 of the specification as follows:

-- In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the body of a subject. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses $74w_L$ such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of the body of a subject and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows

74w may include optical filters $74w_F$ to selectively pass one or more optical wavelengths and reflect and/or absorb other optical wavelengths. --

Please amend the paragraph beginning on page 46, line 7 of the specification as follows:

-- The illustrated monitoring device 70' may be removably attached to the body of a subject via adhesive on one or more portions of the device 70'. In some embodiments, adhesive <u>75</u> may be on the inner body portion 74. In embodiments where the outer body portion is utilized, the adhesive may be on the outer body portion <u>72</u> [[74]]. In some embodiments, the illustrated device 70' may be removably attached to the body of a subject via tape or other known devices. --

This listing of claims replaces all prior versions in the application.

Listing of Claims:

1. (Currently Amended) A monitoring device, comprising:

a band capable of encircling <u>configured to at least partially encircle</u> a portion of the body of a subject, the band comprising:

<u>a generally cylindrical outer body portion and a generally cylindrical inner</u> <u>body portion secured together in concentric relationship, the inner body portion</u> comprising light transmissive material, and having outer and inner surfaces;

a layer of cladding material near the inner body portion inner surface; and at least one window formed in the cladding material that serves as a lightguiding interface to the body of the subject; and

<u>at least one</u> an optical emitter and <u>at least one</u> an optical detector attached to the band; wherein the <u>band comprises</u> light transmissive material <u>is</u> in optical communication with the <u>at least one</u> optical emitter and <u>the at least one</u> optical detector that <u>and</u> is configured to deliver light from the <u>at least one</u> optical emitter to one or more locations of the body of the subject <u>via the at least one window</u> and to collect light from one or more locations of the body of the subject <u>via the at least one window</u> and deliver the collected light to the <u>at least</u> <u>one</u> optical detector.

2. (Original) The monitoring device of Claim 1, wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit.

3. (Cancelled)

4. (Currently Amended) The monitoring device of Claim 1, wherein the band comprises a lens region in optical communication with the <u>at least one</u> optical emitter that focuses light emitted by the <u>at least one</u> optical emitter and/or that collects light reflected from the body.

5. (Cancelled)

6. (Currently Amended) The monitoring device of Claim 1, wherein the band has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

7. (Currently Amended) The monitoring device of Claim 6, <u>wherein the at least</u> one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light reflected by the light <u>reflective</u> reflection material and detected by the <u>second</u> optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the <u>first</u> optical detector.

8. (Currently Amended) The monitoring device of Claim 1, further comprising a signal processor configured to receive and process signals produced by the <u>at least one</u> optical detector.

9. (Original) The monitoring device of Claim 1, further comprising a transmitter configured to transmit signals processed by the signal processor to a remote device.

10. (Currently Amended) The monitoring device of Claim 1, wherein the at least one window comprises at least two windows, and further comprising light blocking material positioned between the <u>at least one</u> optical emitter and <u>the at least one optical</u> detector such that the <u>at least one</u> optical emitter and <u>the at least one optical</u> detector are not in direct optical communication with each other.

11. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength.

12. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

13. (Currently Amended) The monitoring device of Claim 12, <u>wherein the at least</u> one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light blocked by the optical filter and detected by the <u>second</u> optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the <u>first</u> optical detector.

14-17. (Cancelled)

18. (Currently Amended) A monitoring device configured to be attached to the body of a subject, comprising:

an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces;

a base <u>secured to at least one of the outer and inner layers and</u> comprising <u>at least one</u> an optical emitter and <u>at least one</u> an optical detector; and

light transmissive material attached to the base

a layer of cladding material near the outer surface of the inner layer; and

at least one window formed in the layer of cladding material that serves as a lightguiding interface to the body of the subject,

wherein the light transmissive material is in optical communication with the <u>at least</u> <u>one</u> optical emitter and <u>the at least one</u> optical detector, and <u>is</u> configured to deliver light from the <u>at least one</u> optical emitter to one or more portions of the body of the subject <u>via the</u> <u>at least one window</u> and to collect light from one or more locations of the body of the subject <u>via the at least one window</u> and deliver the collected light to the <u>at least one</u> optical detector, and wherein at least one portion of the monitoring device comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

19. (Currently Amended) The monitoring device of Claim 18, further comprising an outer body portion attached to the base and to the light transmissive material, wherein the outer <u>layer body portion and/or inner layer</u> comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

20. (Currently Amended) The monitoring device of Claim 18, wherein the light transmissive material comprises a lens region in optical communication with the <u>at least one</u> optical emitter that focuses light emitted by the <u>at least one</u> optical emitter and/or that collects light reflected from the body.

21. (Cancelled)

22. (Currently Amended) The monitoring device of Claim 18, wherein the light transmissive material has an outer surface and an inner surface, and further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces <u>of the inner layer</u>.

23. (Currently Amended) The monitoring device of Claim <u>22</u> [[18]], wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of the reflected light reflected by the light reflective material and detected by at least one the second optical detector is processed by the signal processor as a motion noise reference for attenuating motion noise from the optical detector signals produced by the first optical detector.

24. (Original) The monitoring device of Claim 18, wherein the monitoring device further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

25. (Currently Amended) The monitoring device of Claim 24, <u>wherein the at least</u> one optical detector comprises first and second optical detectors, and further comprising a <u>signal processor</u>, and wherein at least a portion of the light not passed by the optical filter and detected by at least one the second optical detector is processed by the signal processor as a motion noise reference for attenuating motion noise from the optical detector signals produced by the first optical detector.

26. (Currently Amended) The monitoring device of Claim 18, wherein the base comprises a signal processor configured to receive and process signals produced by the <u>at</u> <u>least one</u> optical detector.

27. (Original) The monitoring device of Claim 18, wherein the base comprises a transmitter configured to transmit signals processed by the signal processor to a remote device.

28. (Currently Amended) The monitoring device of Claim 18, <u>wherein the at least</u> <u>one window comprises at least two windows, and</u> further comprising light blocking material positioned between the <u>at least one</u> optical emitter and <u>the at least one optical</u> detector such that the <u>at least one</u> optical emitter and <u>the at least one optical</u> detector are not in direct optical communication with each other.

29-32. (Cancelled)

33. (New) A monitoring device configured to be attached to the body of a subject, comprising:

a first layer comprising light transmissive material, the first layer having inner and outer surfaces;

a base secured to the first layer and comprising at least one optical emitter and at least one optical detector;

a layer of cladding material near the inner and outer surfaces of the first layer; and

at least one window formed in the layer of cladding material that serves as a lightguiding interface to the body of the subject,

wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector, and is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

34. (New) The monitoring device of Claim 33, wherein the first layer comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject.

35. (New) The monitoring device of Claim 33, wherein the light transmissive material comprises a lens region in optical communication with the at least one optical emitter that focuses light emitted by the at least one optical emitter.

36. (New) The monitoring device of Claim 33, further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces of the first layer.

37. (New) The monitoring device of Claim 36, wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light reflected by the light reflective material and detected by the second optical detector is processed by the signal processor as a motion noise reference for attenuating motion noise from signals produced by the first optical detector.

38. (New) The monitoring device of Claim 33, wherein the monitoring device further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

39. (New) The monitoring device of Claim 38, wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light not passed by the optical filter and detected by the second optical detector is processed by the signal processor as a motion noise reference for attenuating motion noise from signals produced by the first optical detector.

40. (New) The monitoring device of Claim 33, wherein the base comprises a signal processor configured to receive and process signals produced by the at least one optical detector.

41. (New) The monitoring device of Claim 33, wherein the base comprises a transmitter configured to transmit signals processed by the signal processor to a remote device.

42. (New) The monitoring device of Claim 33, wherein the at least one window comprises at least two windows, and further comprising light blocking material positioned between the at least one optical emitter and the at least one optical detector such that the at least one optical emitter and the at least one optical detector are not in direct optical communication with each other.

REMARKS

After the above amendments, Claims 1, 2, 4, 6-13, 18-20, and 22-28 are pending. The drawings are objected to under 37 CFR 1.83(a).

Claims 17 and 32 stand rejected under 35 U.S.C. §112(a), first paragraph, as failing to comply with the enablement requirement.

Claims 1-4, 6-10, 14-20, 22, 23, and 26-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2005/0043600 to Diab et al. ("Diab").

Claims 5 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Diab in view of U.S. Patent Application Publication No. 2009/0054752 to Jonnalagadda et al. ("Jonnalagadda").

Claims 11-13, 24, and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Diab in view of U.S. Patent No. 5,086,229 to Rosenthal et al. ("Rosenthal").

Applicants have amended Claims 1, 4, 6, 7, 8, 10, 13, 18-20, 22, 23, 25, 26, and 28, as indicated above, for clarification. Claims 3, 5, 14-17, 21, and 29-32 have been cancelled without prejudice or disclaimer. New Claims 33-42 have been added.

Applicants respectfully traverse the rejections under §112, §102, and §103 for at least the reasons described herein.

Telephonic Interview

Applicants appreciate the Examiner's courtesy and professionalism in discussing the Action during a telephone interview on May 27, 2014. The present Remarks will document patentability of the claims and will also provide an interview summary for this interview.

During the telephone interview, a draft set of amended claims, submitted to the Examiner prior to the telephone interview, was discussed relative to U.S. Patent Application Publication No. 2005/0043600 to Diab et al., U.S. Patent Application Publication No. 2009/0054752 to Jonnalagadda et al., and U.S. Patent No. 5,086,229 to Rosenthal et al. In addition, U.S. Patent Application Publication No. 2005/0209516 to Fraden was discussed with respect to independent Claim 18.

The above constitutes a complete summary of the telephone interview with the Examiner on May 27, 2014.

Drawing Objections

The drawings are objected to because Figs. 22A, 22B, and 23 allegedly do not illustrate the following features of the claims:

- a. (Claim 4): "a lens region"
- b. (Claim 5): "a phosphor-containing region"
- c. (Claim 11): "at least one optical filter"
- d. (Claim 12): "at least one optical filter"
- e. (Claim 14): "an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor"
- f. (Claim 15): "at least one accelerometer"
- g. (Claim 16): "at least one accelerometer"
- h. (Claim 19): "adhesive in one or more locations"
- i. (Claim 20): "a lens region"
- j. (Claim 21): "a phosphor-containing region"
- k. (Claim 24): "at least one optical filter"
- 1. (Claim 25): "the optical filter"
- m. (Claim 29): "an accelerometer, a capacitive sensor, an inertial sensor, a mechanical sensor, an electromagnetic sensor, a thermal sensor, a nuclear radiation sensor, a biological sensor"
- n. (Claim 30): "at least one accelerometer"
- o. (Claim 31): "at least one accelerometer"

Applicants have provided replacement sheets for Figs. 22B and 23. Specifically, Applicants have amended Figs. 22B and 23 to illustrate a lens region $74w_L$. Support for this feature can be found in the specification at page 43, lines 31-32 and page 45, lines 28-29. No new matter has been entered.

Applicants have amended Figs. 22B and 23 to illustrate an optical filter $74w_F$. Support for this feature can be found in the specification at page 43, line 34 - page 44, line 2 and page 45, lines 32-33. No new matter has been entered.

Applicants have amended Fig. 23 to illustrate adhesive 75. Support for this feature can be found in the specification at page 46, lines 7-9. No new matter has been entered.

Claims 5, 14-16, 21, and 29-31 have been cancelled without prejudice or disclaimer.

In view of the above, the objections to the drawings are overcome.

Specification Objections

The specification is objected to because the status of Patent Application No. 12/691,388 does not include the issued patent status. Applicants have amended the specification as indicated above to include the issued patent status. As such, the objection to the specification is overcome.

Section 112 Rejections

Claims 17 and 32 stand rejected under 35 U.S.C. §112(a), first paragraph, as failing to comply with the enablement requirement. Applicants have cancelled Claims 17 and 32 without prejudice or disclaimer. As such, the rejections of Claims 17 and 32 are rendered moot.

Section 102 Rejections

Claims 1-4, 6-10, 14-20, 22, 23, and 26-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Diab. Applicants respectfully traverse the rejection because Diab does not teach or suggest all of the recitations of amended independent Claims 1 and 18. For example, amended independent Claim 1 recites a monitoring device, comprising:

a band configured to at least partially encircle a portion of the body of a subject, the band comprising:

a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship, the inner body portion comprising light transmissive material, and having outer and inner surfaces;

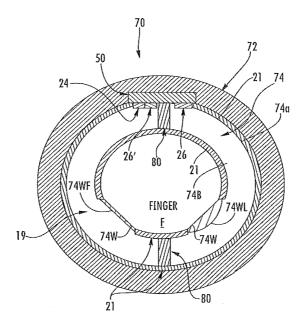
a layer of cladding material near the inner body portion inner surface; and

at least one window formed in the cladding material that serves as a light-guiding interface to the body of the subject; and

at least one optical emitter and at least one optical detector attached to the band;

wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector and is configured to deliver light from the at least one optical emitter to one or more locations of the body of the subject *via the at least one window* and to collect light from one or more locations of the body of the subject *via the at least one window* and deliver the collected light to the at least one optical detector.

Fig. 22B from Applicants' application is set forth below and illustrates a monitoring device 70, as recited in Claim 1.





The illustrated monitoring device 70 includes a generally circular band capable of encircling a finger F of a subject, with a cylindrical outer body portion 72 and a generally cylindrical inner body portion 74 secured together in concentric relationship. (Specification, page 42, lines 27-31.) A layer of cladding material 21 is applied to (or near) the outer surface 74a of the inner body portion 74 and a layer of cladding material 21 is applied to (or near) the inner surface 74b of the inner body portion 74 to define a light-guiding region 19. The inner body portion 74 serves as a light guide that delivers light from the optical emitter 24 to the finger F of a subject at one or more predetermined locations and that collects light from the finger F and delivers the collected light to the optical detectors 26, 26'. (Specification, page 43, lines 17-23.) Windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger F. (Specification, page 43, lines 28-29.)

Diab describes an optical probe suited to reduce noise in measurements taken on an easily compressible material, such as a finger, a toe, a forehead, an earlobe, or a lip. (Diab, Abstract.) The Examiner equates reference numbers 1072 and 1084 of Fig. 28 with first and

second concentric body portions of the band recited in amended Claim 1. (Action, page 6.) Fig. 28 from Diab is set forth below.

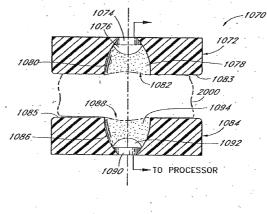




Fig. 28 illustrates a probe 1070 that comprises a transmission assembly 1072, having a light source 1074, an immersion lens 1076, scattering medium 1078, a chamber 1080 defining an aperture 1082 along a support surface 1083 of the transmission assembly. (Diab, ¶ 0157.) A detector assembly 1084 is similarly configured with a support surface 1085, a chamber 1086 defining an aperture 1088 along the support surface 1085, a photodetector 1090, an immersion lens 1092 and scattering medium 1094. (Diab, ¶ 0157.) Fig. 28 further depicts a test material 2000 such as human tissue (e.g., a finger or earlobe) interposed between the light source assembly 1072 and the detector assembly 1084. (Diab, ¶ 0157.)

Clearly, the probe 1070 depicted in Fig. 28 is not a band and is not configured to at least partially encircle a portion of the body of a subject, such as a finger. Neither the transmission assembly 1072 nor the detector assembly 1084 are cylindrical in shape, and the transmission assembly 1072 and the detector assembly 1084 are not secured together in concentric relationship. Moreover, neither the transmission assembly 1072 nor the detector assembly 1084 are of cladding material near the inner surface, and at least one window formed in the cladding material that serves as a light-guiding interface. As such, Diab fails to describe or suggest "a band configured to at least partially encircle a portion of the body of a subject, the band comprising: a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship, the inner body portion comprising light transmissive material, and having outer and inner surfaces; a layer of cladding material near the inner body portion inner

surface; and at least one window formed in the cladding material that serves as a lightguiding interface to the body of the subject," as recited in amended Claim 1. Because Diab fails to teach or suggest all of the recitations of Claim 1, Claim 1 is not anticipated by Diab and the rejection of independent Claim 1 under 35 U.S.C. §102 is overcome. Additionally, dependent Claims 2, 4, and 6-13 are patentable at least by virtue of the patentability of independent Claim 1, from which they depend.

Amended independent Claim 18 recites a monitoring device configured to be attached to the body of a subject, comprising:

an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces;

a base secured to at least one of the outer and inner layers and comprising at least one optical emitter and at least one optical detector;

a layer of cladding material near the outer surface of the inner layer; and at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject,

wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector, and is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

Diab does not teach or suggest the recited structure of amended independent Claim 18. Specifically, Diab does not teach or suggest an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, a layer of cladding material near an outer surface of the inner layer, and at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject. Furthermore, Diab does not teach or suggest a base secured to at least one of the outer and inner layers and that includes at least one an optical emitter and detector, and wherein the light transmissive material is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector. Neither of the immersion lenses 1076, 1092 of the Diab probe 1070 has a layer of cladding material at an outer surface thereof, and a window formed in the layer of cladding material that serves as a light-guiding interface to the body of a subject. Neither of the scattering mediums 1078, 1094 of the Diab

probe 1070 has a layer of cladding material at an outer surface thereof, and a window formed in the layer of cladding material that serves as a light-guiding interface to the body of a subject.

In view of the above, Applicants respectfully submit that Claim 18 is not anticipated by Diab and that the rejection of independent Claim 18 under 35 U.S.C. §102 is overcome. Additionally, dependent Claims 19, 20, and 22-28 are patentable at least by virtue of the patentability of independent Claim 18, from which they depend.

U.S. Patent Application Publication No. 2005/0209516 to Fraden describes various devices for monitoring physiological variables of a patient and in particular to devices for monitoring arterial pulse oximetry and temperature from an ear canal. (Fraden, ¶ 0001.) Fig. 1 from Fraden is set forth below and illustrates one of these devices.

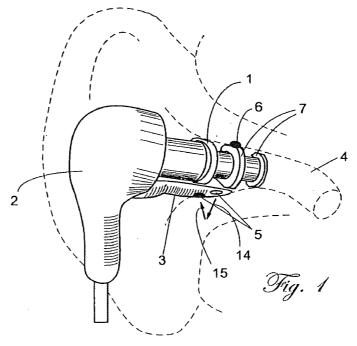


Fig. 1 shows plug 1 attached to ear probe 2; the probe 2 has a sensing extension 3 that carries blood oximetry windows 5. (Fraden, \P 0042.) This combination of extension 3 and a resilient ear plug 1 allows for a secure and stable positioning of the optical windows 5 against ear canal 4 walls. (Fraden, \P 0043.) Extension 3 may be either rigid or somewhat flexible to accommodate variations of the ear canal shapes, while ear plug 1 is acting like a spring

conforming its own contour to the ear canal shape and applying pressure on extension 3, pushing it against the ear canal wall. (Fraden, \P 0043.)

Fraden does not teach or suggest the recited structure of amended independent Claim 18. Specifically, Fraden does not teach or suggest an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, a layer of cladding material near an outer surface of the inner layer, and at least one window formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject. Furthermore, Fraden does not teach or suggest a base secured to the outer and inner layers and that includes at least one an optical emitter and detector, and wherein the light transmissive material is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

In view of the above, Applicants respectfully submit that Claim 18 is patentable over Fraden. Additionally, dependent Claims 19, 20, and 22-28 are patentable at least by virtue of the patentability of independent Claim 18, from which they depend.

Section 103 Rejections

Claims 5 and 21

Claims 5 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Diab in view of Jonnalagadda. Applicants respectfully disagree with the rejections based on Diab and Jonnalagadda. However, to expedite prosecution of the application, Claims 5 and 21 have been cancelled without prejudice or disclaimer. As such, the rejections of Claims 5 and 21 are rendered moot.

Claims 11-13, 24, and 25

Claims 11-13, 24, and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Diab in view of Rosenthal. Claims 11-13 depend from independent Claim 1, and Claims 24 and 25 depend from independent Claim 18. Independent Claims 1 and 18 are patentable over Diab for at least the reasons discussed above. The secondary reference, Rosenthal, fails to rectify the deficiencies of Diab with respect to independent Claims 1 and 18. Rosenthal is only cited for disclosing an optical bandpass filter. (Action, page 9.) The

Examiner does not allege and Rosenthal does not disclose "a band configured to encircle a portion of the body of a subject, the band comprising: a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship, the inner body portion comprising light transmissive material, and having outer and inner surfaces; a layer of cladding material near the inner body portion inner surface; and at least one window formed in the cladding material that serves as a light-guiding interface to the body of the subject," as recited in amended Claim 1. Moreover, the Examiner does not allege and Rosenthal does not disclose "an outer layer and an inner layer secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces; a base secured to the outer and inner layers and comprising at least one optical emitter and at least one optical detector; a layer of cladding material near the outer surface of the inner layer; and at least one window formed in the layer of cladding material that serves as a lightguiding interface to the body of the subject," as recited in amended Claim 18. Thus, Rosenthal fails to rectify the deficiencies of Diab with respect to independent Claims 1 and 18. As such, Claims 11-13, 24, and 25 are patentable and the rejections of Claims 11-13, 24, and 25 under §103 are overcome.

New Claims 33-42 Are Patentable

New independent Claim 33 contains similar recitations as amended independent Claim 18. Thus, for at least the same reasons set forth above with respect to amended independent Claim 18, Applicants respectfully submit that independent Claim 33 and all claims depending therefrom (Claims 34-42) are patentable.

Dependent Claims

As each of the dependent claims depends from a base claim that is believed to be in condition for allowance, Applicants do not believe that it is necessary to argue the allowability of each dependent claim individually. Applicants do not necessarily concur with the interpretation of these claims, or with the bases for rejection set forth in the Action. Applicants therefore reserve the right to address the patentability of these claims individually as necessary in the future.

CONCLUSION

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

Bodd: I

Needham J. Boddie, II Attorney for Applicants Registration No. 40,519

USPTO Customer No. 20792 Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, North Carolina 27627 Telephone: (919) 854-1400 Facsimile: (919) 854-1401 Doc. No. 1495595

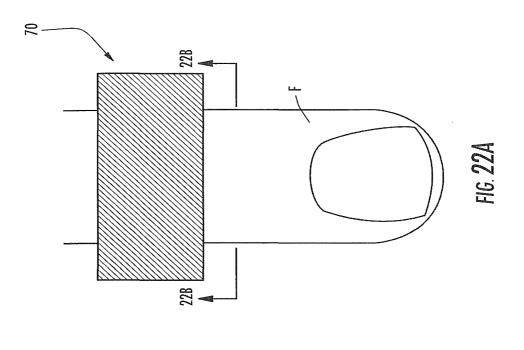
CERTIFICATION OF TRANSMISSION

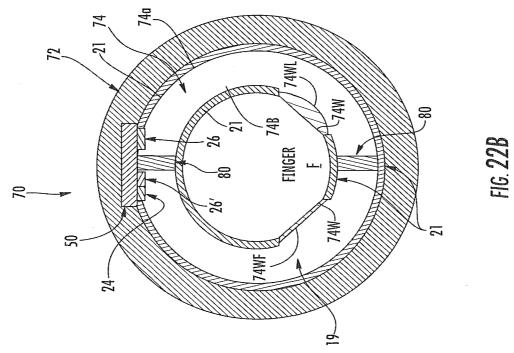
I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 C.F_tR₃§ 1.6(a)(4) to the U.S. Patent and T_rademark Office on **June 9, 2014**.

P Gwen R. Bailey

Replacement Sheet







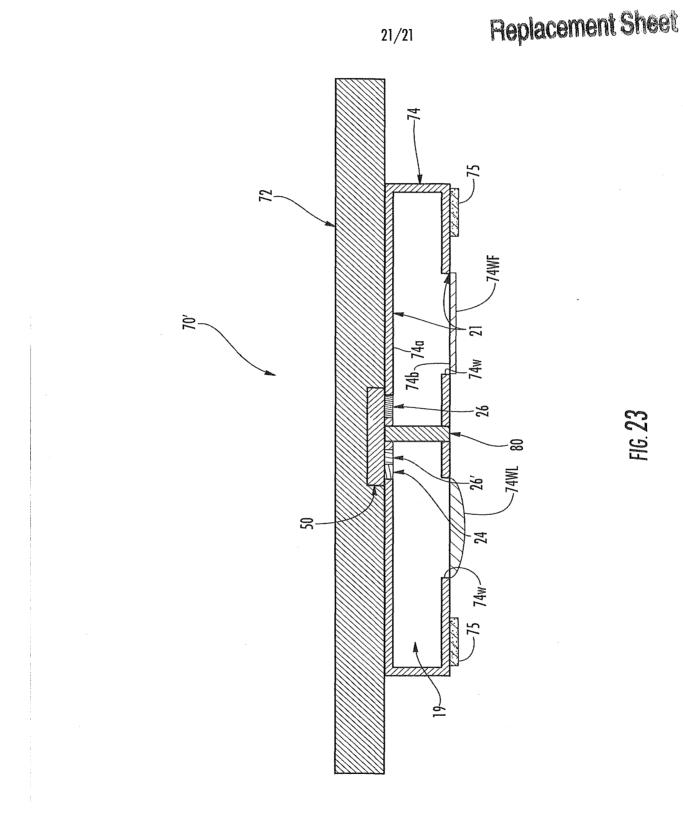


FIG. 23

0196

Electronic Acl	knowledgement Receipt
EFS ID:	19245470
Application Number:	14184364
International Application Number:	
Confirmation Number:	1023
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Gwen Bailey
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT
Receipt Date:	09-JUN-2014
Filing Date:	19-FEB-2014
Time Stamp:	13:10:11
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)/ Multi Message Digest Part /.zip (
1		9653-7TSCT Response.pdf	1911716	yes	21
		5655 / ISCI_Response.poi	f1825b231f9e4049624328810c82bacfd8df 7f13	,	21

	Multip	part Description/PDF files in .	zip description		
	Document De	scription	Start	t End	
	Applicant Arguments/Remarks Made in an Amendment		1	1	
	Drawings-other than black and white line drawings		2	2	
	Specificat	ion	3	4	
	Claims		5	11	
	Applicant Arguments/Remarks Made in an Amendment		12	21	
Warnings:			I		
Information:					
2	Drawings-only black and white line	9653-7TSCT_ReplacementShee	165928	no	2
2	drawings	ts.pdf	444b0595bdaf2b1fc1cdda3ac861528ee56 d5559		Z
Warnings:					
Information:					
		Total Files Size (in bytes)	207	7644	
Post Card, as <u>New Applica</u> If a new appl 1.53(b)-(d) an Acknowledg <u>National Sta</u> If a timely su U.S.C. 371 an	d by the applicant, and including page described in MPEP 503. <u>tions Under 35 U.S.C. 111</u> ication is being filed and the applica nd MPEP 506), a Filing Receipt (37 CF ement Receipt will establish the filin ge of an International Application ur bmission to enter the national stage and other applicable requirements a F	tion includes the necessary of R 1.54) will be issued in due g date of the application. <u>Inder 35 U.S.C. 371</u> of an international applicati orm PCT/DO/EO/903 indicati	components for a filing course and the date sh on is compliant with th ng acceptance of the a) date (see 3 own on this ne condition pplication	57 CFR s ns of 31
national stac	ge submission under 35 U.S.C. 371 wi		e Filing Receipt, in due	course. sary compo	

DocCode – SCORE

SCORE Placeholder Sheet for IFW Content

Application Number: 14184364

Document Date: 06/09/2014

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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 COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Application or Docket Number Filing Date PATENT APPLICATION FEE DETERMINATION RECORD 14/184,364 02/19/2014 To be Mailed Substitute for Form PTO-875 ENTITY: 🛛 LARGE 🗌 SMALL 🗌 MICRO **APPLICATION AS FILED – PART I** (Column 1) (Column 2) FOR NUMBER FILED NUMBER EXTRA RATE (\$) FEE (\$) BASIC FEE N/A N/A N/A (37 CFR 1.16(a), (b), or (c)) SEARCH FEE N/A N/A N/A 37 CFB 1.16(k), (i), or (m) EXAMINATION FEE N/A N/A N/A 37 CFR 1.16(o), (p), or (q) TOTAL CLAIMS minus 20 = X \$ = (37 CFR 1.16(i)) INDEPENDENT CLAIMS minus 3 = X \$ = (37 CFR 1.16(h)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 APPLICATION SIZE FEE for small entity) for each additional 50 sheets or (37 CFR 1.16(s)) fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s) MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j)) * If the difference in column 1 is less than zero, enter "0" in column 2. τοται **APPLICATION AS AMENDED – PART II** (Column 1) (Column 2) (Column 3) CLAIMS HIGHEST REMAINING NUMBER 06/09/2014 PRESENT EXTRA RATE (\$) ADDITIONAL FEE (\$) PREVIOUSLY AFTER **AMENDMEN** AMENDMENT PAID FOR Total (37 CFR 32 Minus ** 32 = 0 x \$80 = 0 1 16(i) Independent ***3 = 0 x \$420 = 0 * З Minus 37 CER 1 16(b) Application Size Fee (37 CFR 1.16(s)) FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) TOTAL ADD'L FEE 0 (Column 1) (Column 2) (Column 3) CLAIMS HIGHEST REMAINING NUMBER PRESENT EXTRA RATE (\$) ADDITIONAL FEE (\$) AFTER PREVIOUSLY AMENDMENT PAID FOR Ľ Total (37 CFR Minus ** X \$ = = AMENDM Minus *** X \$ = .16(h) Application Size Fee (37 CFR 1.16(s)) FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j)) TOTAL ADD'L FEE * If the entry in column 1 is less than the entry in column 2, write "0" in column 3. I IF ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". /MARGARET BYARS/ *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1 This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering,

reparing, 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.

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		UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov		
APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE	
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	
			CONFIRMATION NO. 1023	
20792		PUBLICAT	FION NOTICE	
MYERS BIGEL SIBLEY & S PO BOX 37428	SAJOVEC		C0000000069124711*	

Title:WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

Publication No.US-2014-0171762-A1 Publication Date:06/19/2014

RALEIGH, NC 27627

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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page 1 of 1



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023
	7590 08/14/201 L SIBLEY & SAJOVE		EXAM	IINER
PO BOX 37428	3		FULLER, RO	DNEY EVAN
RALEIGH, NC	2/62/		ART UNIT	PAPER NUMBER
			2852	
			MAIL DATE	DELIVERY MODE
			08/14/2014	PAPER

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.

	Application No. 14/184,364	Applicant(LEBOEUF	
Office Action Summary	Examiner RODNEY FULLER	Art Unit 2852	AIA (First Inventor to File) Status No
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet w	ith the corresponde	nce address
A SHORTENED STATUTORY PERIOD FOR REPL' THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v - 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 earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a l vill apply and will expire SIX (6) MON , cause the application to become Af	reply be timely filed ITHS from the mailing date BANDONED (35 U.S.C. § 1	of this communication. 33).
Status			
1) Responsive to communication(s) filed on <u>6/9/2</u>		<u>.</u>	
2a)⊠ This action is FINAL . 2b)∏ This	action is non-final.		
3) An election was made by the applicant in resp			ring the interview on
; the restriction requirement and election			to the merite is
4) Since this application is in condition for allowar closed in accordance with the practice under <i>E</i>	•	•	
Disposition of Claims*		, 100 O.G. 210	
 5) ∑ Claim(s) <u>1,2,4,6-13,18-20,22-28 and 33-42</u> is/a 5a) Of the above claim(s) is/are withdraw 6) ∑ Claim(s) <u>1,2,4 and 6-13</u> is/are allowed. 7) ∑ Claim(s) <u>18-20,22-28 and 33-42</u> is/are rejected 8) □ Claim(s) is/are objected to. 9) □ Claim(s) is/are objected to. 9) □ Claim(s) are subject to restriction and/o * If any claims have been determined allowable, you may be eleparticipating intellectual property office for the corresponding an http://www.uspto.gov/patents/init_events/pph/index.jsp or send Application Papers 10) □ The specification is objected to by the Examine 11) ⊠ The drawing(s) filed on <u>6/9/2014</u> is/are: a) ⊠ a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 	wn from consideration. I. r election requirement. igible to benefit from the Pat pplication. For more informat an inquiry to <u>PPHfeedback@</u> r. ccepted or b) objected drawing(s) be held in abeyar	ent Prosecution Hig tion, please see <u>@uspto.gov</u> . to by the Examiner nce. See 37 CFR 1.8	5(a).
Priority under 35 U.S.C. § 119 12) ☐ Acknowledgment is made of a claim for foreign Certified copies: a) ☐ All b) ☐ Some** c) ☐ None of the: 1. ☐ Certified copies of the priority document 2. ☐ Certified copies of the priority document 3. ☐ Copies of the certified copies of the priority document 3. ☐ Copies of the certified copies of the priority document ** See the attached detailed Office action for a list of the certified	ts have been received. ts have been received in <i>i</i> writy documents have been u (PCT Rule 17.2(a)).	Application No.	
Attachment(s)			
1) X Notice of References Cited (PTO-892)		Summary (PTO-413)	
2) Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/S Paper No(s)/Mail Date	BF/08b) Paper No(s)/Mail Date 	
U.S. Patent and Trademark Office PTOL-326 (Rev. 11-13) Office Action	Summary	Part of Paper	No./Mail Date 20140808

DETAILED ACTION

1. The present application is being examined under the pre-AIA first to invent provisions.

Remarks

In response to applicant's Amendment, dated 06/09/2014, the examiner acknowledges the addition of claims 33-42. Claims 1, 2, 4, 6-13, 18-20, 22-28 and 33-42 are pending.

3. Regarding the (1) objection to the Specification, (2) objections to the Drawings, and (3) Claim rejections set forth in the Office Action mailed 04/02/2014, the examiner has considered applicant's arguments in light of the amended Drawings, Specification and Claims and withdraws the objections and rejections.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of pre-AIA 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 -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 18, 20, 22, 26, 28, 35, 36, 40, 42 and 33 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Uchida, et al. (US 2003/0109030).

Regarding claim 18, Uchida discloses "an outer layer (Fig. 1, ref.# 10 near substrate) and an inner layer (Fig. 1, ref.# 8) secured together, the inner layer comprising light transmissive material, and having inner and outer surfaces (Fig. 1, ref.#

8: top and bottom); a base (Fig. 1, ref.# 4) secured to at least one of the outer (Fig. 1, ref.# 10 near substrate) and inner layers and comprising at least one optical emitter (Fig. 1, ref.# 1, 2) and at least one optical detector (Fig. 1, ref.# 12, 13); a layer of cladding material (Fig. 1, ref.# 10 near raised portion 5) near the outer surface of the inner layer (Fig. 1, ref.# 8); and at least one window (Fig. 1, ref.# 9) formed in the layer of cladding material that serves as a light- guiding interface to the body of the subject (Fig. 1, ref.# 17), wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector (See optical path shown in Fig. 2), and is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window (Fig. 1, ref.# 11) and deliver the collected light to the at least one optical detector (Fig. 1, ref.# 13)."

Regarding claims 20 and 35, Uchida discloses "wherein the light transmissive material comprises a lens region (Fig. 1, ref.# 9) in optical communication with the at least one optical emitter that focuses light emitted by the optical emitter."

Regarding claims 22 and 36, Uchida discloses "further comprising a light reflective material (Fig. 1, ref.# 7) on at least a portion of one or both of the inner and outer surfaces of the inner layer."

Regarding claims 26 and 40, Uchida discloses "wherein the base comprises a signal processor (Fig. 1, ref.# 14) configured to receive and process signals produced by the at least one optical detector (Fig. 1, ref.# 13)."

Regarding claims 28 and 42, Uchida discloses "wherein the at least one window comprises at least two windows (Fig. 1, ref.# 9, 11), and further comprising light blocking material (Fig. 1, ref. \$ 3, 4) positioned between the at least one optical emitter (Fig. 1, ref.# 1) and the at least one optical detector (Fig 1., ref.# 13) such that the at least one optical emitter and the at least one optical detector are not in direct optical communication with each other (Fig. 1, light must pass through tissue 17)".

Regarding claim 33, Uchida discloses "a first layer (Fig. 1, ref.# 8) comprising light transmissive material, the first layer having inner and outer surfaces; a base (Fig. 1, ref.# 4) secured to the first layer and comprising at least one optical emitter (Fig. 1, ref.# 1) and at least one optical detector (Fig. 1, ref.# 13); a layer of cladding material (Fig. 1, ref.# 10) near the inner and outer surfaces of the first layer; and at least one window (Fig. 1, ref.# 9) formed in the layer of cladding material that serves as a light-guiding interface to the body of the subject (Fig. 1, ref.# 17), wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector (See Fig. 2), and is configured to deliver light from the at least one optical emitter to one or more portions of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window (Fig. 1, ref.# 11) and deliver the collected light to the at least one optical detector (Fig. 1, ref.# 11)."

Claim Rejections - 35 USC § 103

6. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 23, 25, 27, 37, 34, 39 and 41 are rejected under pre-AIA 35 U.S.C.
103(a) as being unpatentable over Uchida, et al. (US 2003/0109030) in view of Diab, et al. (US 2005/0043600).

Regarding claims 19 and 34, Uchida discloses all the structure set forth in the claims except "wherein the outer layer and/or inner layer comprises adhesive in one or more locations that is configured to adhesively secure the device to the body of the subject." However, the use of an adhesive layer to secure a sensor to a body of a subject was well known in the art at the time the invention was made as evident from the teaching of Diab (See Abstract: adhesive; Fig. 29A, ref.# 2005). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Uchida to include an adhesive on the outer or inner layer to securely fix the sensor to a body of the subject in order to prevent movement from the detection site and improve quality of the detected signal.

Regarding claims 23, 25, 37 and 39, Uchida discloses all the structure set forth in the claims except "wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at

least a portion of light reflected by the light reflective material and detected by the second optical detector is processed by the signal processor as a motion noise reference for attenuating motion noise from the signals produced by the first optical detector." However, the use of a second detector and a processor to detect motion noise was well known in the art at the time the invention was made as evident from the teaching of Diab (See paragraph 0144: motion artifacts). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Uchida by including a second detector and processor to determine motion noise in order to improve the quality of the detected signal.

Regarding claims 27 and 41, Uchida discloses all the structure set forth in the claims except "wherein the base comprises a transmitter configured to transmit signals processed by the signal processor to a remote device." However, the use of transmitter with a monitoring device was well known in the art at the time the invention was mad as evident from the teaching of Diab (See Fig. 24, ref.# 630). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Uchida to include a transmitter to transmit signals from the processor to a remote device in order to allow the user to not be connected to wires and allow for user movement.

8. Claims 24 and 38 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Uchida, et al. (US 2003/0109030) in view of Diab, et al. (US

2005/0043600) as applied to claims 18 and 33 above, and further in view of Rosenthal, et al. (US 5,086,229).

Uchida and Diab do not specifically set forth the use of an "optical filter" (i.e., IR filter). Thus, Uchida and Diab do not "wherein the monitoring device further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject." However, the use of optical bandpass filter with a light emitting diode to provide specific wavelength selection was well known in the art at the time the invention was made as evident from the teaching of Rosenthal (See column 5, lines 45-64). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an optical (IR) filter to avoid "laborious characterization and sorting" of LEDs in order to provide a specific wavelength selection as taught by Rosenthal.

Allowable Subject Matter

9. Claims 1, 2, 4 and 6-13 are allowed.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37
CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RODNEY FULLER whose telephone number is (571)272-2118. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Clayton Laballe can be reached on 571-272-1594. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

0210

Page 8

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> /RODNEY FULLER/ Primary Examiner, Art Unit 2852

August 8, 2014

Notice of References Cited	Application/Control No. 14/184,364	Applicant(s)/Patent Under Reexamination LEBOEUF ET AL.	
Notice of Meterences Cited	Examiner	Art Unit	
	RODNEY FULLER	2852	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	А	US-2003/0109030	06-2003	Uchida et al.	435/287.1
	В	US-			
	С	US-			
	D	US-			
	Е	US-			
	F	US-			
	G	US-			
	Н	US-			
	Ι	US-			
	J	US-			
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	L	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	Ν					
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NON-PATENT DOCUMENTS

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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)

Notice of References Cited

Part of Paper No. 20140808

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	1	("8700111").P N .	US-PGPUB; USPAT; USOCR	OR	OFF	2014/08/05 09:59
S2	26	("20050228299" "6371925" "7209775" "20080165017" "20090105556" "20110105869" "20120197093" "8055319" "20050177034" "6783501" "8251903" "20050209516" "20080076972" "20080096726" "20080177162" "6078829" "6808473" "20060009685" "20090054752" "20130131519" "6859658" "20050209516" "20090270698" "8512242" "20090287067" "6080110" "20090030350").PN.	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/05 10:00
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S14	5058	S13 and (guide or waveguide or wave- guide)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/05 10:34
S15	3972	S14 and (oxygen or blood)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/05 10:34
S16	1888	S15 and (ear or finger)		OR	ON	2014/08/05 10:35
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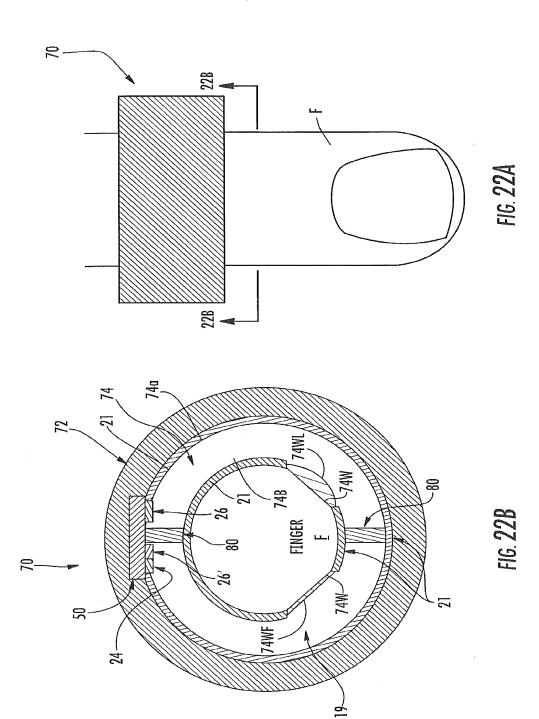
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OK TO ENTER: /RF/







OK TO ENTER: /RF/

In re: LeBoeuf et al. Serial No. 14/184,364 Filed: February 19, 2014 Page 3

In the Specification:

On page 1, line 1, please amend the RELATED APPLICATIONS section as follows:

RELATED APPLICATIONS

This application is a continuation application of pending U.S. Patent Application Serial No. 12/691,388, filed January 21, 2010, <u>now U.S. Patent No. 8,700,111</u>, which claims the benefit of and priority to U.S. Provisional Patent Application No. 61/208,567 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/208,574 filed 02/25/2009, U.S. Provisional Patent Application No. 61/212,444 filed 4/13/2009, and U.S. Provisional Patent Application No. 61/274,191 filed 8/14/2009, the disclosures of which are incorporated herein by reference as if set forth in their entireties.

Please amend the paragraph beginning on page 43, line 28 of the specification as follows:

-- In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the finger F. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses $74w_L$ such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of a finger F and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows 74w may include optical filters $74w_F$ to selectively pass one or more optical wavelengths and reflect and/or absorb other optical wavelengths. --

Please amend the paragraph beginning on page 45, line 25 of the specification as follows:

-- In the illustrated embodiment, windows 74w are formed in the cladding material 21 and serve as light-guiding interfaces to the body of a subject. There may be any number of these windows, as may be required for sufficient optical coupling, and the windows 74w may include lenses $74w_L$ such as those described above (e.g., lens 18L illustrated in Fig. 6), to focus light emitted by the optical emitter 24 onto one or more portions of the body of a subject and/or to focus collected light on the light detectors 26, 26'. Similarly, the windows

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

CPC- SEARCHED					
Symbol	Date	Examiner			

CPC COMBINATION SETS - SEARCHED				
Symbol	Date	Examiner		

US CLASSIFICATION SEARCHED						
Class	Subclass	Date	Examiner			
600	310	8/8/2014	/RF/			

SEARCH NOTES						
Search Notes	Date	Examiner				
600/301, 302, 310, 322, 323, 324 (w/ text search)	8/8/2014	/RF/				
East text search history printout	8/8/2014	/RF/				

INTERFERENCE SEARCH							
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner				

	/RODNEY FULLER/ Primary Examiner.Art Unit 2852
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U.S. Patent and Trademark Office

Part of Paper No. : 20140808

RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITED PROCEDURE - EXAMINING GROUP 2852

Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.

Confirmation No.: 1023

Group Art Unit: 2852

Serial No.: 14/184,364

Filed: February 19, 2014

Examiner: Rodney Evan Fuller

For: WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING (As Amended)

Date: August 18, 2014

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

RESPONSE TO OFFICE ACTION OF AUGUST 14, 2014

Applicants provide the present Response to address the issues raised in the Final Office Action (the "Action") mailed August 14, 2014. Applicants provide the present Response pursuant to the rules stated in revised 37 C.F.R. 1.121 that became effective on July 30, 2003.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Amendments to the Title begin on Page 2 of this paper.

Amendments to the Specification begin on Page 3 of this paper.

Amendments to the claims begin on Page 4 of this paper.

Remarks begin on Page 7 of this paper.

In the Title:

Please amend the Title of the application as follows:

-- WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING --

In the Specification:

Please amend the paragraph beginning on page 5, line 1 of the specification as follows:

-- In some embodiments, an earbud includes at least one lens in optical communication with the light transmissive material. Each lens may be configured to focus light from the optical emitter onto one or more predetermined locations in the ear of a subject and/or to focus collected external light onto the optical detector.

Please amend the paragraph beginning on page 10, line 21 of the specification as follows:

-- Fig. 6 is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.[[.]] --

This listing of claims replaces all prior versions in the application.

Listing of Claims:

1. (Previously Presented) A monitoring device, comprising:

a band configured to at least partially encircle a portion of the body of a subject, the band comprising:

a generally cylindrical outer body portion and a generally cylindrical inner body portion secured together in concentric relationship, the inner body portion comprising light transmissive material, and having outer and inner surfaces;

a layer of cladding material near the inner body portion inner surface; and at least one window formed in the cladding material that serves as a lightguiding interface to the body of the subject; and

at least one optical emitter and at least one optical detector attached to the band; wherein the light transmissive material is in optical communication with the at least one optical emitter and the at least one optical detector and is configured to deliver light from the at least one optical emitter to one or more locations of the body of the subject via the at least one window and to collect light from one or more locations of the body of the subject via the at least one window and deliver the collected light to the at least one optical detector.

2. (Original) The monitoring device of Claim 1, wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit.

3. (Cancelled)

4. (Previously Presented) The monitoring device of Claim 1, wherein the band comprises a lens region in optical communication with the at least one optical emitter that focuses light emitted by the at least one optical emitter.

5. (Cancelled)

6. (Previously Presented) The monitoring device of Claim 1, further comprising a light reflective material on at least a portion of one or both of the inner and outer surfaces.

7. (Previously Presented) The monitoring device of Claim 6, wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light reflected by the light reflective material and detected by the second optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the first optical detector.

8. (Previously Presented) The monitoring device of Claim 1, further comprising a signal processor configured to receive and process signals produced by the at least one optical detector.

9. (Original) The monitoring device of Claim 1, further comprising a transmitter configured to transmit signals processed by the signal processor to a remote device.

10. (Previously Presented) The monitoring device of Claim 1, wherein the at least one window comprises at least two windows, and further comprising light blocking material positioned between the at least one optical emitter and the at least one optical detector such that the at least one optical emitter and the at least one optical detector are not in direct optical communication with each other.

11. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength.

12. (Original) The monitoring device of Claim 1, wherein the band further comprises at least one optical filter configured to selectively pass at least one optical wavelength for transmission into the body of the subject.

13. (Previously Presented) The monitoring device of Claim 12, wherein the at least one optical detector comprises first and second optical detectors, and further comprising a signal processor, and wherein at least a portion of light blocked by the optical filter and

detected by the second optical detector is processed by the signal processor as a noise reference for attenuating motion noise from signals produced by the first optical detector.

14-42. (Cancelled)

<u>REMARKS</u>

After the above amendments, Claims 1, 2, 4 and 6-13 are pending.

Claims 1, 2, 4 and 6-13 are allowed.

Claims 18, 20, 22, 26, 28, 33, 35, 36, 40 and 42 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. 2003/0109030 to Uchida et al.

Claims 19, 23, 25, 27, 34, 37, 39 and 41 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Uchida et al. in view of U.S. Patent Application Publication No. 2005/0043600 to Diab et al.

Claims 24 and 38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Uchida et al. and Diab, and further in view of U.S. Patent No. 5,086,229 to Rosenthal et al.

To advance the application to allowance, Applicants have cancelled Claims 18-20, 22-28 and 33-42 without prejudice or disclaimer.

Applicants have amended the Specification, as indicated above, to correct typographical errors. Applicants have also amended the Title.

In view of the above, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

Needham J. Boddie, II Attorney for Applicants Registration No. 40,519

USPTO Customer No. 20792 Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, North Carolina 27627 Telephone: (919) 854-1400 Facsimile: (919) 854-1401 Doc. No. 1562324

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 C.F.R. § 1.6(a)(4) to the U.S. Patent and Trademark Office on August 18, 2014.

R. Bailey Sulen Gwen R. Bailey

Electronic Acl	knowledgement Receipt
EFS ID:	19892067
Application Number:	14184364
International Application Number:	
Confirmation Number:	1023
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Gwen Bailey
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT
Receipt Date:	18-AUG-2014
Filing Date:	19-FEB-2014
Time Stamp:	15:52:24
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted wi	th Payment	no	no					
File Listin	g:							
Document Number	Document Description	File Name	File Name File Size(Bytes)/ Multi Message Digest Part /.zip					
1		9653-7TSCT Response.pdf	451515	yes	7			
		5655 / ISCI_Response.pdf	540ed4c684a83ae0c359e3e415500edb8da 06cfa	yes	,			

	Multipart Description/PDF files in .zip description							
	Document Description	Start	End					
	Response After Final Action	1	1					
	Specification	2	3					
	Claims	4	6					
	Applicant Arguments/Remarks Made in an Amendment	7	7					
Warnings:								
Information:								
	Total Files Size (in bytes):	45	1515					

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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.

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				Application Number	14/184,364			
INFOR	MATION I	DISCLOSU	RE	Filing Date	02-19-2014			
STATE	EMENT BY	APPLICA	NT	First Named Inventor	Steven Francis LeBoeuf			
•		,		Art Unit	2852			
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Sheet	C1	of	C1	Attorney Docket Number 9653-7TSCT				

				U.S. PATENT DOC	UMENTS	
Examiner Initials*	Cite No.	Nu	Document Number nber-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-	2012/0179011 A1	07-12-2012	Moon et al.	ery UST LAND LAND LAND CONTRACTOR CONTRACTOR
	2.	US-	7,107,088 B2	09-12-2006	Aceti	
	3.	US-	6,358,216 B1	03-19-2002	Kraus et al.	
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	FOREIGN PATENT DOCUMENTS										
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	4.	EP 2 077 091 A2	07-08-2009	PERCEPTION DIGITAL LIMITED							

	NON PATENT LITERATURE DOCUMENTS						
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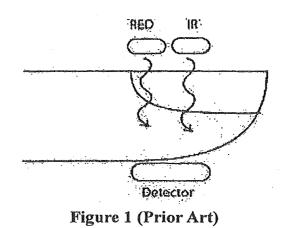
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(19)	Europäisches Patentamt European Patent Office Office européen des brevets	(11) EP 2 077 091 A2
(12)	EUROPEAN PATE	INT APPLICATION
(43)	Date of publication: 08.07.2009 Bulletin 2009/28	(51) Int CI.: <i>A61B 5/024</i> ^(2006.01)
(21)	Application number: 09250024.8	
(22)	Date of filing: 06.01.2009	
	Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK TR Designated Extension States: AL BA RS Priority: 07.01.2008 US 6321 P	 Chan, Kai Kin Hong Kong SAR (HK) Wong, Ming Yip Hong Kong SAR (HK) Yeung, Kai Wai Hong Kong SAR (HK) Chau, Fo Hong Kong SAR (HK)
(50)	21.08.2008 US 195502	(74) Representative: Martin, David John et al
(71)	Applicant: Perception Digital Limited Hong Kong SAR (HK)	Marks & Clerk LLP 5th Floor 14 South Parade
	Inventors: Ma, Chor Tin Hong Kong SAR (HK)	Leeds LS1 5QS (GB)

(54) Exercise device, sensor and method of determining body parameters during exercise

(57) A noninvasive light sensor for detecting heart beat signals has a circular support member engageable circumferentially with a body part of a person. There are a plurality of light emitters and light detectors located in pairs symmetrically about a circumference of the circular support member for respectively emitting light signals into different areas of tissue surrounding the body part, and receiving reflected light signals from the different areas of tissue surrounding the body part.



EP 2 077 091 A2

Printed by Jouve, 75001 PARIS (FR)

Description

Field of the Invention

[0001] The current invention relates to an exercise device for monitoring body parameters of a wearer during exercise. The invention also relates to sensor for determining sensor signals from which body parameters can be derived and to a method of determining body parameters during exercise.

Background to the Invention

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[0002] To achieve fitness goals it is necessary to exercise in the right intensity. Heart rate is one of the most accurate measurements of the intensity or exertion level of an exercise workout. The fitness of the heart is the key to aerobic endurance. Aerobic endurance is extremely important for both general fitness training and professional athletes. Heart monitors are one of the most effective aids for tracking and developing the progress on the path to increased aerobic

15 endurance. For example, to loss weight and bum fat, it is desirable to exercise at 60-70% of one's maximum heart rate. To improve cardiovascular fitness, it is more suitable to exercise at 70-80% of one's maximum heart rate. Exercise at the wrong intensity will just waste the effort or may even harm the body.

[0003] Heart rate can easily be checked by checking the pulses at the wrist manually for, say, 15 seconds during exercise and calculate beats per minute. However, stopping during exercise to count pulse is not only inconvenient, but also disrupts both the workout and the heart rate. This method also introduces pressure to the carotid artery which slows down the pulse. Electronic heart monitors are an effective way to track and record heart rate over the course of an entire workout. They not only provide a complete record of the heart rate for the duration of your workout, but they are also more accurate than manual methods, and can provide other information such as body temperature, Sp02 (Oxyhemoglobin saturation by pulse oximetry) are also important information to determine condition of the body.

- 25 [0004] For professional athletes, cardiovascular fitness is the most significant factor in speed. Measuring the work-rate of the heart is one of the most accurate methods of determining how much benefit an athlete derives from a workout. A heart rate monitor can also help to avoid stressing the body too much. They are a useful tool for maximize the efficiency of the training while minimizing the opportunity for injury. Heart rate monitors also enable professional athletes to exercise below a certain ceiling, i.e. avoid depleting the body's glycogen stores and ensuring that the body has the energy to
- ³⁰ perform intense workouts with vigor. For general fitness training, a heart rate monitor can function as a coach guiding the user when he or she can handle more and work harder.
 [0005] Most popular heart rate monitors use ECG type chest belt with a wireless link to sports watch. The heartbeat is detected by sensing the ECG signal from the chest belt and a pulse is sent to the sports watch via wireless connection.
- This type of heart rate monitor is accurate and reliable, but has the disadvantage that it is not comfortable for the user to wear a plastic belt on the chest during exercise. The belt will also become very dirty after use. Another method of detecting heartbeat is to use IR LED and IR sensor through the ear lobe or finger tip. This type of detector has the intrinsic problem of motion artifact and they are simply not reliable during exercise.
- [0006] There are many devices that can measure body parameters of a person. For example, by using an infrared ear thermometer, clinical thermometer, the user could get his body temperature and by using pulse oximeter the user could get his heartbeat and the amount of oxygen attached to the hemoglobin. However, none of these devices is suitable for continuous monitoring of the body parameter when the user is doing exercise. The thermometer, for example, is not suitable for use in motion. For finger pulse oximeter, study suggested the motion will result in blood volume changes that invalidate its measurement [ref "Motion Artifact in Pulse Oximetry", M.R. Neuman and N. Wang, Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Vol. 12 No. 5, 1990].
- ⁴⁵ [0007] Figure 1 is a schematic illustration is a typical finger type pulse oximeter implementation. Measuring heartbeat rate and Sp02 (blood oxygenation) is based on the absorption of red and infrared light. The technology is very sensitive to motion and hence is generally not suitable for use in personal exercise monitors. A few mechanical designs attempt to improve motion tolerance and enable the measurement to be used later in signal processing such that the heart rate in addition to Sp02 can be derived when the wearer is in motion. The device comprises two light sources, typically using
- 50 LEDs of known wavelength. The wavelengths of the two light sources are 880 920nm (Infrared or IR) and 660nm (Red) respectively. To obtain heart rate (HR) only the IR light source is needed. To calculate blood oxygen levels (pulse oximetry) both the Red and the IR LED's would need to be used. In either case a photo detector is used to sense the light that has been transmitted or reflected into the skin or application sight. This transmission of light into an area of the body that is carrying blood and reflected back to the photo detector will be effected by the pulsilitie flow caused by
- each heartbeat. This slight change in light intensity is detected and extracted to create a waveform commonly known as a plethysmograph. This waveform or the actual detection of the pulsiltile flow can be converted into heart rate in the absent of motion. To calculate pulse oximetry the IR and the red light emissions are separately analyzed and then used in an empirical calculation to generate a predetermined blood oxygen level. The calibration and empirical calculation

can be found in many literatures.

[0008] Figure 2 shows an example of noise induced by motion in an IR LED and IR heartbeat/SpO2 sensor. This noise signal may be of similar or even larger amplitude than the heartbeat signal and they are, in normal situation, in the same frequency band of the heartbeat signal (1-3 Hz). There is no easy method to extract the heartbeat signal from the mixture of the motion signal and heartbeat signal.

[0009] In addition to heart rate people are also interested in measuring the the distance run in an exercise session. There are many pedometer devices in the market that can count steps when a person walks or runs. These pedometers are fairly accurate and can record number of steps for a long period of time. Most of these devices require user to wear the device at particular orientation and position of the body trunk for the devices to work. These devices will usually fail if users are holding the device in hand when running or jogging.

Summary of the Invention

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- [0010] Accordingly, is an object of the present invention to provide an exercise device for determining the body parameters of a wearer during exercise. This particular object of the present invention to provide a sensor and method of determining heartbeat from a sensor signal that overcome or at least ameliorates problems with known devices. It is a second object of the current invention to provide an exercise device the can detect steps and calculate distance run by a user.
 - [0011] According to a first aspect of the invention there is provided a noninvasive light sensor for detecting heart beat signals, comprising:
 - a circular support member engageable circumferentially with a body part of a person,

a plurality of light emitters located about a circumference of the circular support member for emitting light signals into different areas of tissue surrounding the body part, and

²⁵ a plurality of light detectors located about a circumference of the circular support member for receiving reflected light signals from the different areas of tissue surrounding the body part.

[0012] Preferably, the light emitters and light detectors are located in pairs consisting of one of the emitters and one of the detectors.

30 [0013] Preferably, the light emitters comprises both red and infra-red light emitters.

[0014] Preferably, the plurality of light emitters consist of three light emitters located 120 degrees apart about the circumference of the support member.

[0015] Preferably, the plurality of light detectors consist of three light detectors located 120 degrees apart about the circumference of the support member.

³⁵ **[0016]** Preferably, the light emitters and light detectors are located in pairs consisting of one of the emitters and one of the detectors.

[0017] Preferably, the support member is one of a ear bud insertable within an ear canal or a band locatable about a wrist or arm.

- [0018] Preferably, the body part is an ear canal, the circular support member being an ear bud insertable with the an ear canal along an ear canal axis, wherein the plurality of light emitters are located about the periphery of the ear piece for emitting light signals perpendicular to the ear canal axis into the different areas of tissue surrounding the ear canal, and the plurality of light detectors are located about the periphery of the ear piece for member being an ear bud insertable with the an ear canal, and the plurality of light detectors are located about the periphery of the ear piece for receiving reflected light signals from the different areas of tissue surrounding the ear canal.
- [0019] Preferably, the ear piece is resiliently deformable for expansion within the ear canal, such that the ear piece is firmly locatable within the ear canal.
 - **[0020]** Preferably, the ear price comprises an inner layer and an outer layer having a plurality of openings, the light emitters and light detectors located with the inner layer beneath the outer layer openings.
 - [0021] Preferably, the inner lay comprises foam and the outer layer comprises rubber.
 - **[0022]** Preferably, the ear piece has an outer surface for mating with the ear canal and a plurality of openings in the outer surface, the light emitters and light detectors located within the openings.
 - [0023] Preferably, the light emitters and light detectors are located below the outer surface of the ear piece.
 - **[0024]** Preferably, the openings have sides surrounding the light emitters and light detectors, the sides defining a narrow gap above the light emitters and light detectors.
 - [0025] Preferably, the sides of the openings are light absorbent.
- 55 [0026] Preferably, the noninvasive light sensor of further includes an audio speaker and/or a temperature sensor. [0027] Preferably, the body part is a wrist or arm, the support member comprising a band locatable about a wrist or arm, the emitters and detectors located around an inner circumference of the band for respectively emitting light signals into the different areas of arm tissue and receiving reflected light from the different areas of arm tissue.

[0028] According to a second aspect of the invention there is provided a exercise device comprising:

a ear piece insertable with the an ear canal along an ear canal axis, a plurality of light emitters located about the periphery of the ear piece for emitting light signals perpendicular to the ear canal axis into different areas of tissue surrounding the ear canal, a plurality of light detectors located about the periphery of the ear piece for receiving reflected light signals from the different areas of tissue surrounding the ear canal, and a audio speaker,

an audio player for sending audio signals to the audio speaker,

a vital sign monitor that can determine at least one of heart rate, blood oxygen level or body temperature from signals of the emitters and detectors.

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[0029] According to a third aspect of the invention there is provided a exercise system comprising:

an ear piece insertable within an ear canal along a canal axis, the ear piece having a plurality of light sensors and detectors, and a audio speaker,

a computer readable storage medium have space allocated for storage of audio files,

a vital sign monitor programmed to generating a vital sign signal from signals of the emitters and detectors, and an audio player programmed to playback audio files thought the audio speaker in response to the vital sign signal and to vary attributes of the playback audio files in response to the vital sign signal.

20 [0030] Preferably, the attributes of the playback audio files to be varied are beat, tempo, tone and pitch.

[0031] Preferably, the audio player is programmed to vary the attributes by changing the playback audio files.

[0032] Preferably, the vital sign monitor is programmed to generating a heart rate, blood oxygen or temperature signal. [0033] According to a fourth aspect of the invention there is provided a method of determining heart rate of a person during exercise comprising:

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obtaining a plurality of sensor signals from multiple locations about a body part of a person, the sensor signals comprising a heart beat signals and a movement signals,

comparing the signals to separate the heart beat signals and a movement signals, and

determining heart rate from the heart beat signals.

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[0034] Preferably, obtaining a plurality of sensor signals from locations comprises providing a plurality of heart beat sensors for positioning at multiple locations about the body part.

[0035] Preferably, comparing the signals to separate the heart beat signals and a movement signals comprises comparing the sensor signals to find in phase and out of phase components of the sensor signals.

³⁵ **[0036]** Preferably, comparing the signals to separate the heart beat signals and a movement signals comprises finding a covariance between the sensor signals.

[0037] Preferably, determining heart rate from the heart beat signals comprises using match filters.

[0038] According to a fifth aspect of the invention there is provided a method in an exercise device of determining the steps taken by a person during exercise, comprising:

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obtaining a plurality of sensor signals from symmetrical locations about a body part of a person, the sensor signals comprising a heart beat signals and a movement signals,

finding a dominant movement signal, and

determining zero crossing points of the dominant movement signal.

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[0039] Preferably, finding a dominant movement signal comprises finding a movement signal having an amplitude greater than a threshold.

[0040] Preferably, finding a dominant movement signal comprises finding a sum of two sensor signals, finding a product of two times a third sensor signal, and subtracting the product from the sum.

⁵⁰ [0041] Preferably, the third sensor signal has an amplitude lower than amplitudes of the two summed sensor signals.
 [0042] Preferably, determining zero crossing points of the dominant movement signal comprises determining a number of the zero crossing points.

[0043] Preferably, method further comprises finding a product of a step-distance and the number of the zero crossing points and thereby finding a distance traveled by a person exercising.

⁵⁵ **[0044]** Further aspects of the invention will become apparent from the following description.

Brief Description of the Drawings

[0045] An exemplary form of the present invention will now be described by way of example only and with reference to the accompanying drawings, in which:

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Figure 1 is a schematic illustration of prior art operation of a heartbeat sensor/pulse oximeter,

Figure 2 is a graphical illustration of the heartbeat signal with motion noise for a prior art earphone sensor,

¹⁰ Figure 3 is a schematic illustration of a first embodiment of a personal exercise device according to the invention having an earphone type sensor,

Figure 4 is a schematic illustration of the earphone sensor arrangement for device of Figure 3,

¹⁵ Figure 5 is a perspective illustration of an ear bud of the earphone sensor,

Figure 6 is a schematic illustration of a flexible printed circuit for locating and connection of sensors within the ear bud,

Figure 7 is a perspective illustration of the ear bud without a rubber over-molding,

Figure 9 is a perspective illustration of an alternative ear bud type earphone sensor and behind-the-ear parts of the alternative ear bud,

Figure 10 is a perspective illustration of a bud,

Figure 11 is a schematic illustration of a second embodiment of a personal exercise device according to the invention having a arm band type sensor,

Figure 12 is a second schematic illustration of the personal exercise device having a arm band type sensor,

Figure 13 is a schematic illustration of the sensor control and processing means of the exercise device,

³⁵ Figure 14 illustrates decomposition of the noise vector into horizontal and vertical components, and

Figure 15 is a schematic process block diagram of detector sensor signal processing used in the exercise device,

Figure 16 is a graphical illustration of the signal detected during exercise,

Figure 17 is a block diagram of a method for detecting steps taken by a user during walking or running,

Figure 18 is a graphical illustration of the relationship between distance and walking speed,

⁴⁵ Figure 19 is a schematic block diagram of body parameter base playback control in the exercise device, and

Figure 20 is a flow chart of the implementation of the body parameter based playback control.

Description of the Exemplary Embodiments

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[0046] Aspects of the invention will now be illustrated as practiced in a first embodiment of a personal exercise device comprising an earphone sensor for listening to audio files and also for detecting body parameters; such as heartbeat, SpO2 and temperature; during exercise, a signal processing means for resolving sensor information into heartbeat and other body parameters and a workout assistance means for providing feedback of body parameters, exercise instructions and entertainment functions such as, but not limited to, music, video, game, e-book, photo, etc. However, this is not intended to limit the scope of functionality or use of the invention. In a most basic embodiment of the invention the exercise device comprises simply an earpiece sensor and signal processing means for detecting heartbeat for feedback to the user or transmission to another device such as an exercise machine or exercise monitoring equipment. The

Figure 8 is a section illustration of the ear bud,

earphones of the invention include several mechanical design characteristics that ameliorate movement inaccuracies inherent in ear sensors known hitherto. It is not essential to the invention that all such preferred mechanical design characteristics be included in all embodiments of the invention.

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[0047] Figure 3 shows the block diagram of a personal exercise device. A pair of earphones 1 that can be worn by the user is connected to a portable base unit 2 by a cable 3 having conductor means 4, 5 for carrying both audio signals and body parameter sensor signals. The portable base unit 2 has a microprocessor 8, audio module 6 for providing audio signals to the earphones, a sensor module 7 for communicating with the earphone sensors and a user interface/ display module 9 for interaction with the user. In one exercise mode the exercise device determines heartbeat of the user and then controls the playback of audio content in accordance with changes in the heartbeat. The heartbeat is also

- 10 recorded for future reference and for comparing against targeted training level, etc. The earphones 1 may also include an IR thermometer or small thermistor embedded in the earphones 50 for determining body temperature. The bases unit and or earphones 50 may also include an accelerometer/G-sensor for detecting steps from running or walking motion. The earphones may also include a microphone for picking up ambient sound signal and the user could enable or disable or adjusting the ratio of the mixing of ambient sound with content playing back at will. This is necessary
- ¹⁵ because of the mechanical structure for the ear buds blocks a significant part of ambient sound from reaching the user. [0048] The earphone mechanical design is illustrated in Figures 4 through 10. Figure 4 schematically illustrates the sensor arrangement of the earphones. Signal emitter 21, 22, 23 and detector 24, 24, 26 devices are located around the circumferential periphery 27 of the earphone. The emitter and detector devices may be either Red or Infared (IR) or both for detecting heartbeat and optionally SpO2. The ear piece is of a type commonly known as an ear bud 50 which has a substantially cylindrical shape for insertion within the outer ear canal of the wearer. In the preferred embodiment the
- emitters and detectors are grouped in pairs 21-24, 22-25, 23-26 located 120 degrees apart about the circumferential periphery 27 of the ear bud 50. The dashed lines 30, 31, 32 show the path of the IR signals through the soft tissue surrounding the internal wall of the ear canal. A first signal 31 from emitter 21 is detected by detector 25, a second signal 32 from emitter 22 is detected by detector 26 and a third signal 33 from emitter 23 is detected by detector 24. The main
- signal noise is due to radial motion of the ear bud 50 in the x, y plane within the ear cannel because these movement changes the distance between the sensor and the ear canal wall, which affects the transmitted and receive signal. By using the physical construction where the IR sensors are installed in several circular symmetric locations the effect due to motion in the x, y plane can be approximated as a linear effect on the amplitude of the received signal. [0049] Some of the signal emitted from the emitters 21, 22, 23 will be reflected from the skin surface of the ear canal.
- The amount of the IR signals 31, 32, 33 that is reflected from the skin also varies substantially with the aforementioned x, y plane movement of the ear bud 50 within the ear canal. The reflected light is detected by the detectors and must be allowed for in later processing to determine heartbeat and other body parameters from the detected signals. The amount of referred light that is detected by the detectors can be ameliorated by locating the emitters and detectors within recess channels 35, 36, 37 below the outer peripheral surface 28 of the ear bud 50. The recess channels 35, 36, 37
- ³⁵ can comprise air or optical glass mediums and form a narrow angle wave guide for IR signals emitted from the emitters or entering the detectors. These wave guide cannels 35, 36, 37 produces a narrow angle beam to direct the light in such a way to allow the maximum amount signal by increasing the signal path of the light up and into deeper tissue before the light reflects and is captured by the detector. They also limiting large fluctuation in DC single picked up by detectors. [0050] The outer part 38 of the ear bud 50 consists of a soft over-molding made of resiliently deformable memory
- foam or silicone rubber that dampens the effects of motion. The foam is compressed when the ear bud 50 is inserted into the ear canal and expands to hold the bud 50 firmly in the ear canal to ameliorate relative motion between the emitters and detectors and the ear canal wall during exercise movement. One possible optional feature is to make outer piece 38 removable and interchangeable for varying the size and shape to fit a wide variety of users having different size ear canals. The properties (elasticity, softness as known as durometer, memory or rebound rate) of this soft overmolding 38 are chosen to maximizing the damping effects.
- [0051] The depth placement of the emitters and detectors inside the ear is also important, but not essential, to reducing the effects of motion introduced within the ear during exercise. The emitters and detector are placed at the end of the inner part of the ear bud 50 which is further into the ear canal to help reduce the effects of motion. This placement helps reduce the vibration as the inner ear part is more firmly attached to the bone and muscle (non-soft tissue) which does not move as much during exercise.
 - **[0052]** A first arrangement of an ear bud 50 is illustrated in Figures 5 through 8. The interchangeable resilient outer part 38 is sized to fit within the ear canal of a person. Figure 7 illustrates the core parts of the ear bud 50 with the resilient outer part 38 removed. The structure consists of a speaker 44, a hollow inner core 41 for sound conduction from the speaker in to the ear, an resilient inner foam structure 42 for softness and flexibility, a flexible printed circuit (FPC) 43
- ⁵⁵ or thin wirings for connection to emitter and detectors and a rubber over-molding 38 for increase comfort and protection of sensors. The resilient inner foam 42 may be compressed during insertion of the bud 50 into the ear to provide further support in the ear canal.

[0053] The FPC 43 comprises a hub 46 having three 120 degree radially extending arms 47. The emitter and detector

pairs 21-24, 22-25, 23-26 are located at the distal ends of the FPC 43 and are encapsulated with epoxy. The encapsulation provides a round-top to avoid injury to the user when wearing the device and at the same time prevents the emitters and receivers from damage. An alternative approach is to use sensors with suitable packaging. The FPC arms 47 are made of a flexible material so that sensors follow the foam 42 when squeezed into the ear canal. Flexible wiring tracks

- are located along the radial arms 47 connecting the emitters and detectors to solder bonding pads 48 on the hub 46. In one embodiment the FPC and arms is formed as a flex circuit. The hub 46 is located centrally within the back of the ear bud 50 and the radial arms brought forward within slots 45 on the surface of foam 42. The depth of the slots 45 is designed to allow the sensors to be slightly above the foam surface. The foam 42 is then covered with the rubber overmolding 38 for increase comfort and protection of sensors.
- 10 [0054] Figures 9 and 10 illustrate an alternative arrangement of an ear bud 50 in a behind-the-ear design. The cord 3 to each bud 50, hangs around the back of the ear to also help in securing an in ear portion 51 into the ear canal and thus reducing motion introduced into the signal by exercise movement. Another feature of this design is to have the cable 3 enter at the back or bottom of the behind the ear portion. This cable placement design will reduce the motion effects that can be produced by the pulling forces of the cable during movement. Since the cable 3 can exert a force on
- the ear piece the reduction of its size and weight is achieved by locating some of the electronics or circuitry into a behind an ear portion 52 of the earphone. This feature reduces the number of wires and thus thickness and weight of the cable 3. There are many wires needed to drive and capture the signal from the emitters and detector as well as the wires for the audio speakers and the temperature sensor. The circuit design has a communication method between the main unit 2 and the behind the ear portion 52 circuitry.
- 20 [0055] Figures 11 and 12 illustrate a second embodiment of an exercise device according to the invention employing an arm-band type sensor. In the first embodiment the sensor was a circular ear bud for location within an ear canal, with the emitters and detectors located in pairs 120 degrees apart around the outer circumference of the bud for obtaining signals from the tissue surrounding the ear canal. In the arm-band embodiment an annular band 60 is provided which locates about the wrist 61 or upper arm 62 of the user. Emitters and detectors are provided in three pairs 64, 65, 66 at
- ²⁵ locations 120 degrees apart around the inner circumference of the band 60. The emitters and detectors are of the same type as in the ear bud, however the emitters and detectors are located on the inner circumference of the band 60 so as to be pressed up against the skin of the wrist 61 or arm 62 when the band 60 is worn. The sensor signal path is through the tissue of the wrist 61 or arm 62. The band 60 is made of a resilient material so as to fit snugly about the wrist 61 or arm 62 of the wearer and maintain the emitter and detector pairs 64, 65, 66 in position with the arm tissue. The band
- ³⁰ 60 may be a stand alone band or, as illustrated in Figures 11 and 12, may be a support strap for wearing the portable base unit 2 on the wrist 61 or upper arm 62 of the users. The arm-band embodiment may be preferable to those who run or cycle in busy traffic areas and prefer not to impair their hearing with earphones for safety reasons. The embodiment shown in Figure 11 may be, for example, a wrist watch wherein the base unit only provides visual feedback. However, in some embodiments the base unit 2 may also have an ear phone output jack for connection of a standard pair of earphones for listening to music and audio feedback from the portable exercise device if so desired.
- ³⁵ earphones for listening to music and audio feedback from the portable exercise device if so desired. [0056] The head phones 1 and arm bands 60 of embodiments of the invention use multiple pairs of emitters and detectors at symmetrical locations to aid the removal or minimization of the additive noise introduced in to the detected sensor signals by exercise motion of the wearer. The microprocessor 8 of the main unit 2 receives the detected sensor signals and analyses them to detect the wearer's heartbeat and other body parameters, such as SpO2. Figure 13 is a
- 40 schematic block diagram of the sensor control and processing means. A LED driver control is used to send driving signals to the LED emitters 21, 22, 23. The detected signals from detectors 24, 25, 26 are amplified by op-amps 62 with DC bias control 63. The amplified analog signals go through a multiplexer 64 and an analog-to-digital (A/D) converter 65 for input to the Microprocessor 8. The signals are analyzed in Microprocessor 8 to detect the wearer's heartbeat and other body parameters.
- ⁴⁵ [0057] The detected signals 31, 32, 33 are modeled as follows:

(1)
$$m_1(t) = L_1 I_{01}(t)(1 + \gamma_1 h b(t))(1 + N_{s1}(t) + N_{f1}(t) + z_1(t))$$

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(2)
$$m_2(t) = L_2 I_{02}(t) (1 + \gamma_2 h b(t)) (1 + N_{s2}(t) + N_{f2}(t) + z_2(t)),$$

55 and

(3)
$$m_3(t) = L_3 I_{03}(t)(1 + \gamma_3 hb(t))(1 + N_{s3}(t) + N_{r3}(t) + z_3(t))$$

5 Where:

 $m(t), m_2(t), m_3(t)$ are the signal received at the 3 detectors respectively $l_{01}(t), l_{02}(t)l_{03}(t)$ are the transmitted signal to the IR LED emitters respectively L_1, L_2, L_3 are constant gain of each IR sensors hb(t) is the heartbeat signal $\gamma_1, \gamma_2, \gamma_3$ are coupling coefficients of the heartbeat signal hb(t) $N_{s1}(t), N_{s2}(t), N_{s3}(t)$ are slow varying noise in the detected signals $N_{f1}(t), N_{f2}(t), N_{f3}(t)$ are typical additive thermal noise in the detected signals, and

 $z_1(t), z_2(t), z_3(t)$ are noise signals due to motion.

[0058] This model is based on the assumption that the motion signals $z_1(t)$, $z_2(t)$, $z_3(t)$ are in the same plane as the circular plane formed by the 3 sensors (the x-y plane) and they can be decomposed to 2 orthogonal components h(t) and v(t) as shown in Figure 14. Mathematically this is $z_k(t) = \varepsilon_k(h(t)\cos(\theta_k) + v(t)\sin(\theta_k))$, where h(t), v(t) are the motion signal being projected to horizontal and vertical directions and the direction of sensor *k* is θ_k from the horizontal direction and ε_k are coupling coefficients for the motion signal to the sensors. For the three detectors 120 degrees apart θ_k is 90, 210 and 330 degrees.

[0059] We can make the assuming that both γ_k , ε_k are much smaller than 1 and we can represent the received signal as DC and AC components(m_{ack} (t), $m_{dck}(t$)). By calculating the signal AC amplitude when there is no motion, we can normalize the 3 channels gain. Equations (1),(2),(3) can be approximated as :

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$$(4) \quad m_{acl}(t) = hb(t) + N'_{sl}(t) + N'_{fl}(t) + z_{l}'(t)$$

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(5)
$$m_{ac2}(t) = hb(t) + N'_{s2}(t) + N'_{f2}(t) + z_2'(t)$$

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(6)
$$m_{ac3}(t) = hb(t) + N'_{s3}(t) + N'_{f3}(t) + z_{3}'(t)$$

where $N'_{sk}(t)$, $N'_{fk}(t)$, $z_k'(t)$ are scaled versions of the original signals.

[0060] The signal due to heartbeat should have similar effect on the three signals 31, 32, 33 and should be in phase in each signal and differ only by a scaling factor. The sensors are placed evenly in a circle and so the effect of motion in x-y plane should be different for the 3 symmetrically located sensors. When there is no motion, or a very small amount of motion, the maximum signal to noise ratio (SNR) of the heartbeat signal can be obtained by adding up the three AC component input signal, i.e. $y(t) = m_{ac1}(t) + m_{ac2}(t) + m_{ac3}(t)$.

[0061] When there is exercise motion the noise signals $z_1'(t)$, $z_2'(t)$, $z_3'(t)$ become dominated in the received signals 31, 32, 33. We can solve this problem by finding the column vector

$$\hat{w} = \begin{bmatrix} w_1 & w_2 & w_3 \end{bmatrix}^T$$
 such that $\hat{y} = \hat{w}^T M$

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where

$$M = \begin{bmatrix} m_{ac1}[0] & m_{ac1}[1] & \Lambda & \Lambda & m_{ac1}[K-1] \\ m_{ac2}[0] & m_{ac2}[1] & \Lambda & \Lambda & m_{ac2}[K-1] \\ m_{ac3}[0] & m_{ac3}[1] & \Lambda & \Lambda & m_{ac3}[K-1] \end{bmatrix} \text{ and } \hat{y} = \begin{bmatrix} y[0] & y[1] & \Lambda & y[K-1] \end{bmatrix}.$$

and \hat{y} is a linear combination of input signal which maximize :

$$5 \qquad \qquad \frac{\hat{w}^T \hat{s} \hat{s}^T \hat{w}}{\hat{w}^T \mathfrak{R}_{mm} \hat{w}}$$

where $\mathsf{R}_{\textit{mm}}$ is the cross correlation matrix of the 3 signals from motion.

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$$\hat{s} = \begin{bmatrix} s_1 & s_2 & s_3 \end{bmatrix}^T$$

15 is the corresponding gain of the heartbeat signal, in this case where all the 3 input channels are normalized.

$$\hat{s} = \begin{bmatrix} 1 & 1 & 1 \end{bmatrix}^T$$
 and $\mathfrak{R}_{mm} = \mathbf{M}\mathbf{M}^T - \sigma^2 \hat{s} \hat{s}^T$

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where σ^2 is the variance of the heartbeat signal. [0062] Since R_{mm} is positive definite, we can write :

$$\Re_{nm} = R^{\frac{1}{2}} \cdot R^{\frac{1}{2}}$$
 and we write $\hat{u} = R^{\frac{1}{2}} \hat{w}$

$$\hat{w} = R^{-\frac{1}{2}}\hat{u}$$

[0063] The problem becomes :

$$\max_{\|\hat{u}\|=1} \hat{u}^T R^{-\frac{1}{2}} \hat{s} \cdot \hat{s}^T R^{-\frac{1}{2}} \hat{u}$$

40 or

$$\max_{\|\hat{u}\|=1} (\hat{u}^{T} R^{-\frac{1}{2}} \hat{s})^{2}$$

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[0064] The expression is maximum when :

$$\hat{u} = R^{-\frac{1}{2}}\hat{s}$$

$$\therefore \hat{w} = R^{-\frac{1}{2}} (R^{-\frac{1}{2}} \hat{s}) = \Re_{mm}^{-1} \hat{s}$$

where

$$\Re_{nm} = \mathbf{M}\dot{\mathbf{M}}^T - \sigma^2 \hat{s}\hat{s}^T$$

⁵ [0065] The amplitude of 3 input heartbeat signal is normalized by calculating the variance (or standard deviation) of each channel when the user is not running.

[0066] Figure 15 schematically illustrates the processing of the sensor signals 31, 32, 33 to determine heartbeat. The following is a description of each block.

10 Block 71:

[0067] A simple Finite Input Response (FIR) low pass filter is used to remove all high frequency signals. Slow drifting DC offset is removed using a filter or a moving window to extract the DC offset and subtract back from the signal.

15 Block 72:

[0068] The signal amplitude of the heartbeat signal on each sensor is identified when there is no user motion. This is done by calculating the standard deviation of the 3 input signals when there is no motion. The 3 signal paths are then normalized.

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Block 73:

[0069] We then determine whether there is motion. The signal are check in the time domain. If the heartbeat signal dominates, all the 3 signals should be synchronous and in-phase. If the motion of the user is big enough, it is expected that the signal from motion dominates and sensor signals should not be all in phase. The correlation index across the three signals is calculated. The amplitude of the signal when compared with rest time signal amplitude is a clear indicator for motion.

[0070] If there is no motion the three signals are added together (with normalized amplitude) to improve the SNR.

[0071] If there is motion : e.g. running, the acquired signals are cut into blocks of length K for calculating the covariance matrix

$$\Re_{mm} = \mathbf{M}\mathbf{M}^T - \sigma^2 \hat{s} \hat{s}^T \,.$$

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 $\sigma^2 \hat{S} \hat{S}^{\mathsf{T}}$ can be obtained calculating the standard deviation of the 3 input signals when there is no motion. The 3 input signals are then normalized to having signal standard deviation of σ when there is no motion. Then $\sigma^2 \hat{S} \hat{S}^{\mathsf{T}}$ becomes

	1	1	1]
σ^2	1	1	1
	1	1	1

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[0072] We then calculate the vector :

$$w = \Re_{mm}^{-1} \hat{s}$$

All 3 channels are calibrated and normalized when there is no motion

w is a 3x1 column vector :

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 $\hat{y} = \hat{w}^T \mathbf{M}$

y[n] is a linear combination of the 3 input signals

the signal due to motion should be canceled out and preserve the heartbeat signal

[0073] The linear combination may also be done in frequency domain as well. The time domain waveform can be restored using an inverse Fast Fourier Transform (FFT). The signal y[n] should contain the heartbeat signal + noise.

Block 74

[0074] The heartbeat signal is detected using match filters in the time domain. The user's resting heartbeat rate signal can be recorded as templates. The corresponding heart rate of these templates can be calculated and recorded as well. For each range of the heart rate, a template is stored for each user. For the range where there is no recorded template a time wrapping approach is used to predict an approximate template. These templates are then used to build multiple matched filters for the user. The corresponding matched filter will be selected according to current heartbeat rate of the user.

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Block 76

[0075] The peaks of the matched filter output are detected and they are marked as the beat time. The inter-beat intervals are calculated and stored in a buffer.

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Block 77

[0076] Based on the current beat rate, an algorithm was implemented to detect missed and false alarm of the beats. In case of a miss or false alarm the inter-beat intervals will be modified accordingly to improve accuracy of the heart rate calculation.

Block 78

[0077] The heart rate is then calculated from the inter-beat intervals buffer.

[0078] In addition to detecting the heart beat signal, a method is employed to extract the motion signal from the sensor signals. When the user is running, each of the input signals is the sum of the heart beat signal and the motion signal. Figure 16 shows the three sensor signals before and after the user starts to jog or run. Prior to running the three heart beat signals are in phase and of the same amplitude. When the user starts to jog or run the motion signals amplitude varies a lot among the three sensor signals. To accurately detect the step rate instead of the heart rate, it is necessary to remove the heart beat signal from the sensor signals. Step detection is activated only when it is determined that the

user is running, which is described earlier. When user is running or jogging, the standard deviation of the three sensor signals is calculated for certain window width, typical 2 seconds. The standard deviation is use as a parameter representing the amplitude of the sensor signals. If the amplitude of the signal with the biggest amplitude is bigger than the rest time heart beat signal amplitude by certain ratio, in the preferred example 10, it is assumed that the motion signal completely dominates and this biggest emplitude signal is chosen as the motion signal, i.e.

$$y_{MOTION}(t) = m_{ac}_biggest(t)$$

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where $m_{ac-biggest}(t)$ is the input signal with biggest amplitude and the amplitude is bigger than the rest time heart beat signal by 10 times. If no sensor signal is ten times greater than the rest time heart beat signal, the standard deviation of the sensor signals are compared and ranked. The motion signals is the two biggest sensor signals minus two-times the smallest sensor signal, i.e.

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 $y_{MOTION}(t) = m_{ac} _ big_1(t) + m_{ac} _ big_2(t) - 2m_{ac} _ smallest(t)$

where $m_{ac_big1}(t)$, $m_{ac_big2}(t)$ are the 2 input signals with bigger amplitude and $m_{ac_smallest}(t)$ is the input signal with smallest amplitude.

[0079] The reason for this simple formulation is that all the three sensor signals should contain a heart beat signal components with substantial identical amplitude. The components due to heart beat signal should cancel out most of the heart beat signal. The resultant motion signal, $y_{MOTION}(t)$, is a large amplitude sinusoidal signal with good signal to noise ratio and thus a simple zero crossing method can be used to determine the step counts when user is running: Suitable zero crossing methods should be well known in the art. Figure 17 is a flow chart of this method.

[0080] In order to determine distance run the distance per step must be known for the particular user. This can be input manually by user if they know or can calculate their typical stride length, or the device can be put in to calibration

- ¹⁵ mode which requires the user to walk and run for a certain distance. Figure 18 shows the relationship of the step distance and the rate of steps. The data point will then be used to interpolate or extrapolate the cure of step distance versus rate of step. After the steps are detected, the rate of the step and the number of step will be calculated. The rate of steps will be used to estimate the distance traveled of each steps. The step distance is accumulated and will be recorded as the total workout distance traveled when the workout is finished.
- 20 [0081] The exercise device processes, displays and stores health related data, such as heart rate, blood oxygen level (Sp02), body temperature, steps walked or run, entered weight to calculate calories burned and body mass index (BMI). The user connects to the headphones that not only playback audio files but also simultaneously captures end users health related data inside the ear. The data is transferred to the portable entertainment device and workout assistant for processing, displaying/notifying and storing the data.
- ²⁵ [0082] The following various functions are available on the device. This is, however, not an exhaustive list and more or less features may be included in some embodiments.
 - [0083] Preferred features include;-
 - 1. Playback of the audio/video files stored on the device,
 - Determining and displaying the instantaneous heart rate and storing a heart rate profile during an exercise period.
 Storing and displaying the number of steps taken.
 - 4. Determining, displaying and storing the health related status of the end user, including temperature, blood oxygen level and other body parameters.
- 5. Providing visual and audio feedback of target exercise parameters and/or rates to help the end user optimize his physical activity - for example a pre approved beep as a sign to slow down, a pre approved different signal/sound for signaling end user to pick up the pace and a pre defined sound for providing signal on what percentage of the exercise has been completed.
 - 6. Transfer of date to a PC for further analysis, review or summary,
- 7. Providing visual and audio feedback, for example via pause or stop playback, if the device detects one or more
 of the ear buds is not capturing a heartbeat which mean a possible detach and resume playback after the device detects a heartbeat from one or both of the ear buds.

8. Providing visual and audio feedback of target exercise parameters by changing the tempo, pitch, equalizer according to the inputted vital sign so as to raise or reduce the workout intensity of the user sub-consciously - Figures 19 and 20 shows the block diagram of the way to implement the change of audio signal based on vital sign.

45 9. Providing visual and audio feedback of target exercise distance by changing the temp, pitch, equalizer according to the inputted step rate and distance traveled.

Claims

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- 1. A noninvasive light sensor for detecting heart beat signals, comprising:
 - a circular support member engageable circumferentially with a body part of a person,
 - a plurality of light emitters located about a circumference of the circular support member for emitting light signals into different areas of tissue surrounding the body part, and
 - a plurality of light detectors located about a circumference of the circular support member for receiving reflected light signals from the different areas of tissue surrounding the body part.

- 2. The noninvasive light sensor of claim 1 wherein plurality of light emitters consist of three light emitters located 120 degrees apart about the circumference of the support member.
- **3.** The noninvasive light sensor of claims 1 or 2 wherein the plurality of light detectors consist of three light detectors located 120 degrees apart about the circumference of the support member.
- 4. The noninvasive light sensor of any preceding claim wherein the light emitters and light detectors are located in pairs consisting of one of the emitters and one of the detectors.
- 10 5. The noninvasive light sensor of any preceding claim wherein the circular support member being an ear bud insertable with the an ear canal along an ear canal axis, wherein the plurality of light emitters are located about the periphery of the ear piece for emitting light signals perpendicular to the ear canal axis into the different areas of tissue surrounding the ear canal, and the plurality of light detectors are located about the periphery of the ear piece for receiving reflected light signals from the different areas of tissue surrounding the ear canal.
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- 6. The noninvasive light sensor of claim 5 wherein the ear piece is resiliently deformable for expansion within the ear canal, such that the ear piece is firmly locatable within the ear canal.
- 7. The noninvasive light sensor of claims 5 or 6 wherein the ear price comprises an inner layer and an outer layer having a plurality of openings, the light emitters and light detectors located within the outer layer openings.
- 8. The noninvasive light sensor of claim 7 wherein the openings have light absorbent sides surrounding the light emitters and light detectors, the sides defining a narrow gap above the light emitters and light detectors.
- **9.** The noninvasive light sensor of claim 1 wherein the support member comprising a band locatable about a wrist or arm, the emitters and detectors located around an inner circumference of the band for respectively emitting light signals into the different areas of arm tissue and receiving reflected light from the different areas of arm tissue.
 - **10.** A exercise system comprising:

an ear piece insertable within an ear canal along a canal axis, the ear piece having a plurality of light sensors and detectors, and a audio speaker,

- a computer readable storage medium have space allocated for storage of audio files,
- a vital sign monitor programmed to generating a vital sign signal from signals of the emitters and detectors, and an audio player programmed to playback audio files thought the audio speaker in response to the vital sign signal and to vary attributes of the playback audio files in response to the vital sign signal.
- **11.** The exercise system of claim 10 wherein the attributes of the playback audio files to be varied include one or more of beat, tempo, tone, pitch and the audio filed being played.
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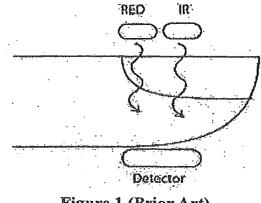
12. The exercise system of claims 10 or 11 wherein the vital sign monitor is programmed to generating a heart rate, blood oxygen or temperature signal.

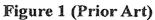
- **13.** A method of determining heart rate of a person during exercise comprising:
 - obtaining a plurality of sensor signals from multiple locations about a body part of a person, the sensor signals comprising a heart beat signals and a movement signals.
 - comparing the signals to separate the heart beat signals and a movement signals, and
 - determining heart rate from the heart beat signals.
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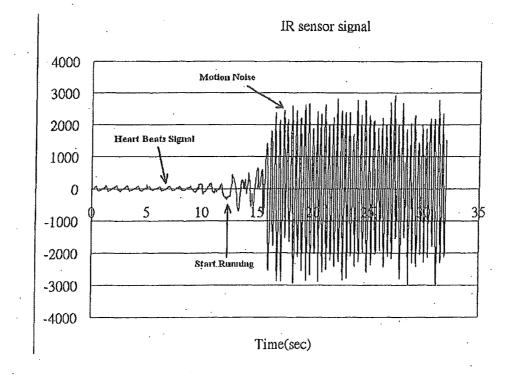
- **14.** The method of claim 13 wherein obtaining a plurality of sensor signals from locations comprises providing a plurality of heart beat sensors for positioning at multiple locations about the body part.
- **15.** The method of claims 13 or 14 wherein comparing the signals to separate the heart beat signals and a movement signals comprises comparing the sensor signals to find in phase and out of phase components of the sensor signals.
- **16.** The method of any one of claims 13 to 15 wherein comparing the signals to separate the heart beat signals and a movement signals comprises finding a covariance between the sensor signals.

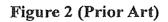
17. The method of any one of claims 13 to 16 wherein determining heart rate from the heart beat signals comprises using match filters.

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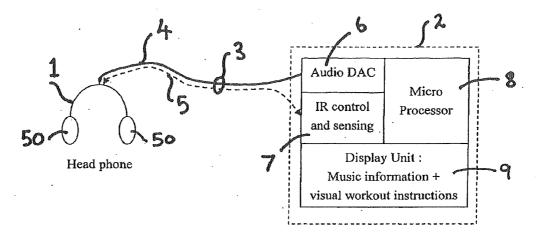
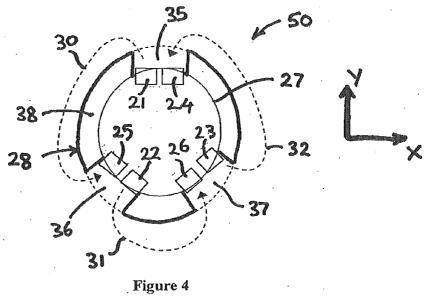


Figure 3



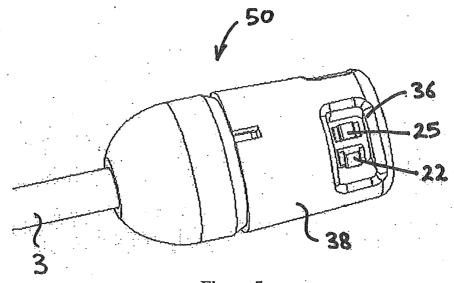


Figure 5

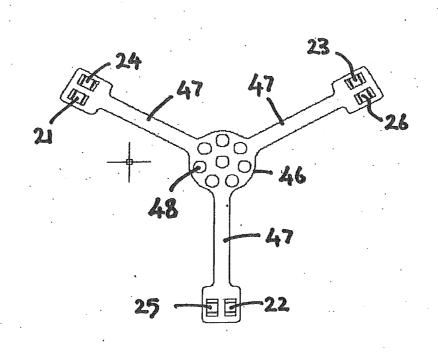


Figure 6

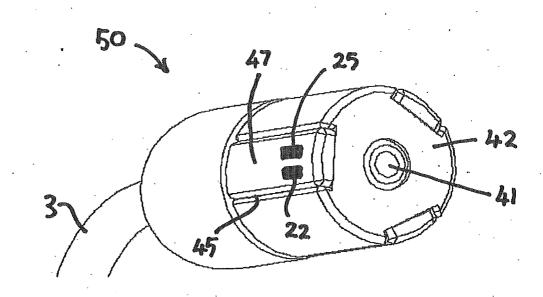
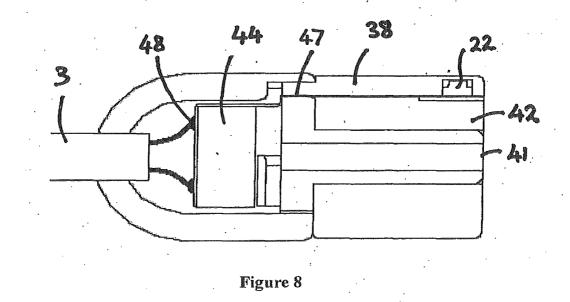
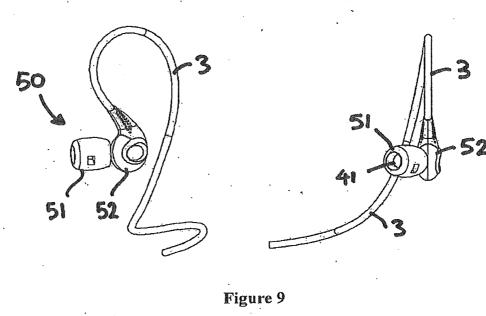


Figure 7





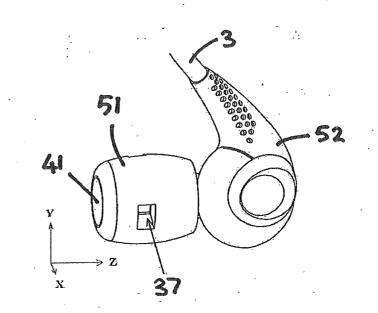


Figure 10

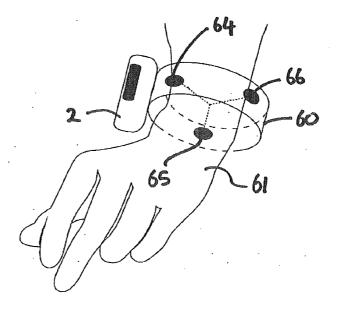


Figure 11

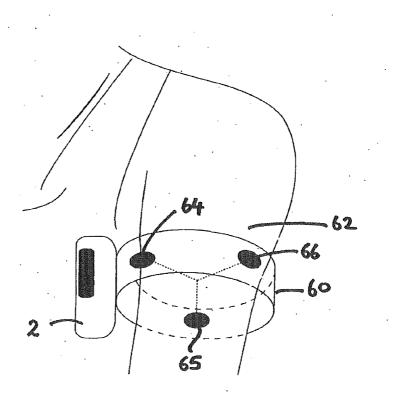


Figure 12

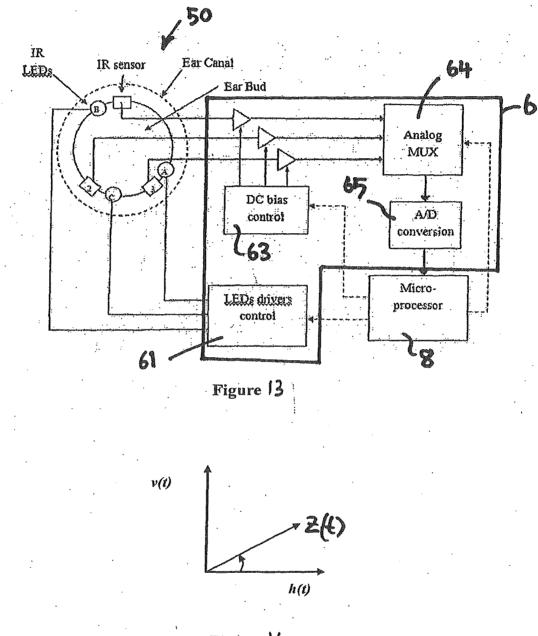
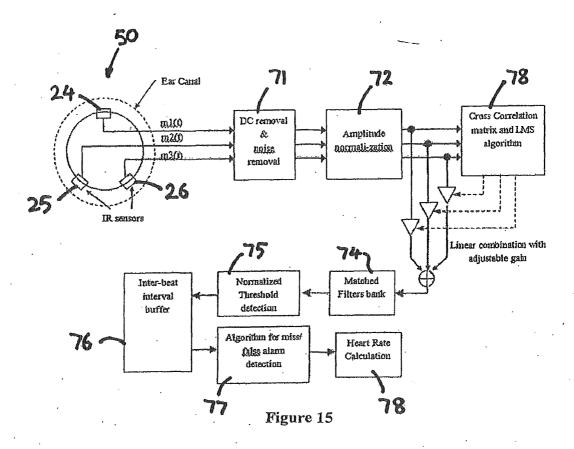


Figure 14,

EP 2 077 091 A2



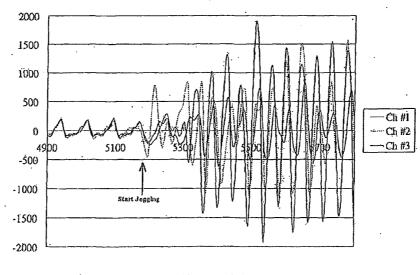


Figure 16

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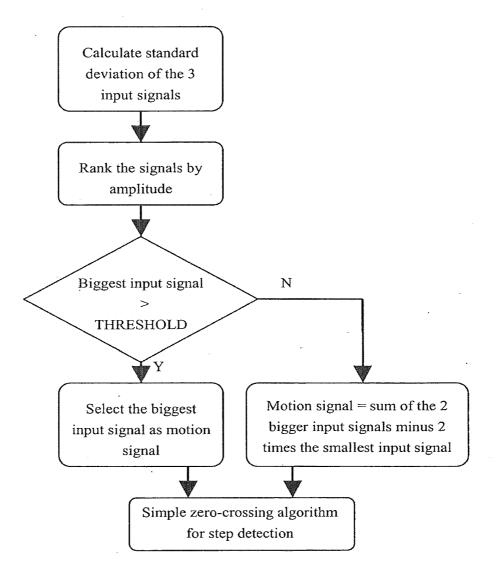


Figure 17

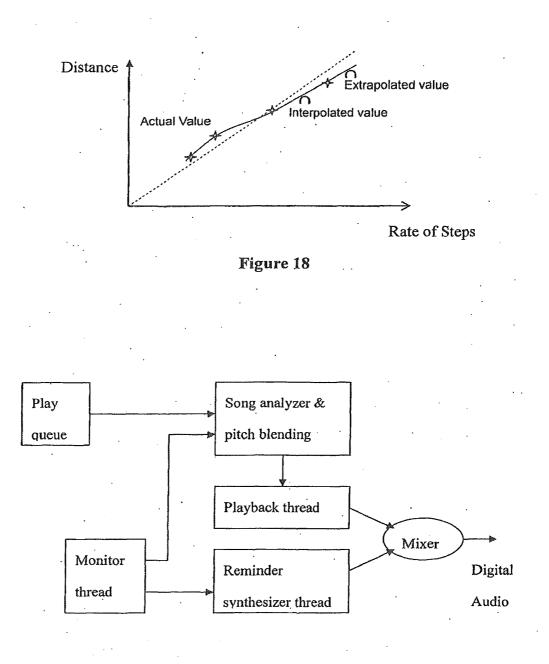


Figure 19

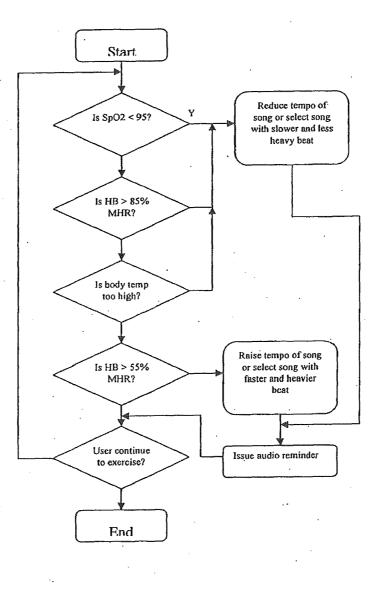


Figure 20

REFERENCES CITED IN THE DESCRIPTION

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Non-patent literature cited in the description

• M.R. Neuman; N. Wang. Motion Artifact in Pulse Oximetry. Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1990, vol. 12 (5 [0006]

Electronic Patent Application Fee Transmittal						
Application Number:	14	184364				
Filing Date:	19	Feb-2014				
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING					
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf					
Filer:	Needham J. Boddie/Susan E. Freedman					
Attorney Docket Number:	9653-7TSCT					
Filed as Large Entity	Filed as Large Entity					
Utility under 35 USC 111(a) Filing Fees						
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)	
Basic Filing:						
Pages:						
Claims:						
Miscellaneous-Filing:						
Petition:						
Patent-Appeals-and-Interference:						
Post-Allowance-and-Post-Issuance:						
Extension-of-Time:						

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
	Tot	al in USD	(\$)	180

Electronic Acl	Electronic Acknowledgement Receipt						
EFS ID:	19984984						
Application Number:	14184364						
International Application Number:							
Confirmation Number:	1023						
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING						
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf						
Customer Number:	20792						
Filer:	Needham J. Boddie/Susan E. Freedman						
Filer Authorized By:	Needham J. Boddie						
Attorney Docket Number:	9653-7TSCT						
Receipt Date:	27-AUG-2014						
Filing Date:	19-FEB-2014						
Time Stamp:	17:20:41						
Application Type:	Utility under 35 USC 111(a)						

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Deposit Acco	unt	500220	500220					
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Payment was	successfully received in RAM	\$180	\$180					
Payment Type	2	Deposit Account	Deposit Account					
Submitted wi	th Payment	yes						

1		9653-7TSCT_2014-08-27_IDS. pdf	324558 	yes	3		
	Multip	part Description/PDF files in .	zip description				
	Document De	scription	Start	E	nd		
	Transmittal Letter		1		2		
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Attorney Docket No. 9653-7TSCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

 In re: LeBoeuf et al.
 Confirmation No.: 1023

 Application No.: 14/184,364
 Examiner: Rodney Evan Fuller

 Filing Date: February 19, 2014
 Group Art Unit: 2852

 For:
 WEARABLE LIGHT GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

August 27, 2014

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Attached is an Information Disclosure Statement listing of documents, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with 37 C.F.R. § 1.98(a)(2)(ii).

In accordance with 37 CFR 1.97(b), the information disclosure statement is being filed:

- (1) within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
- (2) within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- (3) before the mailing of a first Office Action on the merits; or
- (4) before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

In accordance with **37 CFR 1.97(c)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(b) above, but before the mailing date of any of a final action under §1.113, a notice of allowance under §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by <u>one</u> of the following:

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; <u>or</u>

■ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; or

(2) The fee set forth in 1.17(p);

PATENT

In re: LeBoeuf et al. Application No.: 14/184,364 Filing Date: February 19, 2014 Page 2 of 2

In accordance with **37 CFR 1.97(d)**, the information disclosure statement is being filed after the period specified in 37 CFR 1.97(c) above, but on or before payment of the issue fee, and is accompanied by **both** of the following:

(1) The statement specified under **37 CFR 1.97(e)**, as follows:

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; <u>or</u>

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the information disclosure statement; and

 \boxtimes (2) The fee set forth in §1.17(p);

In accordance with **37 CFR 1.97(g)**, the information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with **37 CFR 1.97(h)**, the information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56(b).

The Director is hereby authorized to charge the fee specified in 37 C.F.R. § 1.17(p), and any fee deficiency or credit any overpayment, to Deposit Account No. 50-0220; or

☐ No fee is believed due. However, the Director is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted, Needham J. Boddie, II Registration No. 40,519 Attorney for Applicant 3

Customer Number 20792 Myers Bigel Sibley & Sajovec, P.A. P.O. Box 37428, Raleigh, NC 27627 919-854-1400 919-854-1401 (Fax)

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1,6(a)(4) to the U.S. Patent and Trademark Office on August 27, 2014.



UNITED STATES PATENT AND TRADEMARK OFFICE

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	www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20792 7590 09/05/2014 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627

EXAMINER	

FULLER, RODNEY EVAN

ART UNIT PAPER NUMBER

2852

DATE MAILED: 09/05/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023

TITLE OF INVENTION: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/05/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED</u>. 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 <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. <u>THIS STATUTORY PERIOD CANNOT BE EXTENDED</u>. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: <u>Mail</u> Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

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

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²⁰⁷⁹² 7590 09/05/2014 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627

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.

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023

TITLE OF INVENTION: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/05/2014
EXAN	IINER	ART UNIT	CLASS-SUBCLASS			
FULLER, RODNEY EVAN 2852		600-310000	-			
 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 		or agents OR, alternativ (2) The name of a single registered attorney or a	3 registered patent attorn	er a 2		

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

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

(A) NAME OF ASSIGNEE	
----------------------	--

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

4a. The following fee(s) are submitted:	4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)
Issue Fee	\Box A check is enclosed.
Publication Fee (No small entity discount permitted)	Payment by credit card. Form PTO-2038 is attached.
Advance Order - # of Copies	The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number (enclose an extra copy of this form).
5. Change in Entity Status (from status indicated above)	
Applicant certifying micro entity status. See 37 CFR 1.29	<u>NOTE:</u> Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
Applicant asserting small entity status. See 37 CFR 1.27	<u>NOTE:</u> If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
Applicant changing to regular undiscounted fee status.	<u>NOTE:</u> Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.
NOTE: This form must be signed in accordance with 37 CFR 1.31 an	d 1.33. See 37 CFR 1.4 for signature requirements and certifications.
Authorized Signature	Date
Typed or printed name	Registration No
	Page 2 of 3
PTOL-85 Part B (10-13) Approved for use through 10/31/2013.	OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FITBIT, Ex. 1002

	ted States Pate	NT AND TRADEMARK OFFICE	UNITED STATES DEPAR United States Patent and ' Address: COMMISSIONER F P.O. Box 1450 Alexandria, Virginia 223 www.uspto.gov	Frademark Office OR PATENTS
APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023
20792 75	90 09/05/2014		EXAM	INER
MYERS BIGEL PO BOX 37428	SIBLEY & SAJOVE	2C	FULLER, RO	DNEY EVAN
RALEIGH, NC 27	627		ART UNIT	PAPER NUMBER
			2852	
			DATE MAILED: 09/05/201	4

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

(Applications filed on or after May 29, 2000)

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

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

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

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

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

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

Privacy Act Statement

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

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

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

	Application No. 14/184,364	Applicant(s	
Notice of Allowability	Examiner	Art Unit	AIA (First Inventor to File) Status
,	RODNEY FULLER	2852	No
The MAILING DATE of this communication apper All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(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
1. This communication is responsive to <u>applicant's Amendmer</u> 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 requirement and election have been incorporated into this ac		ne interview on	; the restriction
 The allowed claim(s) is/are <u>1.2,4 and 6-13</u>. As a result of the Prosecution Highway program at a participating intellectual please see <u>http://www.uspto.gov/patents/init_events/pph/ind</u> 	I property office for the correspondin	g application. I	For more information,
4. Acknowledgment is made of a claim for foreign priority unde	er 35 U.S.C. § 119(a)-(d) or (f).		
Certified copies:			
 a) ☐ All b) ☐ Some *c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 2. ☐ Certified copies of the priority documents have 	been received in Application No.		
3. Copies of the certified copies of the priority doe	cuments have been received in this r	national stage a	application from the
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.		complying with	the requirements
5. CORRECTED DRAWINGS (as "replacement sheets") must	t be submitted.		
including changes required by the attached Examiner's Paper No./Mail Date	s Amendment / Comment or in the O	ffice action of	
Identifying indicia such as the application number (see 37 CFR 1, each sheet. Replacement sheet(s) should be labeled as such in th			(not the back) of
6. DEPOSIT OF and/or INFORMATION about the deposit of B attached Examiner's comment regarding REQUIREMENT FC			he
Attachment(s)			
1. I Notice of References Cited (PTO-892)	5. 🔲 Examiner's Amendr	ment/Commen	t
2. Information Disclosure Statements (PTO/SB/08),	6. 🔲 Examiner's Stateme	ent of Reasons	for Allowance
 Paper No./Mail Date <u>8/27/2014</u> 3. Examiner's Comment Regarding Requirement for Deposit of Biological Material 	7. 🗌 Other		
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date			
/RODNEY FULLER/			
Primary Examiner, Art Unit 2852			
U.S. Patent and Trademark Office			
	ice of Allowability	Part of Pape	r No./Mail Date 20140831

Receipt date: 08/18/2014

OK TO ENTER: /RF/

In re: LeBoeuf et al. Serial No. 14/184,364 Filed: February 19, 2014 Page 2

In the Title:

Please amend the Title of the application as follows:

-- WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING -- In re: LeBoeuf et al. Serial No. 14/184,364 Filed: February 19, 2014 Page 3

In the Specification:

Please amend the paragraph beginning on page 5, line 1 of the specification as follows:

-- In some embodiments, an earbud includes at least one lens in optical communication with the light transmissive material. Each lens may be configured to focus light from the optical emitter onto one or more predetermined locations in the ear of a subject and/or to focus collected external light onto the optical detector. --

Please amend the paragraph beginning on page 10, line 21 of the specification as follows:

-- Fig. 6 is a side section view of a light-guiding earbud for a headset, according to some embodiments of the present invention.[[.]] --

Receipt date: 08/18/2014

14184364 - GAU: 2852

OK TO ENTER: /RF/

RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITED PROCEDURE - EXAMINING GROUP 2852

Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.

Confirmation No.: 1023

Group Art Unit: 2852

Serial No.: 14/184,364

Filed: February 19, 2014

Examiner: Rodney Evan Fuller

For: WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING (As Amended)

Date: August 18, 2014

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

RESPONSE TO OFFICE ACTION OF AUGUST 14, 2014

Applicants provide the present Response to address the issues raised in the Final Office Action (the "Action") mailed August 14, 2014. Applicants provide the present Response pursuant to the rules stated in revised 37 C.F.R. 1.121 that became effective on July 30, 2003.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Amendments to the Title begin on Page 2 of this paper.

Amendments to the Specification begin on Page 3 of this paper.

Amendments to the claims begin on Page 4 of this paper.

Remarks begin on Page 7 of this paper.

				Co	Complete if Known			
				Application Number	14/184,364			
INFOR	MATION I	DISCLOSU	RE	Filing Date	02-19-2014			
STATEMENT BY APPLICANT			NT	First Named Inventor	Steven Francis LeBoeuf			
				Art Unit	2852			
(use as many sheets as necessary)		Examiner Name	Rodney Evan Fuller					
Sheet	C1	of	C1	Attorney Docket Number	9653-7TSCT			

				U.S. PATENT DOC	UMENTS	
Examiner Initials*	Cite No.	Nu	Document Number mber-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-	2012/0179011 A1	07-12-2012	Moon et al.	······································
	2.	US-	7,107,088 B2	09-12-2006	Aceti	
	3.	US-	6,358,216 B1	03-19-2002	Kraus et al.	
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	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document Country Code, Number, Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т		
	4.	EP 2 077 091 A2	07-08-2009	PERCEPTION DIGITAL LIMITED				
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	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	Т	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RF/

Examiner		Date	
Signature	/Rodney Fuller/	Considered	08/31/2014
*EXAMINER: Ini	tial if reference considered	whether or not citation is in conformance with	MPEP 609 Draw line through

*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.

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Search Notes	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED				
Symbol	Date	Examiner		

US CLASSIFICATION SEARCHED							
Class	Subclass	Date	Examiner				
600	310	8/31/2014	/RF/				

SEARCH NOTES		
Search Notes	Date	Examiner
600/301, 302, 310, 322, 323, 324 (w/ text search)	8/31/2014	/RF/
East text search history printout	8/31/2014	/RF/

INTERFERENCE SEARCH								
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner					
	Interference search printout	8/31/2014	/RF/					

	/RODNEY FULLER/ Primary Examiner.Art Unit 2852
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U.S. Patent and Trademark Office

Part of Paper No.: 20140831

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

CPC					
Symbol				Туре	Version
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A61B	5	1	1455	1	2013-01-01
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CPC Combination Sets							
Symbol			Туре	Set	Ranking	Version	

NONE	Total Claims Allowed:				
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/RODNEY FULLER/ Primary Examiner.Art Unit 2852	08/31/2014	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	22B		
U.S. Patent and Trademark Office		Part of Paper No. 20140831			

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

	US OR	IGINAL CL	GINAL CLASSIFICATION							INTERNATIONAL	CLA	SS	FIC	ΑΤΙ	ON
	CLASS			SUBCLASS					С	LAIMED			N	ION-	CLAIMED
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NONE		Total Claims Allowed:				
(Assistant Examiner)	(Date)	1	1			
/RODNEY FULLER/ Primary Examiner.Art Unit 2852	08/31/2014	O.G. Print Claim(s)	O.G. Print Figure			
(Primary Examiner)	(Date)	1	22B			
U.S. Patent and Trademark Office	nt and Trademark Office Part of Paper No. 20140					

	Application/Control No.	Applicant(s)/Patent Under Reexamination
Issue Classification	14184364	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

	Claims renumbered in the same order as presented by applicant							СР	A C] T.D.	[] R.1.	47		
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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NONE		Total Claims Allowed:			
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/RODNEY FULLER/ Primary Examiner.Art Unit 2852	08/31/2014	O.G. Print Claim(s)	O.G. Print Figure		
(Primary Examiner)	(Date)	1	22B		
U.S. Patent and Trademark Office Part of Paper No. 20140					

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	(("20120179011") or ("7107088") or ("6358216")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/08/31 11:47
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L4	39	3 and cladding	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/08/31 11:53
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L8	19	("2010/0298653").URPN.	USPAT	OR	ON	2014/08/31 11:55
L9	7	("2010/0217103").URPN.	USPAT	OR	ON	2014/08/31 11:55
L10	3	("2010/0168531").URPN.	USPAT	OR	ON	2014/08/31 11:55
L11	38	("2006/0009685").URPN.	USPAT	OR	ON	2014/08/31 11:55
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L13	127	("2004/0054291").URPN.	USPAT	OR	ON	2014/08/31 11:56

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EAST Search History

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L19	32	18 and cladding	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/31 11:57
L20	24	19 and (aperture or window)	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/31 11:57
L21	10	20 and cylindrical	US-PGPUB; USPAT; USOCR	OR	ON	2014/08/31 11:57
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EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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Attorney Docket No.: 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.Confirmation No.: 1023Serial No.: 14/184,364Group Art Unit: 2852Filed: February 19, 2014Examiner: Fuller, Rodney Evan

For: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

September 10, 2014

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

AMENDMENT AFTER NOTICE OF ALLOWANCE PURSUANT TO 37 CFR 1.312

This Amendment is responsive to the "Notice of Allowance and Fee(s) Due" mailed September 5, 2014. Applicants provide the present Response pursuant to the rules stated in revised 37 C.F.R. 1.121 that became effective on July 30, 2003.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Amendments to the Title begin on Page 2 of this paper. Remarks begin on Page 3 of this paper. In re: LeBoeuf *et al.* Serial No.: 14/184,364 Filed: February 19, 2014 Page 2 of 3

In the Title:

Please amend the title as follows:

WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

In re: LeBoeuf *et al.* Serial No.: 14/184,364 Filed: February 19, 2014 Page 3 of 3

REMARKS

The present Amendment is being filed to assure that the correct title is used on the issued patent for the above-identified application. In particular, the title was amended as noted above in the Response to Office Action of August 14, 2014, as filed on August 18, 2014, yet the Notice of Allowance contains an incorrect title. Accordingly, Applicants respectfully request entry of this Amendment and issuance of the present application with the correct title.

Respectfully submitted,

Bodd I

Needham J. Boddie, II Attorney for Applicants Registration No. 40,519

USPTO Customer No. 20792 Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, North Carolina 27627

Telephone: (919) 854-1400 Facsimile: (919) 854-1401

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 CFR 1.6(a)(4) to the U.S. Patent and Trademark Office on September 10, 2014.

Name: Candi L. Riggs

Electronic Acl	knowledgement Receipt
EFS ID:	20102895
Application Number:	14184364
International Application Number:	
Confirmation Number:	1023
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Candi Riggs
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT
Receipt Date:	10-SEP-2014
Filing Date:	19-FEB-2014
Time Stamp:	17:02:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted wi	th Payment	no	no				
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Document Number	Document Description	File Name File Size(Bytes)/ Multi Message Digest Part /.zip					
1		AmendmentAfterAllowance.	172364	yes	з		
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	Amendment after Notice of Allowance (Rule 312)	1	1			
	Specification	2	2			
	Applicant Arguments/Remarks Made in an Amendment	3	3			
Warnings:		1 1				

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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

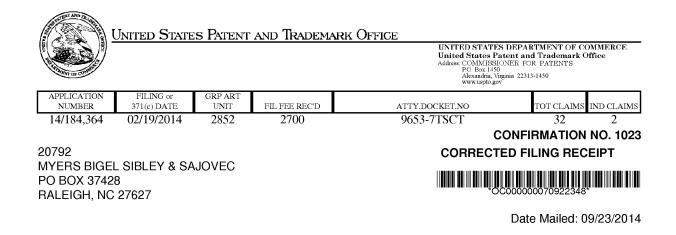
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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.



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)

Steven Francis LeBoeuf, Raleigh, NC; Jesse Berkley Tucker, Knightdale, NC; Michael Edward Aumer, Raleigh, NC;
Applicant(s)
Valencell, Inc., Raleigh, NC
Assignment For Published Patent Application
Valencell, Inc., Raleigh, NC
Power of Attorney: The patent practitioners associated with Customer Number 20792

Domestic Priority data as claimed by applicant

This application is a CON of 12/691,388 01/21/2010 PAT 8700111 which claims benefit of 61/208,567 02/25/2009 and claims benefit of 61/208,574 02/25/2009 and claims benefit of 61/212,444 04/13/2009 and claims benefit of 61/274,191 08/14/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <u>http://www.uspto.gov</u> 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 - A proper Authorization to Permit Access to Application by Participating Offices (PTO/SB/39 or its equivalent) has been received by the USPTO.

page 1 of 3

If Required, Foreign Filing License Granted: 03/07/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/184,364**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No Title

WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING

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).

page 2 of 3

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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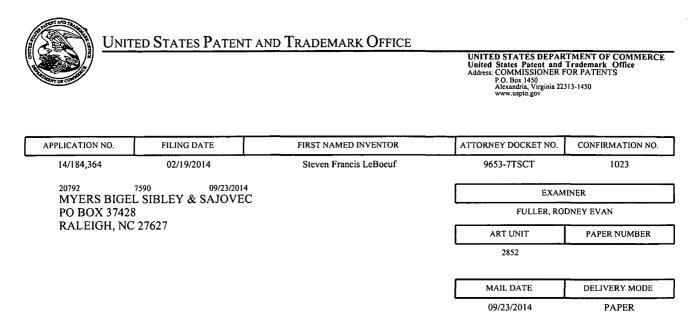
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page 3 of 3



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.

e sur d'an an a	Application No.	Applicant(s)
	14/184,364	
Response to Rule 312 Communication	Examiner	Art Unit
The MAILING DATE of this communication a	appears on the cover sheet	with the correspondence address –
. ⊠ The amendment filed on <u>10 September 2014</u> under 37 a) ⊠ entered.	CFR 1.312 has been conside	red, and has been:
b) 🔲 entered as directed to matters of form not affectin	g the scope of the invention.	
c) disapproved because the amendment was filed a Any amendment filed after the date the issue f and the required fee to withdraw the applicatio	ee is paid must be accompan	
d) 🔲 disapproved. See explanation below.		
e) 🔲 entered in part. See explanation below.		
PUBLISHING DIVISION		
	·····	
Patent and Trademark Office DL-271 (Rev. 04-01) Reponse to R	ule 312 Communication	Part of Paper No.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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

7590 MYERS BIGEL SIBLEY & SAJOVEC

20792

PO BOX 37428 RALEIGH, NC 27627 09/05/2014

Commissioner	for	Pat	tent	k
DO D 1450				

P.O. Box 1450 Alexandria, Virginia 22313-1450 or <u>Fax</u> (571)-273-2885

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(8) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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

(Depositor's nam	ne)
(Signatu	ire)
(Da	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	02/19/2014	Steven Francis LeBoeuf	9653-7TSCT	1023

TITLE OF INVENTION: WEARABLE LIGHT-GUIDING BANDS AND PATCHES FOR PHYSIOLOGICAL MONITORING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/05/2014
EXAN	IINER	ART UNIT	CLASS-SUBCLASS	1		
FULLER, RO	DNEY EVAN	2852	600-310000		7	
 Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 			or agents OR, alternativ	3 registered patent attor	neys -	el Sibley & Sajovec
			THE PATENT (print or typ			
PLEASE NOTE: Un recordation as set for	less an assignee is ident th in 37 CFR 3.11. Com	ified below, no assignee pletion of this form is NC	data will appear on the p T a substitute for filing an	atent. If an assignee is id assignment.	dentified below, the doc	ument has been filed for
(A) NAME OF ASSI				and STATE OR COUNT		
Valencell, Ir	IC.		Raleigh, NC			
Please check the approp	rlate assignee category or	categories (will not be p	rinted on the patent) :	Individual 🗴 Corporat	ion or other private group	entity Government
	are submitted: No small entity discount j # of Copies	permitted)	 b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo 	use first reapply any prev d. Form PTO-2038 is atta v authorized to charge the sit Account Number <u>50–</u>	ched.	
5. Change in Entity Sta	tus (from status indicate	d above)				
Applicant certifyi	ng micro entity status. Se	ee 37 CFR 1.29	<u>NOTE:</u> Absent a valid ce	rtification of Micro Entity entity amount will not be	Status (see forms PTO/	SB/15A and 15B), issue
Applicant assertir	g small entity status. See	37 CFR 1.27		was previously under mic s of entitlement to micro e		
Applicant changing	ng to regular undiscounte	d fee status.		x will be taken to be a not		
NOTE: This form must	be signed in accordance v	with 37 CFR 1.31 and 1.3	3. See 37 CFR 1.4 for sign	ature requirements and ce	rtifications.	
Authorized Signature	_ 27	Boddi I		DateOctober 6	<u>, 2</u> 014	
Typed or printed nam	eNeedham J. Bo	oddie, II		Registration No.	40,519	
<u></u>	<u>, , , , , , , , , , , , , , , , , , , </u>		Page 2 of 3			

PTOL-85 Part B (10-13) Approved for use through 10/31/2013.

OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal								
Application Number:	14	184364						
Filing Date:	19	-Feb-2014						
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING							
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf							
Filer:	Needham J. Boddie/Candi Riggs							
Attorney Docket Number:	96:	53-7TSCT						
Filed as Large Entity								
Utility under 35 USC 111(a) Filing Fees								
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:	Post-Allowance-and-Post-Issuance:							
Utility Appl Issue Fee		1501	1	960	960			
Extension-of-Time:								

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
	Total in USD (\$) 9			

Electronic Acknowledgement Receipt					
EFS ID:	20336123				
Application Number:	14184364				
International Application Number:					
Confirmation Number:	1023				
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING				
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf				
Customer Number:	20792				
Filer:	Needham J. Boddie/Candi Riggs				
Filer Authorized By:	Needham J. Boddie				
Attorney Docket Number:	9653-7TSCT				
Receipt Date:	06-OCT-2014				
Filing Date:	19-FEB-2014				
Time Stamp:	14:31:29				
Application Type:	Utility under 35 USC 111(a)				

Payment information:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)			
File Listing:								
Authorized U	ser							
Deposit Acco	unt	500220	500220					
RAM confirma	ation Number	705						
Payment was	successfully received in RAM	\$960	\$960					
Payment Type	2	Deposit Account	Deposit Account					
Submitted wi	th Payment	yes	yes					

		Total Files Size (in bytes):	15	34786	
Information:					
Warnings:					
2			3621674d888538d632ac9bc59cdedac188c 29c60		
2	Fee Worksheet (SB06)	fee-info.pdf	30869	no	2
Information:					
Warnings:					
I	issue ree rayment (rro osb)	pdf	4cb91a963c5b168bc1fcbcd3539fe38e5925 d22c	no	
1	Issue Fee Payment (PTO-85B)	9653-7TSCT_FeesTransmittal.	153917	no	1

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.

				Complete if Known				
				Application Number	To Be Assigned			
INFORMATION DISCLOSURE				Filing Date	Concurrently Herewith			
STATEMENT BY APPLICANT			NT	First Named Inventor	Steven Francis LeBeouf			
				Art Unit				
(use as i	(use as many sheets as necessary)		Examiner Name					
Sheet	A1	of	A2	Attorney Docket Number	9653-7TSCT			

Examiner	Cite		Document Number	U.S. PATENT DOC Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.	Number-Kind Code (if known)		- MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevan Figures Appear
	1.	US-	2013/0131519	05-2013	LeBoeuf et al.	·
	2.	US-	2012/0197093	08-2012	LeBoeuf et al.	
	3.	US-	2011/0105869 A1	05-2011	Wilson et al.	
	4.	US-	2009/0287067 A1	11-2009	Dorogusker et al.	
	5.	US-	2009/0270698 A1	10-2009	Shioi et al.	
	6.	US-	2009/0105556 A1	04-2009	Fricke et al.	
	7.	US-	2009/0054752 A1	02-2009	Jonnalagadda et al.	
	8.	US-	2009/0030350 A1	01-29-2009	Yang et al.	
	9.	US-	2008/0177162 A1	07-2008	Bae et al.	
	10.		2008/0165017 A1	07-2008	Schwartz	
	11	US-	2008/0096726 A1	04-2008	Riley et al.	
	12	US-	2008/0076972 A1	03-2008	Dorogusker et al.	
	13		2006/0009685	01-12-2006	Finarov et al.	
	14	US-	2005/0228299	10-13-2005	Banet	
	15	US-	2005/0209516	09-22-2005	Fraden	
	16	US-	2005/0177034 A1	08-2005	Beaumont	
	17	US-	8,512,242 B2	08-2013	LeBoeuf et al.	
	18	US-	8,251,903 B2	08-2012	LeBoeuf et al.	
	19	US-	8,055,319 B2	11-2011	Oh et al.	
	20		7,209,775 B2	04-2007	Bae et al.	
	21		6,859,658 B1	02-2005	Krug	
	22	US-	6,808,473 B2	10-2004	Hisano et al.	
	23		6,371,925 B1	04-2002	Imai et al.	
()	. 1 24		6,783,501 B2	08-31-2001	Takahashi et al.	August 31, 2004
g e(s) app			6,080,110 A	06-2000	Thorgersen	
cument,	26	US-	6,078,829 A	06-2000	Uchida et al.	

/M.I.G./

1

·٢	FOREIGN PATENT DOCUMENTS										
	Examiner Initials*			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear					
		27	WO 2013/038296 A1	03-21-2013	KONINKLIJKE PHILIPS ELECTRONICS N.V.						
Γ		28	JP 2007-185348	07-26-2007	OLYMPUS CORP						
ſ		29	JP 2001-025462	01-30-2001	DENSO CORP						

Examiner Signature	/Rodney Fuller/	Date Considered	03/26/2014				
*EXAMINED, Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through							

*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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RF/



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/184,364	11/11/2014	8886269	9653-7TSCT	1023

20792 7590 10/22/2014 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627

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):

Valencell, Inc., Raleigh, NC, Assignee (with 37 CFR 1.172 Interest); Steven Francis LeBoeuf, Raleigh, NC; Jesse Berkley Tucker, Knightdale, NC; Michael Edward Aumer, Raleigh, NC;

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)

Attorney Docket No. 9653-7TSCT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al.U.S. Patent No.: 8,886,269Application No.: 14/184,364Issued: November 11, 2014Filed: February 19, 2014Confirmation No. 1023For: WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING

January 6, 2015

Commissioner for Patents Attn: Certificate of Correction Branch P.O. Box 1450 Alexandria, VA 22313-1450

REQUEST FOR ENTRY OF CERTIFICATE OF CORRECTION UNDER 35 U.S.C. §254 AND 37 C.F.R. §1.322 AND 35 U.S.C. §255 AND 37 C.F.R. §1.323

Sir:

The Applicant(s) of record for the above-referenced patent hereby requests, pursuant to 35 U.S.C. §254 and 37 C.F.R. §1.322 and 35 U.S.C. §255 and 37 C.F.R. §1.323, that a Certificate of Correction be issued. This request is made in order to correct the mistake(s) incurred through both the fault of the Applicant(s) and the U.S. Patent and Trademark Office. A fee in the amount of \$100.00 as set forth under 37 CFR §1.20(a) is submitted herewith. This amount is believed to be correct; however, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account 50-0220.

The mistakes appearing in the patent are set forth with corrections on the Certificate of Correction enclosed herewith.

Respectfully submitted,

Needham J. Boddie, II Registration No. 40,519

Customer No.: 20792 Myers Bigel Sibley & Sajovec, P.A. P. O. Box 37428, Raleigh, NC 27627 Telephone: (919) 854-1400 Facsimile: (919) 854-1401

CERTIFICATION OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 1.6(a)(4) to the U.S. Patent and Trademark Office on January 6, 2015.

Lonoro Cathy L Leonard

PTO/SB/44 (09-07) Approved for use through 08/31/2010. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. (Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO.:	8,886,269
APPLICATION NO.:	14/184,364
ISSUE DATE:	November 11, 2014
INVENTOR(S):	LeBoeuf et al.

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

On Title Page: Abstract, Line 3:

Please correct "The band includes comprises" to read -- The band includes --

In the Patent:

Column 1, Line 3: Please correct "U.S. Patent No. 8,7000,111," to read -- U.S. Patent No. 8,700,111, --

In the Claims: Column 30, Claim 1, Lines 36 and 37: Please correct "outer inner surface;" to read -- outer and inner surfaces; --

Column 31, Claim 11, Line 30: Please correct "by the optical detector." to read -- by the first optical detector. --

MAILING ADDRESS OF SENDER: Myers, Bigel, Sibley & Sajovec P.O. Box 37428 Raleigh, NC 27627

Electronic Patent Application Fee Transmittal							
Application Number:	14	184364					
Filing Date:	19-	Feb-2014					
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING						
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf						
Filer:	Needham J. Boddie/Cathy Leonard						
Attorney Docket Number:	96	53-7TSCT					
Filed as Large Entity							
Filing Fees for Utility under 35 USC 111(a)							
Description		Fee Code	Quantity	Amount	Sub-Total in USD(\$)		
Basic Filing:							
Pages:							
Claims:							
Miscellaneous-Filing:							
Petition:							
Patent-Appeals-and-Interference:							
Post-Allowance-and-Post-Issuance:							
Certificate of Correction		1811	1	100	100		

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

Electronic Acknowledgement Receipt				
EFS ID:	21131529			
Application Number:	14184364			
International Application Number:				
Confirmation Number:	1023			
Title of Invention:	WEARABLE LIGHT-GUIDING BANDS FOR PHYSIOLOGICAL MONITORING			
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf			
Customer Number:	20792			
Filer:	Needham J. Boddie/Cathy Leonard			
Filer Authorized By:	Needham J. Boddie			
Attorney Docket Number:	9653-7TSCT			
Receipt Date:	06-JAN-2015			
Filing Date:	19-FEB-2014			
Time Stamp:	14:56:52			
Application Type:	Utility under 35 USC 111(a)			

Payment information:

Submitted with Payment	yes			
Payment Type	Deposit Account			
Payment was successfully received in RAM	\$100			
RAM confirmation Number	1149			
Deposit Account	500220			
Authorized User				
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:				

File Listing:									
Document Number	Document Description	File Name	File Name File Size(Bytes)/ Message Digest		Pages (if appl.)				
1 Request for Certificate of Correction	Request for Certificate of Correction	9653-7TSCT_Request_for_COC.	170140	no	2				
	pdf	df67584cbf0b28cfeca4e7fd187a0ef249769 52c		<u>ح</u>					
Warnings:									
Information:									
2 Fee Worksheet (SB06)	fee-info.pdf	30781	no	2					
		74bbcd1e587a868aa462cbe73bb510c6872 d6d56							
Warnings:									
Information:									
		Total Files Size (in bytes)	200921						

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 CERTIFICATE OF CORRECTION

 PATENT NO.
 : 8,886,269 B2

 APPLICATION NO.
 : 14/184364

 DATED
 : November 11, 2014

 INVENTOR(S)
 : LeBoeuf et al.

Page 1 of 1

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

<u>On Title Page:</u> Abstract, Line 3: Please correct "The band includes comprises" to read -- The band includes --

In the Specification: Column 1, Line 3: Please correct "U.S. Patent No. 8,7000,111," to read -- U.S. Patent No. 8,700,111, --

In the Claims: Column 30, Claim 1, Lines 36 and 37: Please correct "outer inner surface;" to read -- outer and inner surfaces; --

Column 31, Claim 11, Line 30: Please correct "by the optical detector." to read -- by the first optical detector. --

> Signed and Sealed this Thirty-first Day of March, 2015

Michelle K. Lee

Michelle K. Lee Director of the United States Patent and Trademark Office