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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 1 of 2

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

**Express Mail Label No.** _____

## INVENTOR(S)

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| | | |
| | | |

Additional inventors are being named on the _____ separately numbered sheets attached hereto.

## TITLE OF THE INVENTION (500 characters max):

Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☑ The address corresponding to Customer Number: 20792

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## ENCLOSED APPLICATION PARTS (*check all that apply*)

☐ Application Data Sheet. See 37 CFR 1.76.
☐ CD(s), Number of CDs _____
☑ Drawing(s) *Number of Sheets* 18
☐ Other (specify) _____
☑ Specification (e.g., description of the invention) *Number of Pages* 29

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HIMPP 1031
IPR2023-01205
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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET – Page 2 of 2

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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SIGNATURE _____ DATE February 2, 2015

TYPED OR PRINTED NAME Needham J. Boddie, II REGISTRATION NO. 40,519 (*if appropriate*)

TELEPHONE 919-854-1400 DOCKET NUMBER 9653-30PR2

# METHODS AND APPARATUS FOR IMPROVING SIGNAL QUALITY IN WEARABLE BIOMETRIC MONITORING DEVICES

## FIELD OF THE INVENTION

The present invention relates generally to monitoring devices and, more particularly, to monitoring devices for measuring physiological information.

## BACKGROUND OF THE INVENTION

Photoplethysmography (PPG) is based upon shining light into the human body and measuring how the scattered light intensity changes with each pulse of blood flow. The scattered light intensity will change in time with respect to changes in blood flow or blood opacity associated with heart beats, breaths, blood oxygen level ($SpO_2$), and the like. Such a sensing methodology may require the magnitude of light energy reaching the volume of flesh being interrogated to be steady and consistent so that small changes in the quantity of scattered photons can be attributed to varying blood flow. If the incidental and scattered photon count magnitude changes due to light coupling variation between the source or detector and the skin or other body tissue, then the signal of interest can be difficult to ascertain due to large photon count variability caused by motion artifacts. Changes in the surface area (and volume) of skin or other body tissue being impacted with photons, or varying skin surface curvature reflecting significant portions of the photons may also significantly impact optical coupling efficiency. Physical activity, such as walking, cycling, running, etc., may cause motion artifacts in the optical scatter signal from the body, and time-varying changes in photon intensity due to motion artifacts may swamp-out time-varying changes in photon intensity due to blood flow changes. Environmental artifacts, such as ambient light noise, as well as motion-coupled ambient light

noise can further swamp-out blood-flow related signals. Each of these changes in optical coupling can dramatically reduce the signal-to-noise ratio (S/N) of biometric PPG information to total time-varying photonic interrogation count. This can result in a much lower accuracy in metrics derived from PPG data, such as heart rate and breathing rate.

The signal quality from a biometric sensors, such as a PPG sensor, in a wearable monitoring device increases when the monitoring device is worn correctly and decreases when the monitoring device is worn incorrectly. For example, a user may go for a run with a biometric earbud and expect accurate heart rate zone information from the sensor(s) therein, only to find the sensor data is erroneous due to a poor fitting of the biometric earbud within the ear. Unfortunately, without some way to measure signal quality, a user may not know if sensor signal quality is adequate.

## 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 wearable biometric monitoring device is configured to assess the biometric signal quality of one or more sensors associated with the biometric monitoring device, determine how the user should adjust the device to improve the biometric fit, and instruct the user to wear the device a certain way (e.g., audio-visually via a remote device). In some embodiments, this may involve an iterative approach. In some embodiments, communicating instructions to a user may include instructing the user to execute a testing regimen while wearing the device. The testing regimen facilitates an estimation of a signal quality that can be used to provide feedback to the user that he/she needs to adjust the device to improve the biometric fit (and hence the biometric signal quality).

According to some embodiments of the present invention, a method of monitoring signal quality of a wearable biometric monitor having at least one sensor configured to detect and/or measure physiological information

from a subject wearing the biometric monitor and at least one processor in communication with the at least one sensor that is configured to receive and analyze signals produced by the at least one sensor includes instructing the subject via the at least one processor to begin an exercise regimen, measuring signal quality produced by the at least one sensor during the exercise regimen, and communicating information to the subject regarding the signal quality during the exercise regimen. In some embodiments, the biometric monitor is configured to be integrated within an earbud. In some embodiments, the biometric monitor is configured to be integrated within an audio headset, a wrist strap, a wrist watch, an ankle bracelet, or an armband. In other embodiments, the biometric monitor comprises a band that configured to at least partially encircle a portion of the body of a subject, such as a limb, a nose, an earlobe, and/or a digit, etc.

In some embodiments, instructing the subject to begin an exercise regimen comprises sending an audio and/or visual communication to a remote device in communication with the biometric monitor. In other embodiments, instructing the subject to begin an exercise regimen comprises causing the biometric monitor and/or a remote device to vibrate.

Communicating information to the subject regarding the signal quality may include communicating instructions to the subject to adjust the biometric monitor relative to the body of the subject if the signal quality is below a threshold level. Communicating information to the subject regarding the signal quality also may include communicating information to the subject that the signal quality is above a threshold level.

In some embodiments, communicating information to the subject regarding the signal quality comprises sending an audio and/or visual communication to a remote device in communication with the biometric monitor. In other embodiments, communicating information to the subject regarding the signal quality comprises causing the biometric monitor and/or a remote device to vibrate.

In some embodiments, the biometric monitor includes an actuator, and the method further comprises automatically adjusting the biometric monitor relative to the body of the subject via the actuator if the signal quality is below a threshold level.

In some embodiments, the biometric monitor includes a motion

sensor, and the method further comprises determining if the subject has begun the exercise regimen by detecting a change in subject activity via the motion sensor.

In some embodiments, the biometric monitor includes a motion sensor, and the method further comprises determining if the subject is wearing the biometric monitor by determining if body motion over a period of time is above a threshold.

According to some embodiments of the present invention, a method of generating a physiological assessment of a subject includes collecting physiological information and/or motion information from the subject via at least one wearable device having at least one physiological sensor and/or at least one motion sensor, determining a quality level for the physiological information and/or motion information at one or more selected times during the period of time, and generating a physiological assessment for the subject using the physiological information and/or motion information at the one or more selected times that has a quality level above a threshold level.

According to some embodiments of the present invention, a method of generating a physiological assessment of a subject includes collecting physiological information and/or motion information from a subject via at least one wearable device having at least one physiological sensor and/or at least one motion sensor, determining one or more time periods when the wearable device is being worn by the subject, and generating a physiological assessment for the subject using the physiological information and/or motion information obtained during the one or more time periods when the wearable device is being worn by the subject.

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 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 a block diagram of a wearable biometric monitoring device that can communicate with a remote device, such as a smartphone, according to some embodiments of the present invention.

Figs. 2A-2B illustrate a biometric monitoring device that can be positioned within an ear of a subject, according to some embodiments of the present invention.

Fig. 3A illustrates a biometric monitoring device that can be positioned around an appendage of the body of a subject, according to some embodiments of the present invention.

Fig. 3B is a cross sectional view of the biometric monitoring device of Fig. 3A.

Fig. 4 is a flowchart of operations for monitoring and improving signal quality of a wearable biometric monitor, according to some embodiments of the present invention.

Figs. 5A-5B, 6A-6B, 7A-7B and 8A-8B illustrate communications sent to a user in the form of graphical illustrations, according to some embodiments of the present invention.

Fig. 9 is a graphical illustration of a time-domain PPG waveform produced by a wearable biometric monitoring device according to some embodiments of the present invention and where there are negligible motion artifacts associated with the waveform.

Fig. 10 is a graphical illustration of a time-domain PPG waveform produced by a wearable biometric monitoring device according to some embodiments of the present invention and where there are substantial motion artifacts associated with the waveform.

Fig. 11A illustrates an exemplary spectrogram of a PPG signal from a user wearing a biometric monitoring device according to some embodiments of the present invention and without active motion noise removal.

Fig. 11B illustrates the removal of motion noise from the

spectrogram of Fig. 11A via one or more filters.

Fig. 12 is an exemplary plot of signal quality Qs over time for an exemplary run by a user wearing a biometric monitoring device according to some embodiments of the present invention.

Fig. 13 is a plot of signal quality Qs over time for a user conducting a self-fitting test, according to some embodiments of the present invention.

Fig. 14 is a plot of signal quality Qs over time for a user conducting an instructed "quick test" regimen, according to some embodiments of the present invention.

Fig. 15 is a flowchart of operations for generating biometric assessments of subjects wearing a biometric monitor, according to some embodiments of the present invention.

Fig. 16 illustrates heart rate data over time produced by both high quality and low quality sensor signals.

Fig. 17 is a plot of HRR (Heart Rate Recovery) over time for a user and also includes information about the confidence of HRR score for each data point.

Fig. 18 is a flowchart of operations for generating biometric assessments of subjects only when a biometric monitor is being worn, 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.

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 also be understood that, when a feature or element is referred to as being "secured", "connected", "attached" or "coupled" to another feature or element, it can be directly secured, 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 secured", "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.

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.

As used herein, the terms "comprise", "comprising", "comprises", "include", "including", "includes", "have", "has", "having", or variants thereof are open-ended, and include one or more stated features, integers, elements, steps, components or functions but does not preclude the presence or addition of one or more other features, integers, elements, steps, components, functions or groups thereof. Furthermore, as used herein, the common abbreviation "e.g.", which derives from the Latin phrase "exempli gratia," may be used to introduce or specify a general example or examples of a previously mentioned item, and is not intended to be limiting of such item. The common abbreviation "i.e.", which derives from the Latin phrase "id est," may be used to specify a particular item from a more general recitation.

As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

As used herein, phrases such as "between X and Y" and "between about X and Y" should be interpreted to include X and Y. As used herein,

phrases such as "between about X and Y" mean "between about X and about Y." As used herein, phrases such as "from about X to Y" mean "from about X to about Y."

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 specifically indicated otherwise.

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

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. Well-known functions or constructions may not be described in detail for brevity and/or clarity.

The term "about", as used herein with respect to a value or

number, means that the value or number can vary by +/- 20%, 10%, 5%, 1%, 0.5%, or even 0.1%.

The terms "sensor", "sensing element", and "sensor module", as used herein, are interchangeable and refer to a sensor element or group of sensor elements that may be utilized to sense information, such as information (e.g., physiological information, body motion, etc.) from the body of a subject and/or environmental information in a vicinity of the subject. A sensor/sensing element/sensor module may comprise one or more of the following: a detector element, an emitter element, a processing element, optics, mechanical support, supporting circuitry, and the like. Both a single sensor element and a collection of sensor elements may be considered a sensor, a sensing element, or a sensor module.

The term "wearable sensor module", as used herein, refers to a sensor module configured to be worn on or near the body of a subject.

The terms "monitoring device" and "biometric monitoring device", as used herein, are interchangeable and include any type of device, article, or clothing that may be worn by and/or attached to a subject and that includes at least one sensor/sensing element/sensor module. Exemplary monitoring devices may be embodied in an earpiece, a headpiece, a finger clip, a digit (finger or toe) piece, a limb band (such as an arm band or leg band), an ankle band, a wrist band, a nose piece, a sensor patch, eyewear (such as glasses or shades), apparel (such as a shirt, hat, underwear, etc.), a mouthpiece or tooth piece, contact lenses, or the like.

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 "headset", as used herein, is intended to include 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 biometric monitoring devices, as described herein, may include mono headsets (a device having only one earbud, one earpiece, etc.) and stereo headsets (a

device having two earbuds, two earpieces, etc.), earbuds, hearing aids, ear jewelry, face masks, headbands, and the like. In some embodiments, the term "headset" may include broadly headset elements that are not located on the head but are associated with the headset. For example, in a "medallion" style wireless headset, where the medallion comprises the wireless electronics and the headphones are plugged into or hard-wired into the medallion, the wearable medallion would be considered part of the headset as a whole. Similarly, in some cases, if a mobile phone or other mobile device is intimately associated with a plugged-in headphone, then the term "headset" may refer to the headphone-mobile device combination. The terms "headset" and "earphone", as used herein, are interchangeable.

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.

The term "body" refers to the body of a subject (human or animal) that may wear a monitoring device, according to embodiments of the present invention.

The term "processor" is used broadly to refer to a signal processor or computing system or processing or computing method which may be localized or distributed. For example, a localized signal processor may comprise one or more signal processors or processing methods localized to a general location, such as to a wearable device. Examples of such wearable devices may comprise an earpiece, a headpiece, a finger clip, a digit (finger or toe) piece, a limb band (such as an arm band or leg band), an ankle band, a wrist band, a nose piece, a sensor patch, eyewear (such as glasses or shades), apparel (such as a shirt, hat underwear, etc.), a mouthpiece or tooth piece, contact lenses, or the like. Examples of a distributed processor comprise "the cloud", the internet, a remote database, a remote processor computer, a plurality of remote processors or computers in communication with each other, or the like, or processing methods distributed amongst one or more of these elements. The key difference is that a distributed processor may include delocalized elements, whereas a localized processor may work independently of a distributed processing system. As a specific example, microprocessors, microcontrollers, ASICs (application

specific integrated circuit), analog processing circuitry, or digital signal processors are a few non-limiting examples of physical signal processors that may be found in wearable devices.

The term "remote" does not necessarily mean that the "remote device" is a wireless device or that it is a long distance away from a device in communication with a "remote device". Rather, the term "remote" is used to reference a device or system that is distinct from another device or system or that is not substantially reliant on another device or system for core functionality. For example, a computer wired to a wearable device may be considered a remote device, as the two devices are distinct and/or not substantially reliant on each other for core functionally. However, any wireless device (such as a portable device, for example) or system (such as a remote database for example) is considered remote to any other wireless device or system.

In the following figures, various monitoring devices will be illustrated and described for attachment to the ear or an appendage 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. Monitoring devices 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, earlobe, and elsewhere (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. A particularly distinct pulsatile blood flow waveform can be discerned optically, via PPG, between the anti-tragus and concha region of the ear. The ear is also at or 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.

Fig. 1 is a schematic diagram of a wearable monitoring device 10, according to some embodiments of the present invention. The wearable

biometric monitoring device 10 may be an earbud module configured to be positioned within the ear of a subject, may be in the form of a sensor band configured to be secured to an appendage (e.g., an arm, wrist, hand, finger, toe, leg, foot, neck, etc.) of a subject, may be worn internally in the body (e.g., within the mouth as with a mouth guard, etc.), may be a sensor device configured to be adhesively secured to any portion of the body of a subject. Wearable monitoring devices, according to some embodiments of the present invention, may also be integrated within an audio headset, a wrist strap, a wrist watch, an ankle bracelet, a headband, an armband, etc. Wearable monitoring devices, according to some embodiments of the present invention, may also be utilized in various devices and articles including, but not limited to, patches, clothing, etc. Embodiments of the present invention can be utilized wherever PPG and blood flow signals can be obtained and at any location on the body of a subject. Embodiments of the present invention are not limited to the illustrated monitoring devices.

Figs. 2A-2B illustrate a monitoring apparatus 20 configured to be secured to an ear of a subject, according to some embodiments of the present invention. The illustrated apparatus 20 includes an earpiece body or housing 22, a sensor module 24, a stabilizer 25, and a sound port 26. When positioned within the ear of a subject, the sensor module 24 has a region 24a configured to contact a selected area of the ear. The illustrated sensor region 24a is contoured (i.e., is "form-fitted") to matingly engage a portion of the ear between the anti tragus and acoustic meatus, and the stabilizer is configured to engage the anti-helix. However, monitoring devices in accordance with embodiments of the present invention can have sensor modules with one or more regions configured to engage various portions of the ear. Various types of device configured to be worn at or near the ear may be utilized in conjunction with embodiments of the present invention.

Figs. 3A-3B illustrate a monitoring apparatus 30 in the form of a sensor band 32 configured to be secured to an appendage (e.g., an arm, wrist, hand, finger, toe, leg, foot, neck, etc.) of a subject. The band 32 includes a sensor module 34 on or extending from the inside surface 32a of the band 32. The sensor module 34 is configured to detect and/or measure physiological information from the subject and includes a sensor region 34a that is contoured

to contact the skin of a subject wearing the apparatus 30.

Embodiments of the present invention may be utilized in various devices and articles including, but not limited to, patches, clothing, etc. Embodiments of the present invention can be utilized wherever PPG and blood flow signals can be obtained and at any location on the body of a subject. Embodiments of the present invention are not limited to the illustrated monitoring devices.

The sensor modules 24, 34 for the illustrated monitoring devices 20, 30 of Figs. 2A-2B and 3A-3B are configured to detect and/or measure physiological information from the subject. In some embodiments, the sensor modules 24, 34 may be configured to detect and/or measure one or more environmental conditions in a vicinity of the subject wearing the monitoring device 20, 30.

A sensor module utilized in accordance with embodiments of the present invention may be an optical sensor module that includes at least one optical emitter and at least one optical detector. Exemplary optical emitters include, but are not limited to light-emitting diodes (LEDs), laser diodes (LDs), compact incandescent bulbs, micro-plasma emitters, IR blackbody sources, or the like. In addition, a sensor module may include various types of sensors including and/or in addition to optical sensors. For example, a sensor module may include one or more inertial sensors (e.g., an accelerometer, piezoelectric sensor, vibration sensor, photoreflector sensor, etc.) for detecting changes in motion, one or more thermal sensors (e.g., a thermopile, thermistor, resistor, etc.) for measuring temperature of a part of the body, one or more electrical sensors for measuring changes in electrical conduction, one or more skin humidity sensors, and/or one or more acoustical sensors.

Referring back to Fig. 1, the various components of a wearable biometric monitoring device 10, according to embodiments of the present invention, are illustrated. The biometric monitoring device 10 includes one or more sensors 12 (e.g., one or more sensors in the sensor regions 24, 34 of the devices in Figs. 2 and 3), and at least one processor 14 that is coupled to the sensor(s) 12 and that is configured to receive and analyze signals produced by the sensor(s). The illustrated biometric monitoring device 10 also includes a communication component 16 and an adjustment mechanism 18.

The communication component 16 allows the processor(s) 14 to communicate with a wearer of the biometric monitoring device 10 via a remote device 40, such as a smart phone, computer, etc. In some embodiments, the communication component 16 and processor component 14 may be integrated together, such as with a wireless processor, such as a Bluetooth chipset, WiFi chipset, ZigBee chipset, or the like.

The adjustment mechanism 18 may be any type of device that facilitates proper placement of the biometric monitoring device 10 relative to the body of the subject. Exemplary adjustment mechanisms 18 may include, but are not limited to, spacers, padding, straps, ear gel devices, ear stabilization pieces (such as pieces designed to fit within regions of the ear to stabilize an earbud within the ear), adjustment holes (such as the holes used to adjust a belt or wristband on the body via a bar or wedge that fits in the holes and secures the belt or band), ratcheting mechanism(s), spring mechanisms (such as structure that compresses a part of the housing or sensor region to the body of a subject), threaded mechanisms (such as a jackscrew, etc.), fluid compression mechanisms, air pumping mechanisms, etc. In some cases, the adjustment mechanism may be autonomous and may not require physical adjustment by the subject wearing the device.

It should be understood that the wearable device 10 may comprise all or only part of the illustrated components (i.e., sensor(s)12, processor(s) 14, communication component(s)16, or adjustment mechanism 18). In the case where the wearable device comprises only some of these components, the functionality of the remaining components may be realized all or in part by a remote device 40. The remote device may be in wired or wireless communication with the wearable device 10. Non-limiting examples of such remote devices may include a smartphone or other type of phone, a sensor hub, a computer, a smart pad, a cloud-based processing system, a wearable accessory, a control box, a "medallion", a smartwatch, smart glasses, etc.

Referring now to Fig. 4, operations for adjusting signal quality of one or more sensors of a wearable biometric monitoring device 10, according to some embodiments of the present invention, are illustrated. Initially, the wearer of a biometric monitoring device 10 is instructed via the processor(s) 14 to initiate a signal quality test (Block 100). The signal quality test may involve

various activities that result in motion noise. For example, the user may be instructed to run in place (or jump, dance, cycle, etc.) for a short time interval (e.g., a few seconds, etc.). The processor(s) 14 then determines the quality of the signal(s) from the sensor(s) of the biometric monitoring device 10 during the quality test regimen (Block 110). Additional operations associated with determining the signal quality may include determining if the biometric monitoring device 10 is being worn by the user and determining if the user is actually following the quality test regimen (i.e., running in place, etc.) by checking readings from one or more sensors in the device, such as a PPG sensor and/or an accelerometer associated with the biometric monitoring device 10.

Next, the processor(s) 14 determines what information to communicate to the wearer of the biometric monitoring device 10 (Block 120) and communicates this information to the user (Block 130). For example, the processor(s) determines whether the fit of the biometric monitoring device 10 is okay or whether the user needs to readjust the biometric monitoring device 10 in some way, and this information is communicated to the user. For example, if the biometric monitoring device 10 is positioned correctly (i.e., sensor signal quality is acceptable), the processor(s) 14 communicates this information to the user. If the biometric monitoring device 10 is not positioned correctly (i.e., sensor signal quality is not acceptable), the processor(s) 14 communicates this information to the user.

Information communicated to the user may be audibly and/or visually communicated. For example, Figs. 5A-5B, 6A-6B, 7A-7B, and 8A-8B illustrate various visual communications to a user regarding whether the fit of the biometric monitoring device 10 is okay or whether the user needs to readjust the biometric monitoring device 10 in some way. These visual communications may be made to the user via the wearable biometric monitoring device 10 and/or via a remote device 40 (e.g., a smartphone, computer, etc.) in communication with the biometric monitoring device 10.

Fig. 5A illustrates a communication sent to a user in the form of a graphical illustration 200 that a biometric monitoring device 10 in the form of an earbud is positioned inside the ear of the user at an incorrect angle. Fig. 5B illustrates a communication sent to a user in the form of a graphical illustration 202 that a biometric monitoring device 10 in the form of an earbud is positioned

inside the ear of the user at the correct angle.

Fig. 6A illustrates a communication sent to a user in the form of a graphical illustration 204 that a biometric monitoring device 10 in the form of an earbud is positioned outside the ear of the user at an incorrect angle. Fig. 6B illustrates a communication sent to a user in the form of a graphical illustration 206 that a biometric monitoring device 10 in the form of an earbud is positioned outside the ear of the user at the correct angle.

Fig. 7A illustrates a communication sent to a user in the form of a graphical illustration 208a that a biometric monitoring device 10 in the form of an earbud is positioned correctly within the ear of a user. Fig. 6B illustrates a communication sent to a user in the form of a graphical illustration 208b that a biometric monitoring device 10 in the form of an earbud is positioned at an incorrect angle within the ear of the user.

Figs. 8A and 8B illustrate communications sent to a user in the form of graphical illustrations 210a, 210b with instructions for properly positioning a biometric monitoring device 10 in the form of an earbud within the ear of the user. For example, the graphical illustration 210a of Fig. 8A instructs the user to place the earbud inside the ear, and the graphical illustration 210b of Fig. 8B instructs the user to rotate the earbud forward such that the earbud arm fits between the intertragic notch and "locks" the sensor region of the earbud inside the ear.

The aforementioned examples of audio-visual communication to the user are illustrative only and not meant to be limiting. For example, if a PPG sensor is located at the tip of an earbud, and if the signal quality from that PPG sensor is deemed to be insufficient, the visual presentation to the user may suggest that the subject place the ear tip deeper in the ear, change the ear tip gel, rotate the tip, etc. Similarly, for the case of a band, such a wristband, comprising a PPG sensor, the visual presentation may suggest that the subject tighten the band, change the band fitting, rotate the band, etc.

Referring now to Fig. 9, a time-domain PPG waveform 300 is illustrated. The illustrated waveform 300 is from the sensor(s) within a biometric monitoring device 10 worn by a user and illustrates the condition where there are negligible motion artifacts associated with the waveform as a result of user motion, footsteps, breathing, etc. The illustrated waveform 300 illustrates two

heartbeats of the user. Fig. 10 illustrates a time-domain PPG waveform 302 from the sensor(s) within a biometric monitoring device 10 worn by a user where there are substantial motion artifacts. The actual heart beat waveform 300 is illustrated in dotted line and is masked by the substantial motion artifacts.

Fig. 11A illustrates an exemplary spectrogram 400 of a PPG signal from a user wearing a biometric monitoring device 10 and without active motion noise removal. The spectrogram 400 includes, not only heart rate (HR) signals 402, but also motion signals from body motion 404 and motion signals from user breathing 406. In Fig. 11B, active motion noise removal via one or more filters associated with the processor(s) 14 have removed the motion signals from body motion 404 and motion signals from user breathing 406. Noise attenuation and removal is described in detail in U.S. Patent No. 8,157, 730, U.S. Patent No. 8,251,903, U.S. Patent Application Publication No. 2008/0146890, U.S. Patent Application Publication No. 2010/0217098, U.S. Patent Application Publication No. 2010/0217102, U.S. Provisional Patent Application No. 61/750,490, PCT Application No. US2012/071593, PCT Application No. US2012/071594, and PCT Application No. US2012/048079, which are incorporated herein by reference in their entireties.

If multiple wavelengths are used in PPG sensing, such as the case for pulse oximetry, then there will be multiple spectrograms with similar spectral profiles. And the ratio of functions of $A(\omega_{HR})_{\lambda 1}$ with respect to functions of $A(\omega_{HR})_{\lambda 2}$ ... $A(\omega_{HR})_{\lambda n}$ may be proportional to the concentration of various types of hemoglobin in the blood. For example, the $SpO_2$ concentration of blood may be proportional to $A(\omega_{HR})_{\lambda 1}/A(\omega_{HR})_{\lambda 2}$ (where $\lambda 1$ may be a shorter wavelength than $\lambda 2$) or a ratio of functions of these spectral amplitudes.

According to some embodiments of the present invention, signal quality from a sensor in the biometric monitoring device 10 can be determined by the following equation:

$$\text{Signal Quality} = Q_S \propto \frac{(A(\omega_{HR}))}{\sum A(\omega_i)}$$

In other words, signal quality Qs is proportional to heart rate signal divided by the sum of the signal components associated with user motion.

This formula may be useful once a spectrogram is generated for a PPG signal

collected by the sensor(s) 12. In the spectral domain, the signal quality Qs may be expressed as a ratio of the spectral amplitude at the HR frequency divided by a sum of various other spectral amplitudes that may also exist in the spectrogram. Similarly, the signal quality Qs may be related to a ratio of functions of various spectral amplitudes. The signal quality Qs may be assessed either before or after motion-artifact removal, but in the case of assessing signal quality post-motion-artifact removal, the sum of spectral amplitudes in the denominator is likely to be smaller than for the case of assessing signal quality pre-motion-artifact removal, as suggested by Fig. 11A and Fig. 11B. Thus, when there are less spectral artifacts from motion artifacts and other unwanted time-varying artifacts, the signal quality Qs is likely to be higher than for the case where many such artifacts are present.

The formula for assessing signal quality is not meant to be limiting. Various other formulas or methods may be used to assess signal quality according to embodiments of the present invention. For example, a different, simpler formula may assess only the magnitude of the spectral amplitude at the HR frequency. A different, more complicated formula may assess the ratio of 2 or more signal qualities, as calculated from the above formula for multiple PPG wavelengths. Additionally, a time-domain approach may be preferred in some embodiments. For example, the peak amplitude of a time-domain photoplethysmogram (such the PeakAC as shown in Fig. 9) may be calculated and used to assess signal quality, with higher PeakAC correlating with higher Qs. In the time domain, a more complicated method may be to assess Qs by the ratio: PeakAC/PeakCadence, where PeakCadence refers to the peak amplitude of an accelerometer output at the user's cadence (step rate, jumping rate, cycling rate, etc.). Additionally, the spectral and time-domain approaches described above for a PPG sensor may also be applied for the case where the sensors comprise an ECG sensor ( such as that used in ECG leads, ECG chest straps or ECG wristbands) and an inertial sensor (such as an accelerometer).

Embodiments of the present invention may also be applied for measuring PPG from the ear canal, body temperature from the tympanic membrane, or various other biometrics at various locations of the body. For the case of an in-ear measurement, a user may be instructed via the wearable monitor 10 and/or remote device 40 to wiggle their ear or talk while PPG or body

temperature is being measured from the ear canal or tympanic membrane. The signal quality Qs may then be calculated for these activities to make certain the signal quality is above the minimum acceptable value. In contrast, a user measuring PPG and skin temperature at the leg may be instructed to stomp the leg while signal quality Qs is being assessed.

The processor(s) 14 may also determine that the position of the wearable device 10 is not sufficient for accurate biometric monitoring. For example, the processor 14 may process signal readings from an accelerometer 12 to determine if the wearable device is being worn correctly with respect to the ground. One methodology for determining the location of ground via an accelerometer may be to assess three (3) or more axes of the accelerometer to determine the vector of 1G of force, using commonly known trigonometric methods, and then to assess whether that vector is sufficiently aligned with a desired vector for that 1G of force. For example, it may be desired that an accelerometer placed in an earbud have ~1G of force directly along the Z-vector. If the location of the 1G of force is found by the processor to be close enough to the axis along the Z-vector, then the processor may determine that the earbud is being worn properly (Fig. 5B, 6B, & 7A); otherwise, the processor may determine that the earbud is not being worn properly (Fig. 5A, 6A, & 7B). In some cases, determining that the subject is wearing the monitoring device 10 appropriately may involve audio-visual feedback from the monitoring device 10 and/or a remote device 40. For example, a prompt may notify the a user to wear a wristband with the sensor region 34 located at a certain spot along the wrist. The processor 14 may then determine whether the device is being worn appropriately in accordance with the audio-visual instructions.

Fig. 12 is an exemplary plot 500 of signal quality Qs (as may be determined by methods described earlier as well as other methods) over time for an exemplary run by a user wearing a biometric monitoring device 10. The dotted line 502 represents the minimum signal quality Qs that is acceptable for producing accurate physiological information. The signal quality Qs may dip below the minimum acceptable quality during certain aspects of the run, such as during erratic running motion or high ambient light interference. The processor(s) 14 may determine that the signal quality Qs is too low for the measured biometric to be accurate, preventing the errant biometric reading from being

applied towards a physiological assessment. For example, post analysis on the running data generated by the sensor(s) 12 in the wearable biometric monitoring device 10 may be generated by processing biometrics (heart rate, breathing rate, R-R interval, HRV, blood pressure, etc.) and activity metrics (cadence, speed, pace, distance, total steps, etc.) together. As a specific example, by processing heart rate and cadence together over time, the processor(s) 14 may determine when the user has started and stopped an exercise and may then determine the user's heart rate recovery (the change in heart rate from the stop of exercise and 1 minute or more following the stop of exercise). But, if the signal quality Qs is determined to be below the minimum allowable level of quality during the relevant data collection period (in this case the period between the stop of the exercise and a minute or more afterwards), then the processor(s) 14 may determine that heart rate recovery cannot be accurately determined. Alternatively, the processor(s) 14 may estimate the heart rate recovery with the errant data along with an assessment that the confidence of the estimation is poor, and both of the estimate and signal quality may be reported to the user audio-visually.

Fig. 13 is a plot 500 of signal quality Qs over time for a user conducting a self-fitting test, according to some embodiments of the present invention. The dotted line 502 represents the minimum signal quality Qs that is acceptable for producing accurate physiological information. The illustrated plot 500 can be presented to the user via a display in a remote device 40 in communication with the biometric monitoring device 10.

At time $t_0$, the user attaches the biometric monitoring device 10 to his/her body (e.g., inserts earbud sensor module in ear, straps on a wristband sensor module, etc.) and turns the biometric monitoring device on. At time $t_a$, the user receives the first indication of signal quality and, as illustrated, it is below the minimum signal quality line 502. At time $t_b$, the user makes one or more adjustments to the biometric monitoring device at this point to improve the signal quality. For example, the user repositions the biometric monitoring device 10 relative to the body, adds a spacer or gel device to create a better fit relative to the body, tightens a strap securing the biometric monitoring device 10 to the body, etc. As a result of the user adjustment, the signal quality improves as illustrated between time $t_b$ and time $t_c$.

However, as illustrated in Fig. 13, the user continues to adjust the biometric monitoring device 10 and the signal quality falls below the minimum signal quality line 502 by time $t_d$. The user continues adjustment of the biometric monitoring device until the signal quality is raised above the minimum signal quality line 502. At time $t_e$, the user is happy with the signal quality and keeps the biometric monitoring device 10 in place.

Fig. 14 is a plot 500 of signal quality Qs over time for a user conducting an instructed "quick test" regimen, according to some embodiments of the present invention. The dotted line 502 represents the minimum signal quality Qs that is acceptable for producing accurate physiological information. The illustrated plot 500 can be presented to the user via a display in a remote device 40 in communication with the biometric monitoring device 10.

At time $t_0$, the user attaches the biometric monitoring device 10 to his/her body (e.g., inserts earbud sensor module in ear, straps on a wristband sensor module, etc.) and turns the biometric monitoring device on. At time $t_a$, the user is instructed to execute a "quick test" regimen, such as running in place for a short period of time (e.g., 15 seconds, etc.). As illustrated, between the time $t_a$ and $t_b$, the signal quality is above the minimum line 502, and this is because the user is at rest and motion artifacts are not impairing the signal 500. However, when the user starts the "quick test" regimen (i.e., running in place), the signal quality falls below the minimum signal quality line 502. The user is then instructed to adjust the biometric monitoring device 10 at time $t_d$ (e.g., reposition the biometric monitoring device 10 relative to the body, add a spacer or gel device to create a better fit relative to the body, tighten a strap securing the biometric monitoring device 10 to the body, etc.) and repeat the "quick test" regimen (e.g., running in place). As a result of the user adjustment, the signal quality improves as illustrated at time $t_e$. The signal quality remains above the minimum signal quality line 502 at time $t_f$ after the "quick test" regimen.

The methods described for determining the quality of a biometric signal may be applied towards facilitating accurate autonomous biometric assessments by assuring the utilization of only highly accurate data. For example, as summarized in Fig. 15, for a subject donning a wearable sensor device, the device may collect sensor data (Block 600), determine the biometric signal quality (Block 610), record the biometric data (comprising both sensor

data and biometric signal quality data) (Block 620), and then mark (i.e., label or identify) biometric data readings that have sufficient and/or insufficient quality for an accurate assessment (Block 630). Once sufficient quality data is identified and isolated from data having insufficient data quality, this quality data may be used to generate an accurate assessment for the subject (Block 640). As a specific example, a fitness assessment for the subject may be generated by assessing only those biometric data points that are found to have sufficient quality for the assessment.

As another example, an accurate fitness assessment may require inputting more vetted data points into the assessment model than those that have been vetted by the wearable device to be of sufficient quality. In such case, the fitness assessment may be generated by factoring both types of data points (e.g., data points having sufficient signal quality (vetted data points) and data points not having sufficient quality) by extrapolating or otherwise interpolating between data points that are marked as having sufficient data quality. A specific example of this is presented in Fig. 16 for the case of determining heart rate recovery for heart rate data having both high quality and low quality sensor signals. In Fig. 16, plot 700 represents high quality sensor signals and plot 710 represents low quality sensor signals. In Fig. 16, the dotted line 702 is interpolated between two regions of high quality data, where the signal confidence is above the 100% confidence threshold. Note that for this heart rate recovery assessment to be completely autonomous, contextual information may be required to be known, such as whether the person was exercising for a sufficient period of time, if they were at an elevated heart rate or exertion level, and/or when the person stopped exercising. This type of contextual information may be input by the user via a user interface or provided by processing data from an accelerometer or other motion-tracking device that is integrated within the wearable device.

It should also be noted that, for the example of Fig. 16, an alternative method of generating the fitness assessment may be to generate an assessment plus assessment confidence using all data points, whether they be marked as sufficient or insufficient in quality. In this case, an interpolation may not be required, as all data points are used to make the assessment but a "score" or "confidence" of the overall assessment (in this example a heart rate

recovery assessment) is generated by weighting high- and low-quality data points. In a specific example of this, if 20% of the data points required to generate a fitness assessment have been found to be of insufficient signal quality, then the assessment may be calculated using 100% of the data points but with a note that the assessment confidence score is less than100%. Additionally, if an assessment is taken over the course of time, then a notification may be given to the user when the assessment was calculated with 100% confidence and less than 100% confidence, such as the case for Fig. 17, where a plot 800 of HRR (Heart Rate Recovery) vs. time is presented for a user along with information about the confidence of that HRR score for each data point.

The methods described for determining the quality of a biometric signal may be applied towards facilitating accurate autonomous biometric assessments by assuring the utilization of data collected only when a device is being worn. For example, a wearable sensor device may comprise sensors that cannot innately determine if the sensor is being worn by the subject. Thus, without an intelligent way of determining that a sensor is being worn, erroneous assessments may be generated. As a specific example, a person wearing an optical heart rate monitor may find that removing the monitor from the body and placing that monitor on a counter yields erroneous heart rate readings, perhaps due to the device picking up ambient light flicker and/or scattered light from table vibrations. In such case, an assessment of that subject's average heart rate for the day, or calories burned for the day, may be wildly skewed. A method of addressing this problem is summarized in Fig. 18.

In Fig. 18, a wearable device may collect sensor data from a user (Block 900), determine if the sensor is being worn (Block 910), and record the biometric data (comprising both sensor data and biometric signal quality data) (Block 920). The wearable device may be programmed to mark when the biometric data readings are found to be associated with the device not being worn (Block 930), such as the case for very low signal quality. Then an accurate assessment may be generated for the subject by factoring (weighting) sensor readings marked for periods where the wearable device was determined to be worn (Block 940), as described above with respect to Fig. 16. Techniques for determining whether a device is being worn by the user have been described above; however, an additional technique may comprise averaging motion signals

collected by a motion sensor, such as an accelerometer, over a period of time to determine whether the average motion is high enough to be classified as "being worn" motion.

A variety of methods may be used to determine whether a device is being worn. For example, the signal quality may be assessed by processing sensor readings to see if they are within an acceptable range. For example, the output of a photodetector in a wearable PPG sensor may be processed to determine if the DC background is above or below a certain threshold associated with being worn or not worn. In many optical configurations, the DC background will be lower than a certain threshold when a PPG sensor is away from the body. Similarly, the output of a temperature sensor, such as a tympanic temperature sensor or skin sensor or the like, may be processed to determine if the temperature is above or below a certain threshold associated with being worn. In this case, the processor may look for a temperature reading within a reasonable range associated with human-generated heat; being inside that range may trigger a "flag" (such as a 1 or 0 bit) that the device is being worn, whereas outside that range may change the flag to not being worn. The output of a motion sensor may also be used to determine if a wearable device is being worn. For example, the output of an accelerometer may be processed to assess micro-motions associated with a human subject at rest or processed to assess larger motions associated with gross body motion. The presence of at least sufficient micro-motions may be used to generate a "flag" that the device is being worn.

Because sensor readings may be slightly different for different subjects in the case of a wearable device being worn/not-worn, the generation of an accurate "being worn flag" may require that the processor be trained for that particular subject. For example, the subject may be asked to input, via a user interface, when they are wearing the wearable device and when they are not wearing the wearable device. The processor may then assess sensor readings to determine the unique "signature" of that subject for the device being worn and/or for the device being not worn. This signature may be programmed and associated with the wearable device such that a more accurate determination of being worn/not worn may be generated in the future for that subject.

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

THAT WHICH IS CLAIMED IS:

1. A method of monitoring signal quality of a wearable biometric monitor, wherein the monitor includes at least one sensor configured to detect and/or measure physiological information from a subject wearing the biometric monitor and at least one processor in communication with the at least one sensor that is configured to receive and analyze signals produced by the at least one sensor, the method comprising the following steps performed via the at least one processor:

instructing the subject to begin an exercise regimen;

measuring signal quality produced by the at least one sensor during the exercise regimen; and

communicating information to the subject regarding the signal quality during the exercise regimen.

2. The method of Claim 1, wherein communicating information to the subject regarding the signal quality comprises communicating instructions to the subject to adjust the biometric monitor relative to the body of the subject if the signal quality is below a threshold level.

3. The method of Claim 1, wherein communicating information to the subject regarding the signal quality comprises communicating information to the subject that the signal quality is above a threshold level.

4. The method of Claim 1, wherein instructing the subject to begin an exercise regimen comprises sending an audio and/or visual communication to a remote device in communication with the biometric monitor.

5. The method of Claim 1, wherein communicating information to the subject regarding the signal quality comprises sending an audio and/or visual communication to a remote device in communication with the biometric monitor.

6. The method of Claim 1, wherein instructing the subject to begin an exercise regimen comprises causing the biometric monitor and/or a remote device to vibrate.

7. The method of Claim 1, wherein communicating information to the subject regarding the signal quality comprises causing the biometric monitor and/or a remote device to vibrate.

8. The method of Claim 1, wherein the biometric monitor includes an actuator, and further comprising automatically adjusting the biometric monitor relative to the body of the subject via the actuator if the signal quality is below a threshold level.

9. The method of Claim 1, wherein the biometric monitor includes a motion sensor, and further comprising determining if the subject has begun the exercise regimen by detecting a change in subject activity via the motion sensor.

10. The method of Claim 1, wherein the biometric monitor is configured to be integrated within an earbud.

11. The method of Claim 1, wherein the biometric monitor is configured to be integrated within an audio headset, a wrist strap, a wrist watch, an ankle bracelet, or an armband.

12. The method of Claim 1, wherein the biometric monitor comprises a band configured to at least partially encircle a portion of the body of a subject, and wherein the portion of the body comprises a limb, a nose, an earlobe, and/or a digit.

13. The method of Claim 1, wherein the biometric monitor includes a motion sensor, and further determining if the subject is wearing the biometric monitor by determining if body motion over a period of time is above a threshold.

14. A method of generating a physiological assessment of a subject, the method comprising:

collecting physiological information and/or motion information from the subject over a period of time via at least one wearable device, wherein the at least one wearable device includes at least one physiological sensor and/or at least one motion sensor;

determining a quality level for the physiological information and/or motion information at one or more selected times during the period of time; and

generating a physiological assessment for the subject using the physiological information and/or motion information at the one or more selected times that has a quality level above a threshold level.

15. A method of generating a physiological assessment of a subject, the method comprising:

collecting physiological information and/or motion information from a subject via at least one wearable device, wherein the at least one wearable device includes at least one physiological sensor and/or at least one motion sensor;

determining one or more time periods when the wearable device is being worn by the subject; and

generating a physiological assessment for the subject using the physiological information and/or motion information obtained during the one or more time periods when the wearable device is being worn by the subject.

## ABSTRACT OF THE DISCLOSURE

A wearable biometric monitoring device is configured to assess the biometric signal quality of one or more sensors associated with the monitoring device, determine how the user should adjust the device to improve the biometric fit, and instruct the user to wear the biometric monitoring device a certain way. Communicating instructions to a user may include instructing the user to execute a testing regimen while wearing the biometric monitoring device. The testing regimen facilitates an estimation of a signal quality that can be used to provide feedback to the user that he/she needs to adjust the device to improve the biometric fit and the biometric signal quality.

1639616

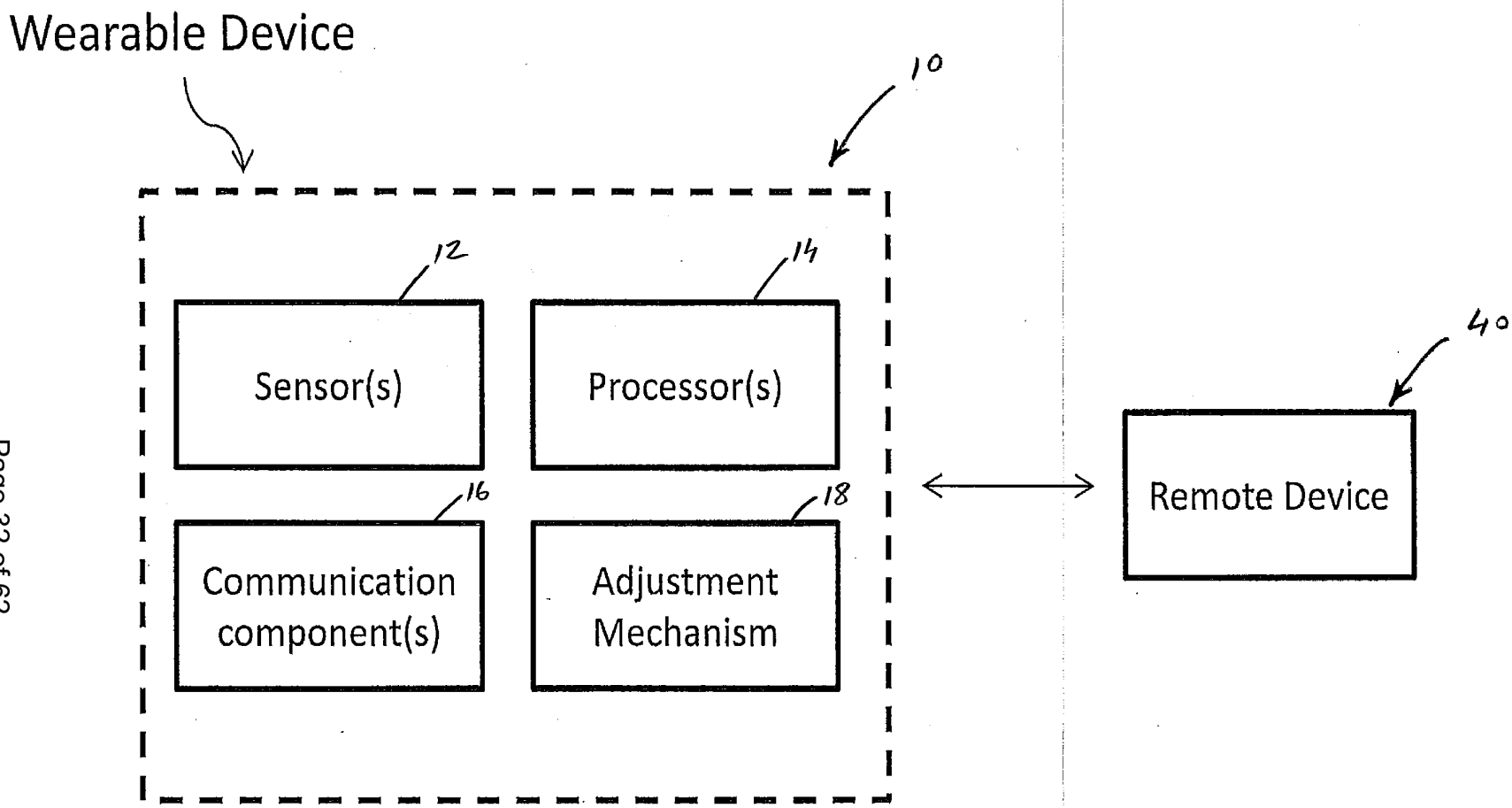

Wearable Device
10
12
14
Sensor(s)
Processor(s)
16
18
Communication component(s)
Adjustment Mechanism
40
Remote Device

FIG. 1

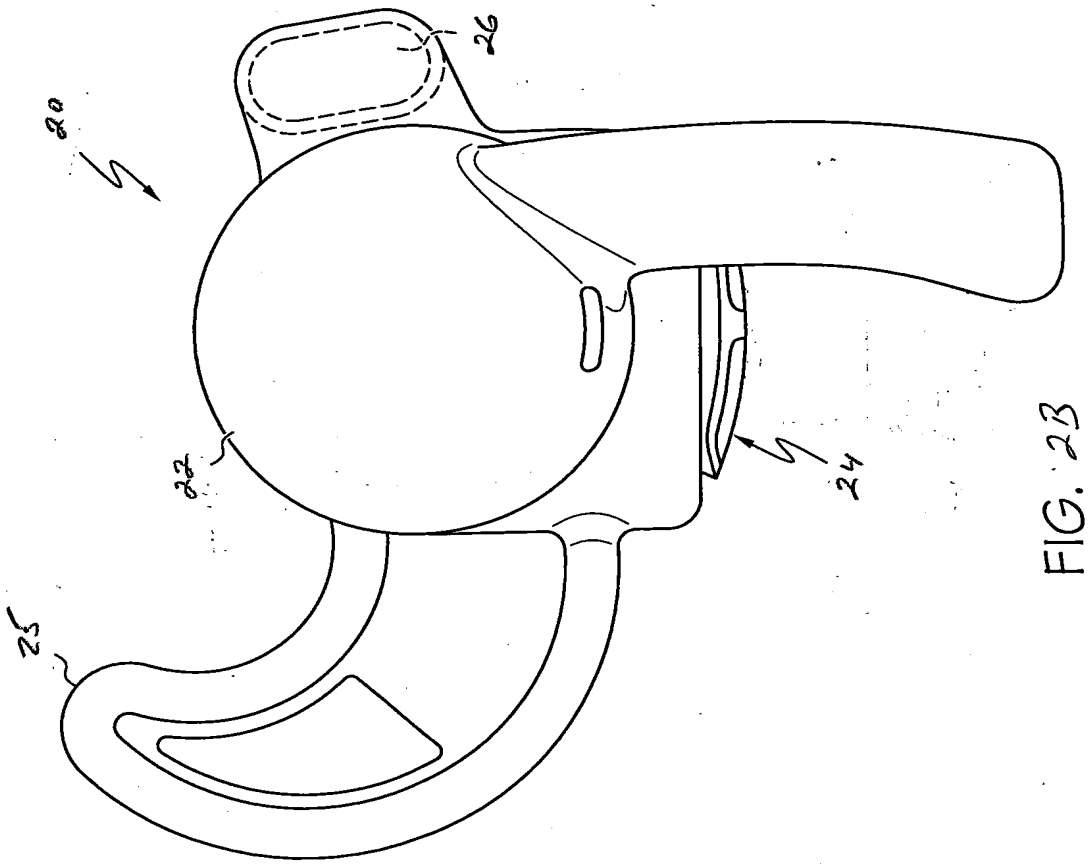



FIG. 2B

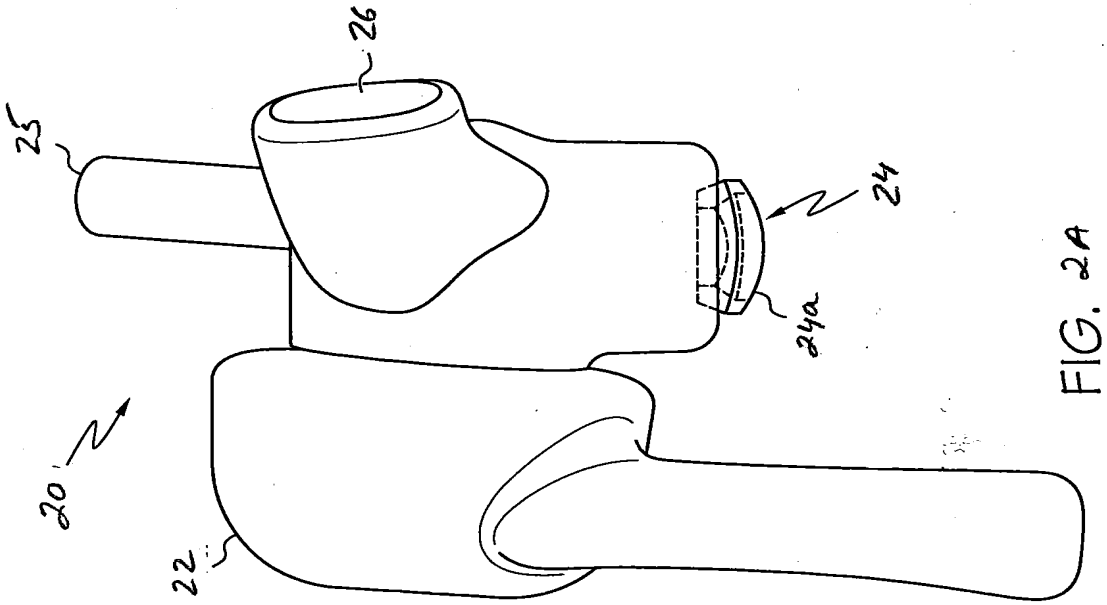



FIG. 2A

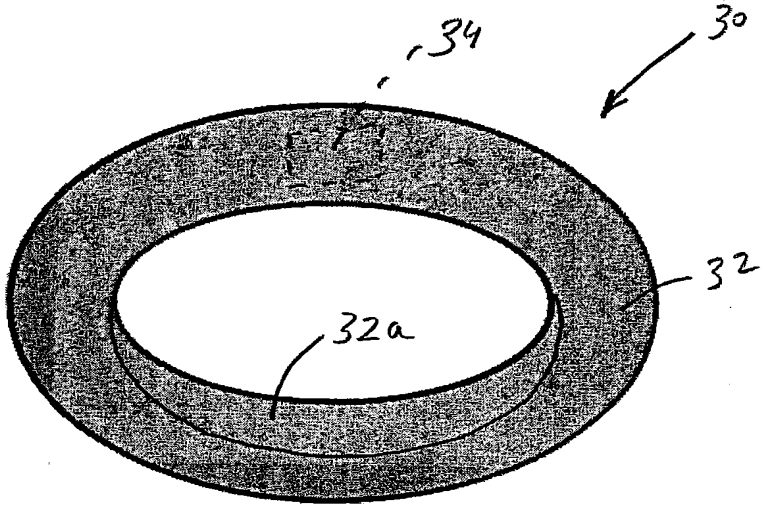



FIG. 3A

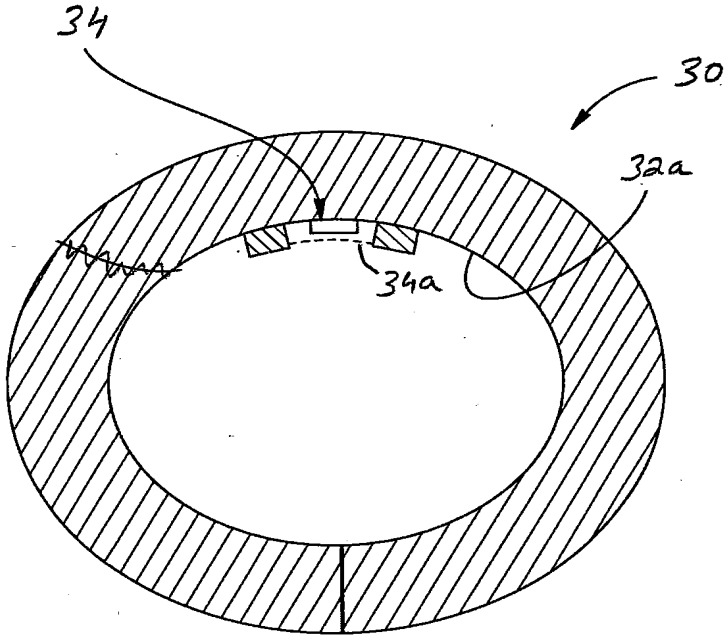



FIG. 3B

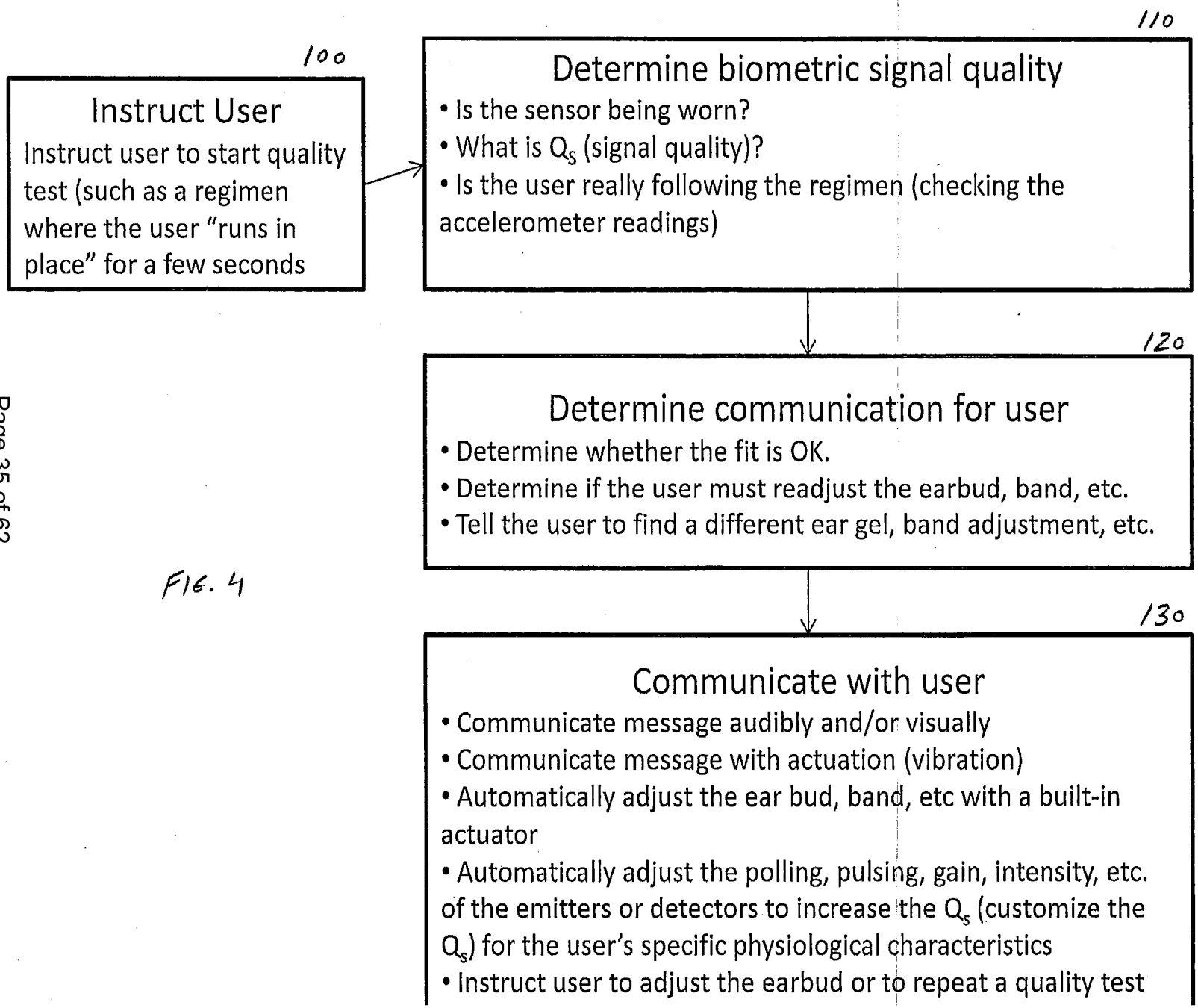
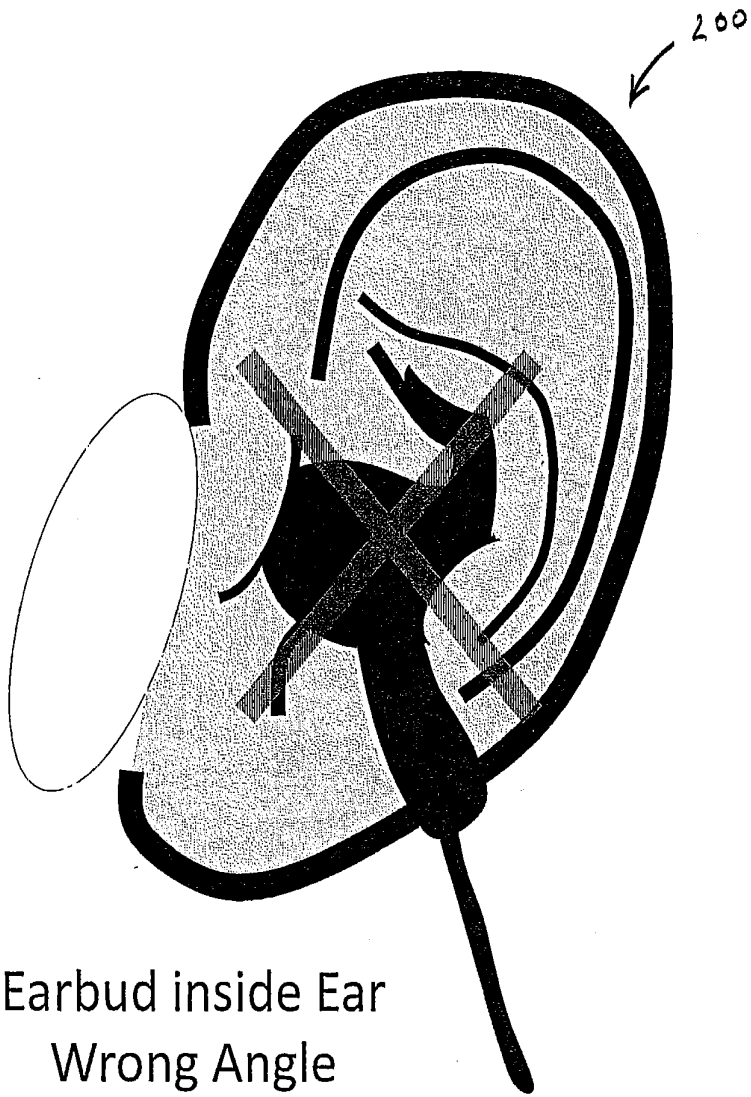
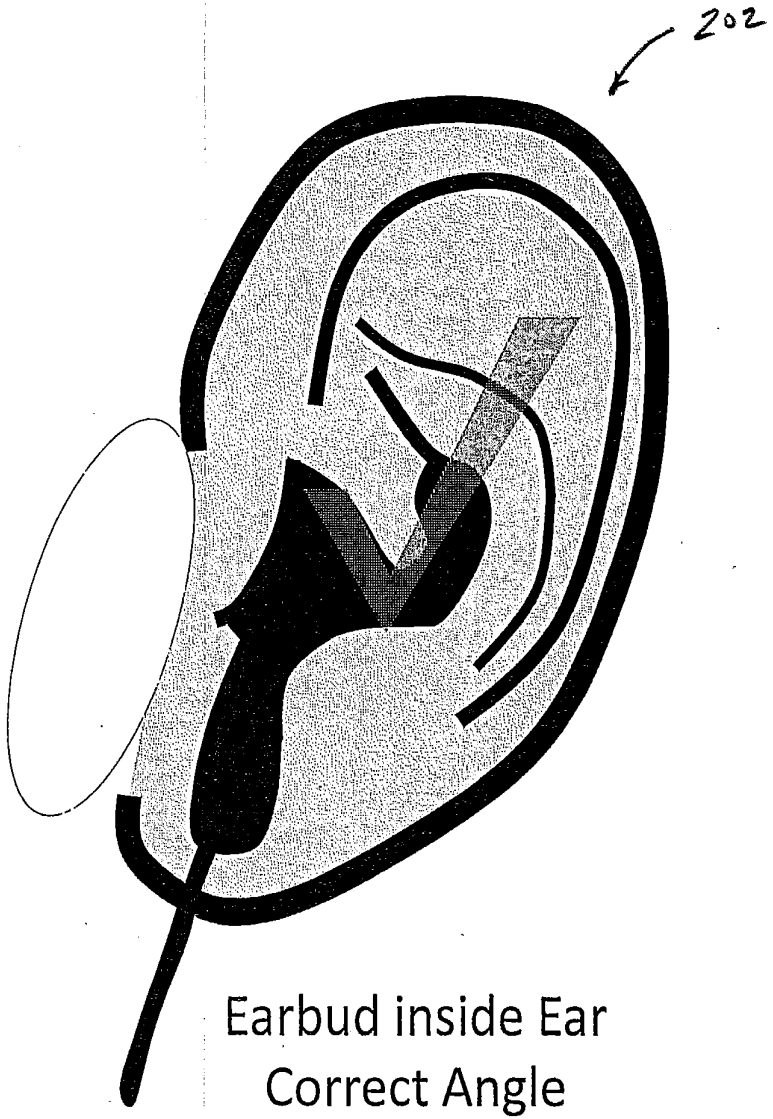

100
Instruct User
Instruct user to start quality test (such as a regimen where the user "runs in place" for a few seconds
110
Determine biometric signal quality
• Is the sensor being worn?
• What is $Q_S$ (signal quality)?
• Is the user really following the regimen (checking the accelerometer readings)
120
Determine communication for user
• Determine whether the fit is OK.
• Determine if the user must readjust the earbud, band, etc.
• Tell the user to find a different ear gel, band adjustment, etc.
130
Communicate with user
• Communicate message audibly and/or visually
• Communicate message with actuation (vibration)
• Automatically adjust the ear bud, band, etc with a built-in actuator
• Automatically adjust the polling, pulsing, gain, intensity, etc. of the emitters or detectors to increase the $Q_s$ (customize the $Q_s$) for the user's specific physiological characteristics
• Instruct user to adjust the earbud or to repeat a quality test

FIG. 4



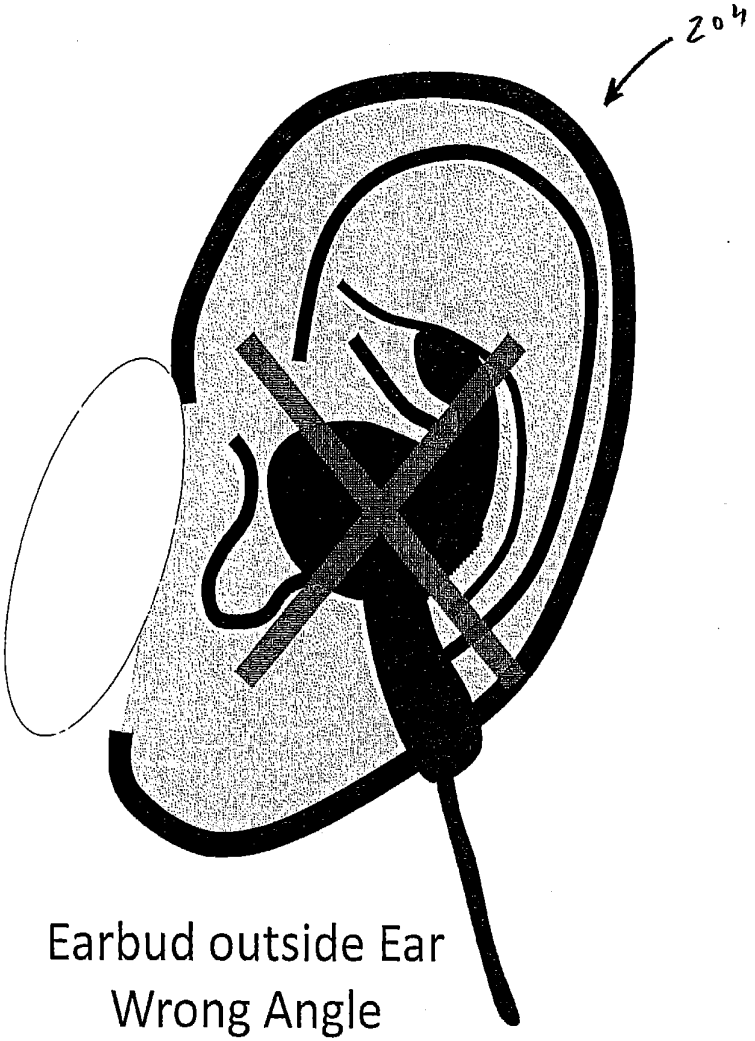

Earbud inside Ear
Wrong Angle

FIG. 5A



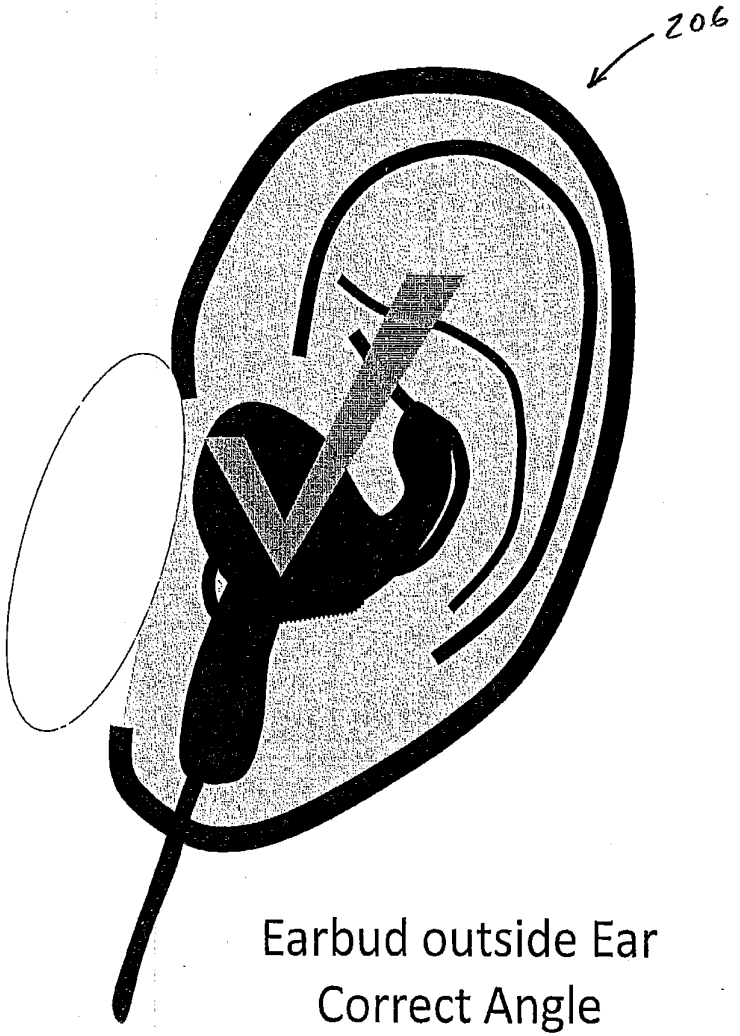

Earbud inside Ear
Correct Angle

FIG. 5B




Earbud outside Ear
Wrong Angle

FIG. 6A




Earbud outside Ear
Correct Angle

FIG. 6B

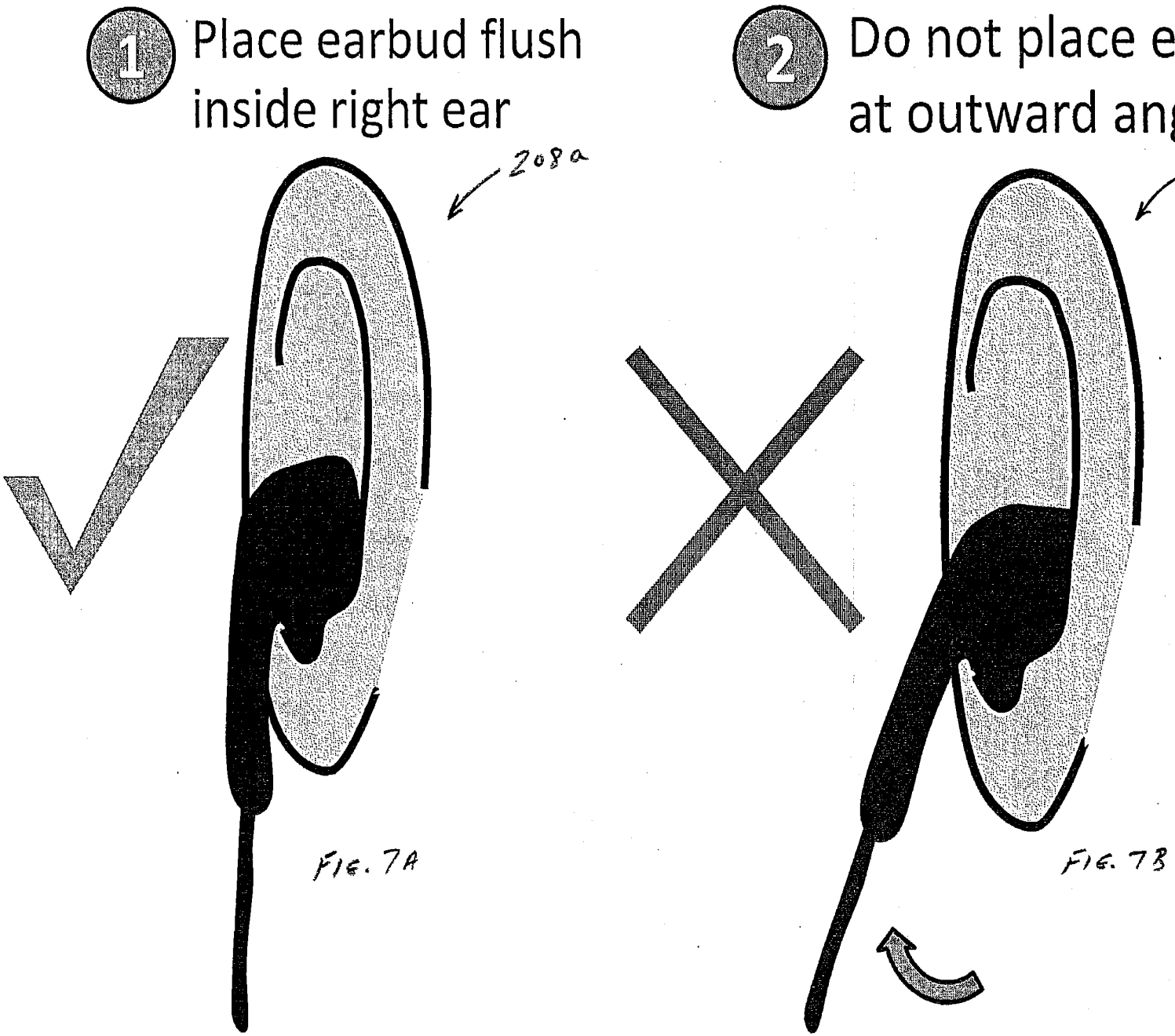

1
Place earbud flush inside right ear
208a
2
Do not place earbud at outward angle
208b

FIG. 7A

FIG. 7B

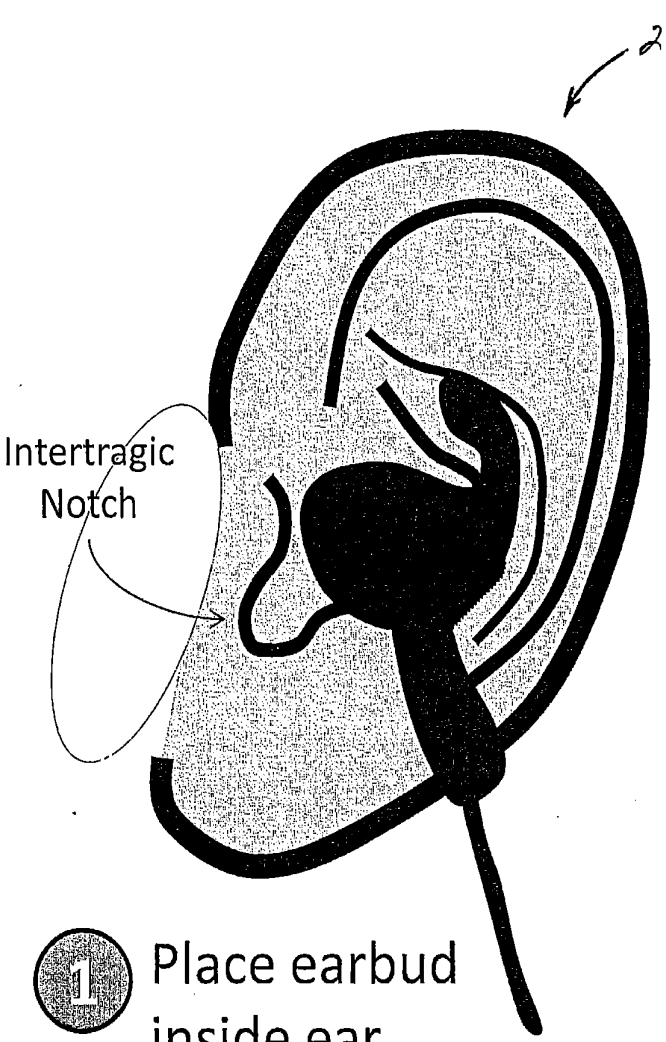

210a
Intertragic
Notch
1
Place earbud
inside ear

FIG. 8A

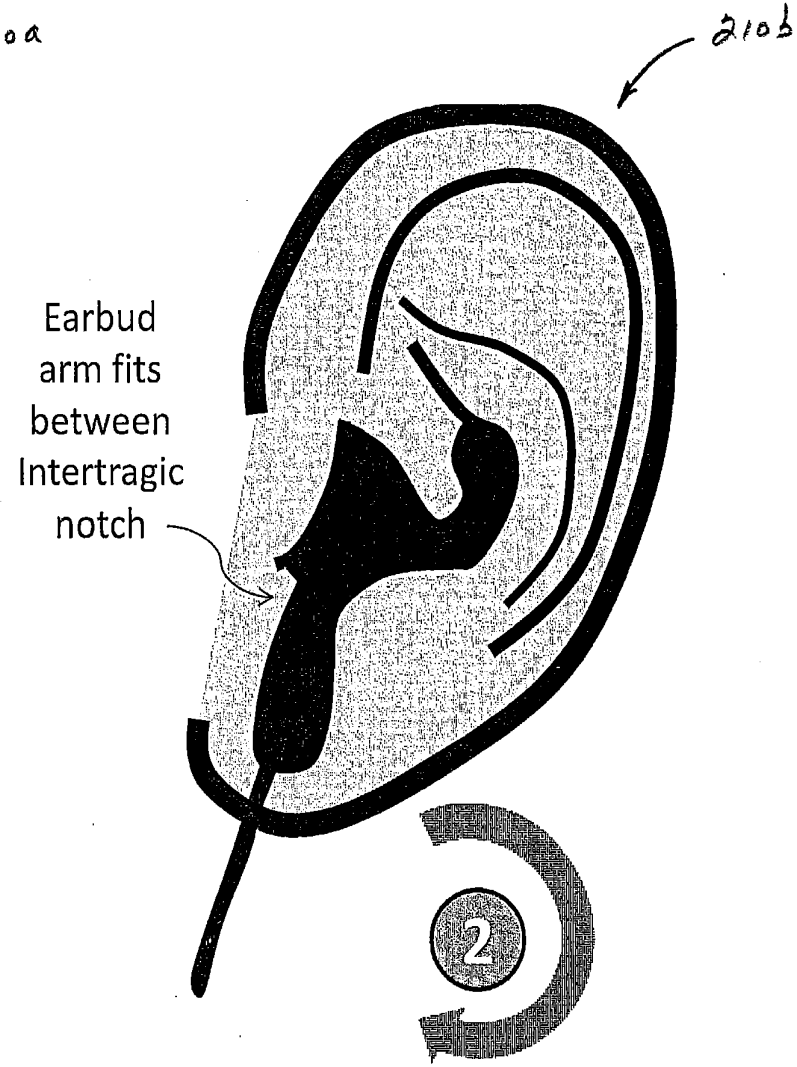

210b
Earbud
arm fits
between
Intertragic
notch
2

FIG. 8B

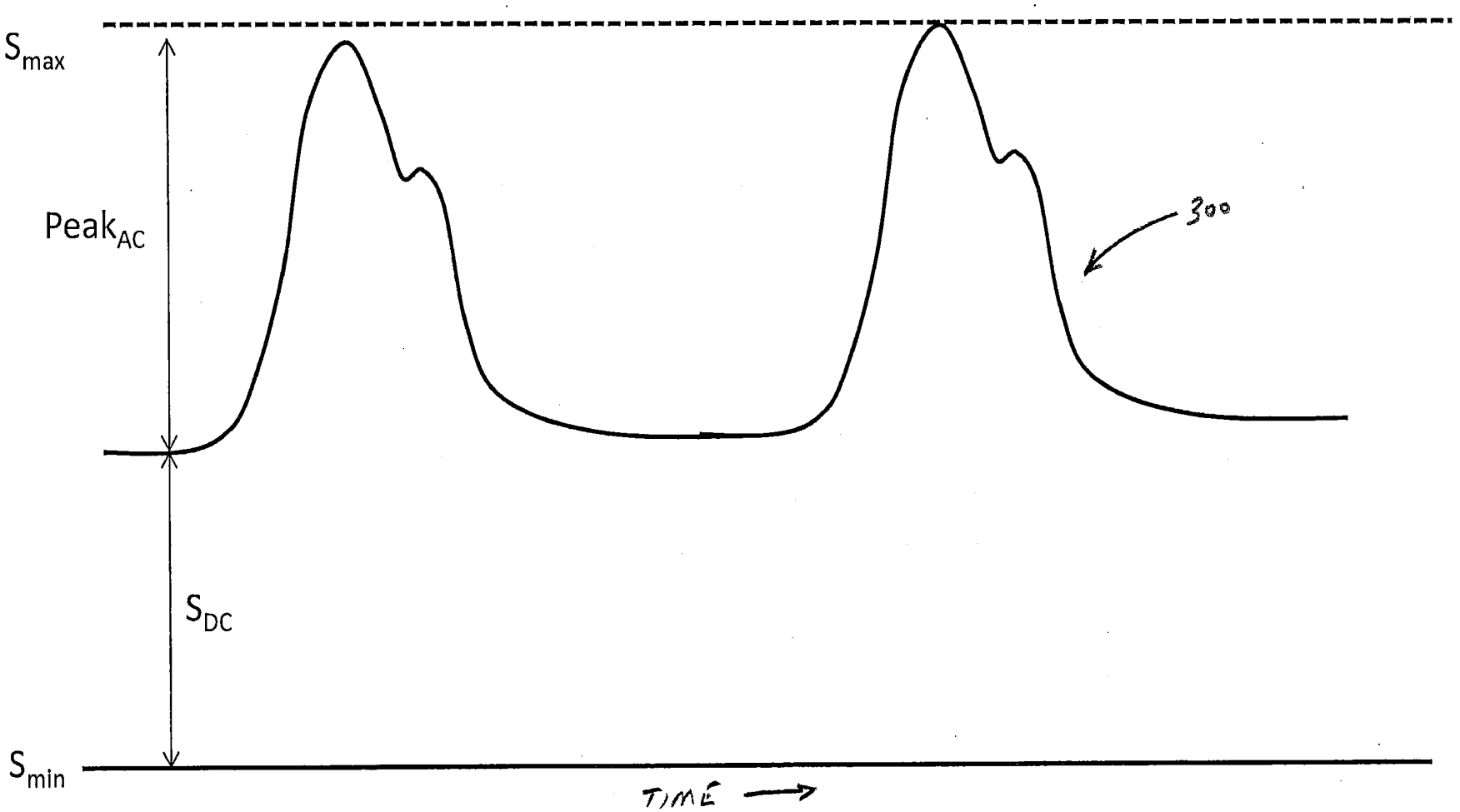
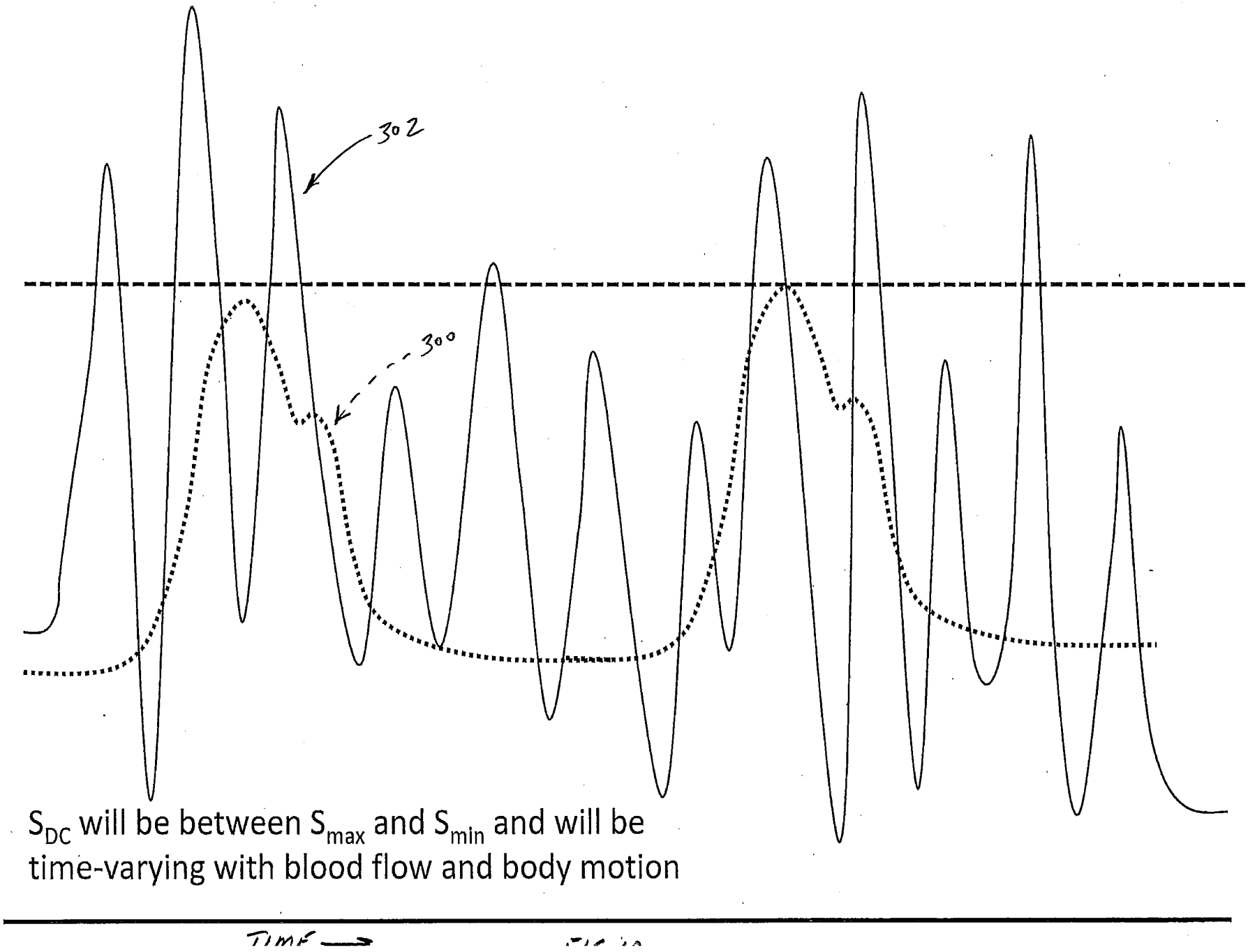



FIG. 9




$S_{DC}$ will be between $S_{max}$ and $S_{min}$ and will be time-varying with blood flow and body motion

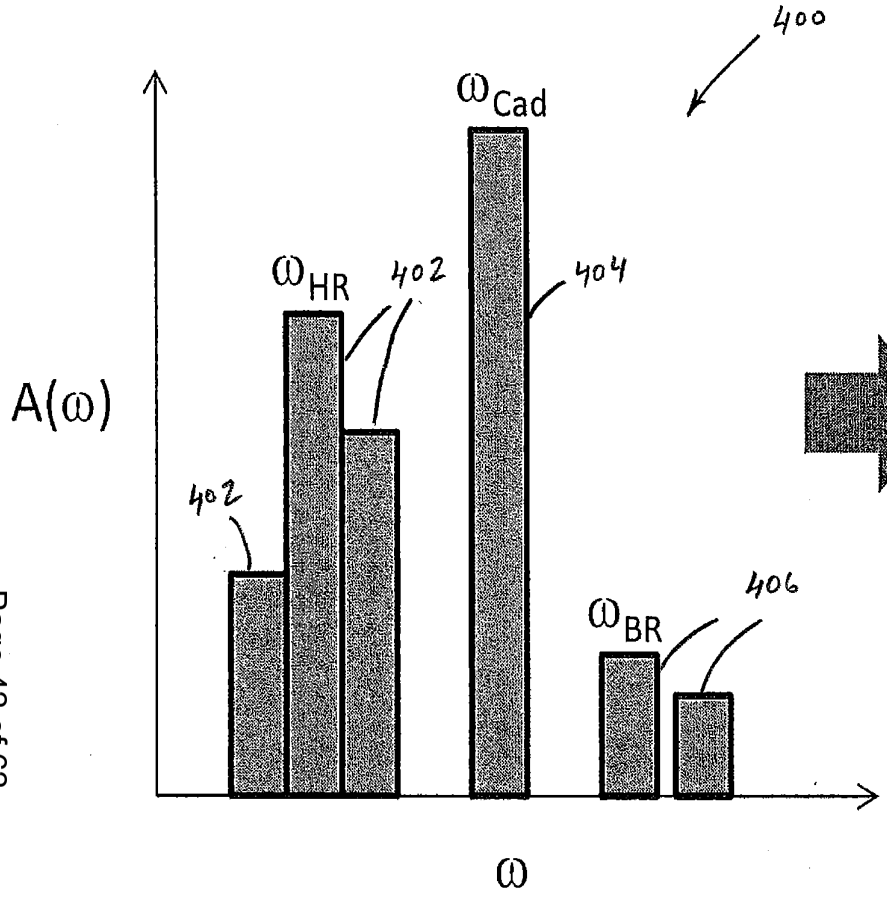



FIG. 11A

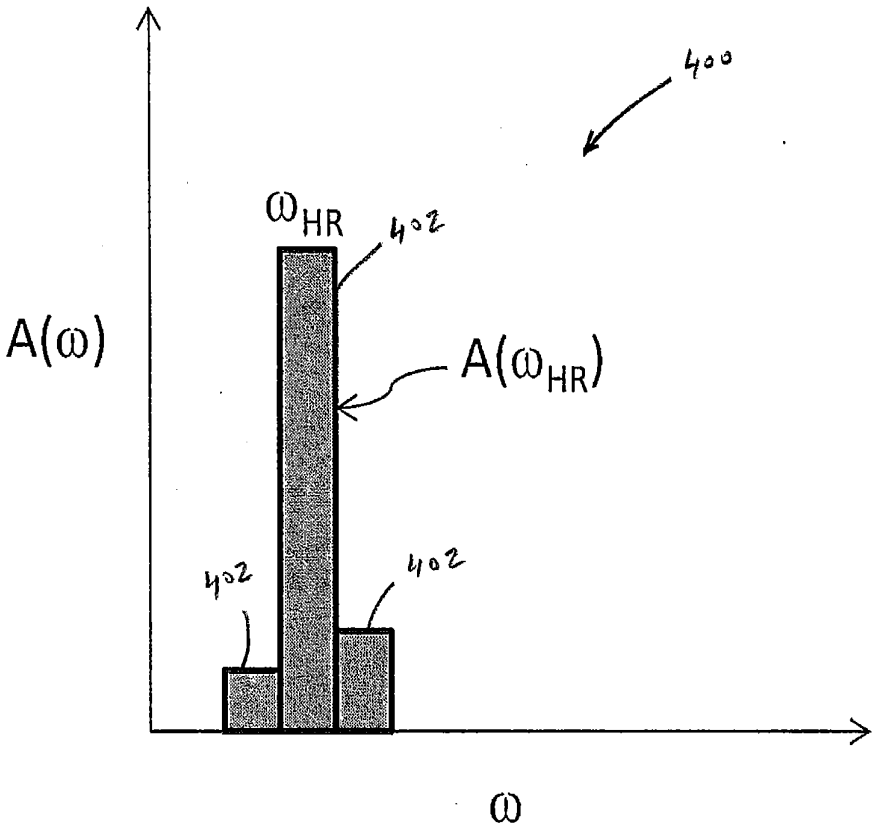



FIG. 11B

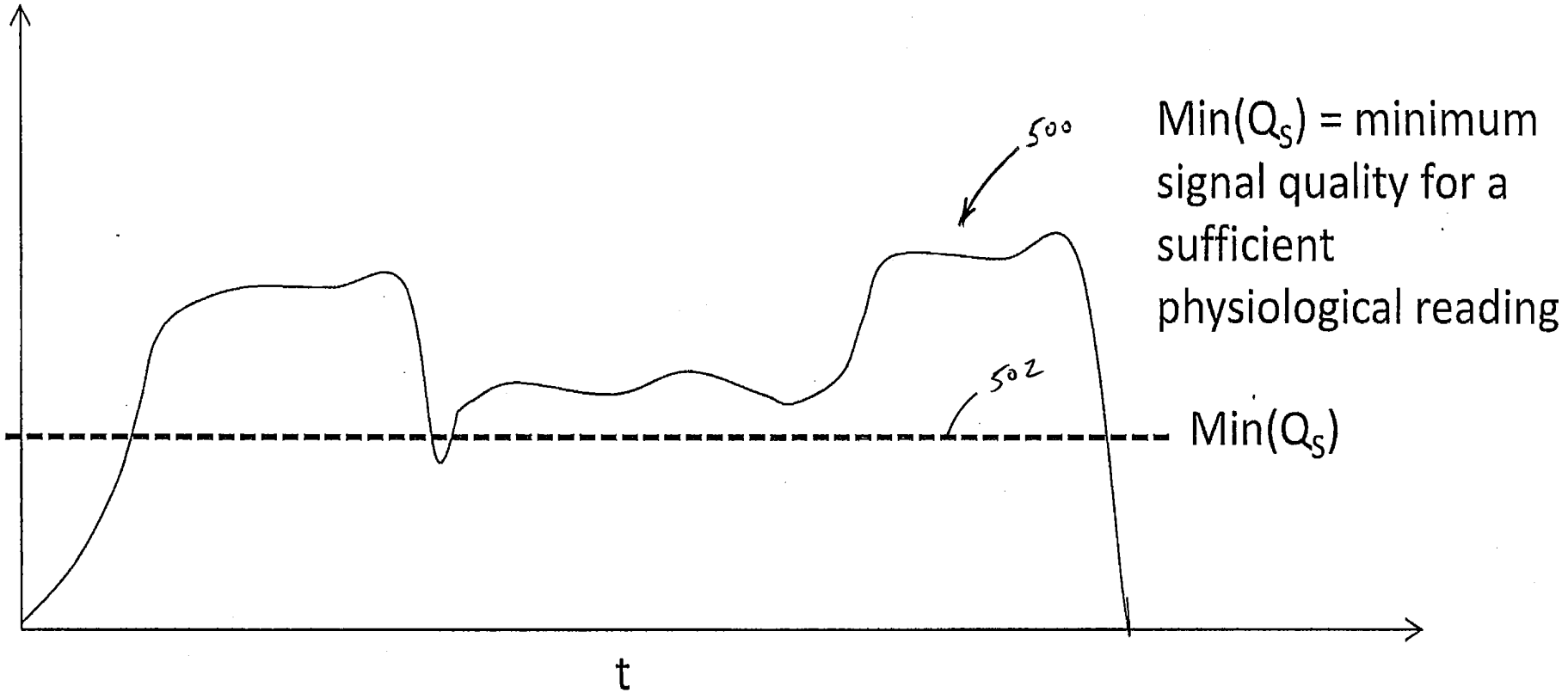

500
Min($Q_S$) = minimum signal quality for a sufficient physiological reading
$Q_S$
502
Min($Q_S$)
t

FIG. 12

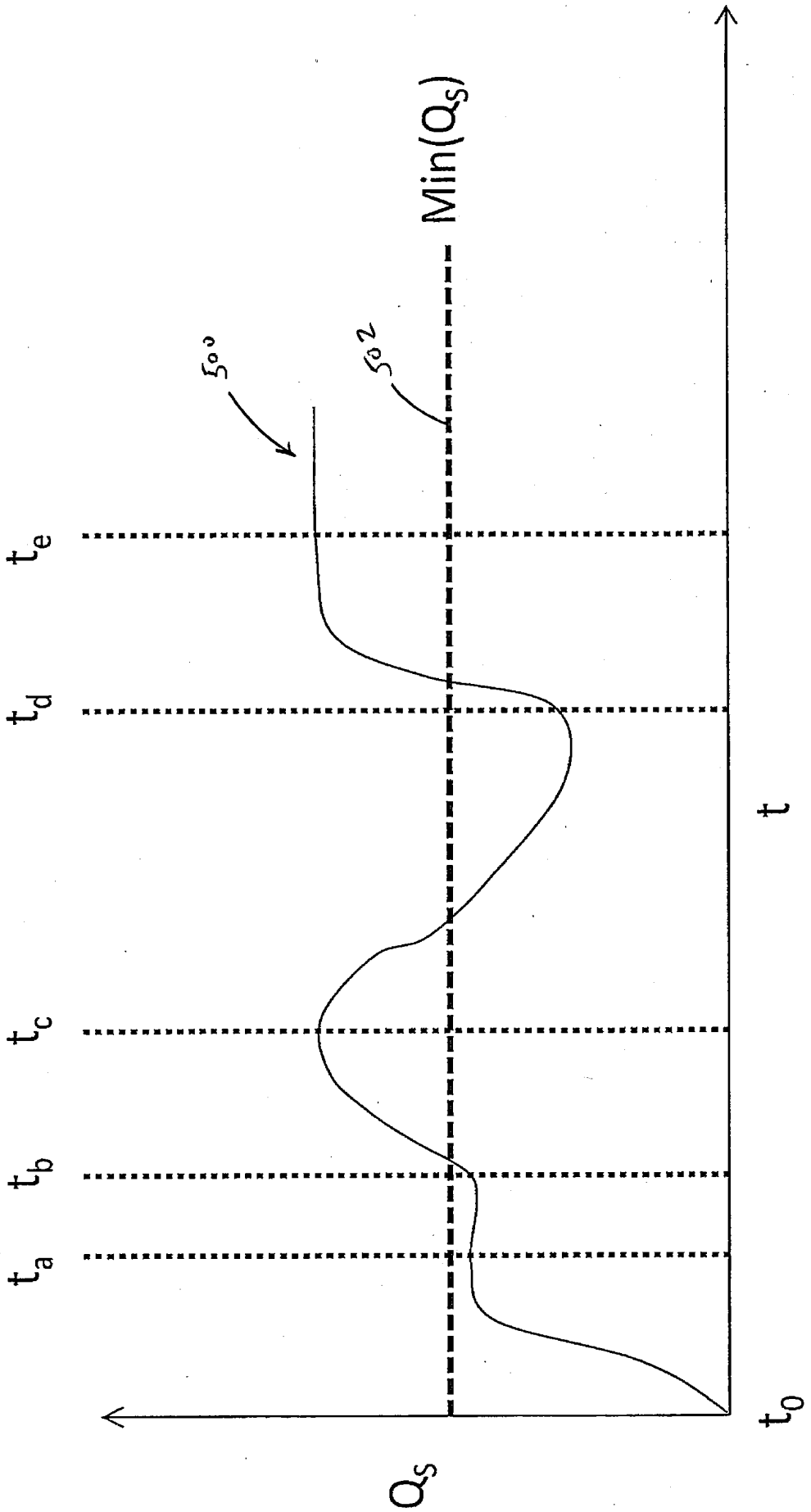



FIG. 13

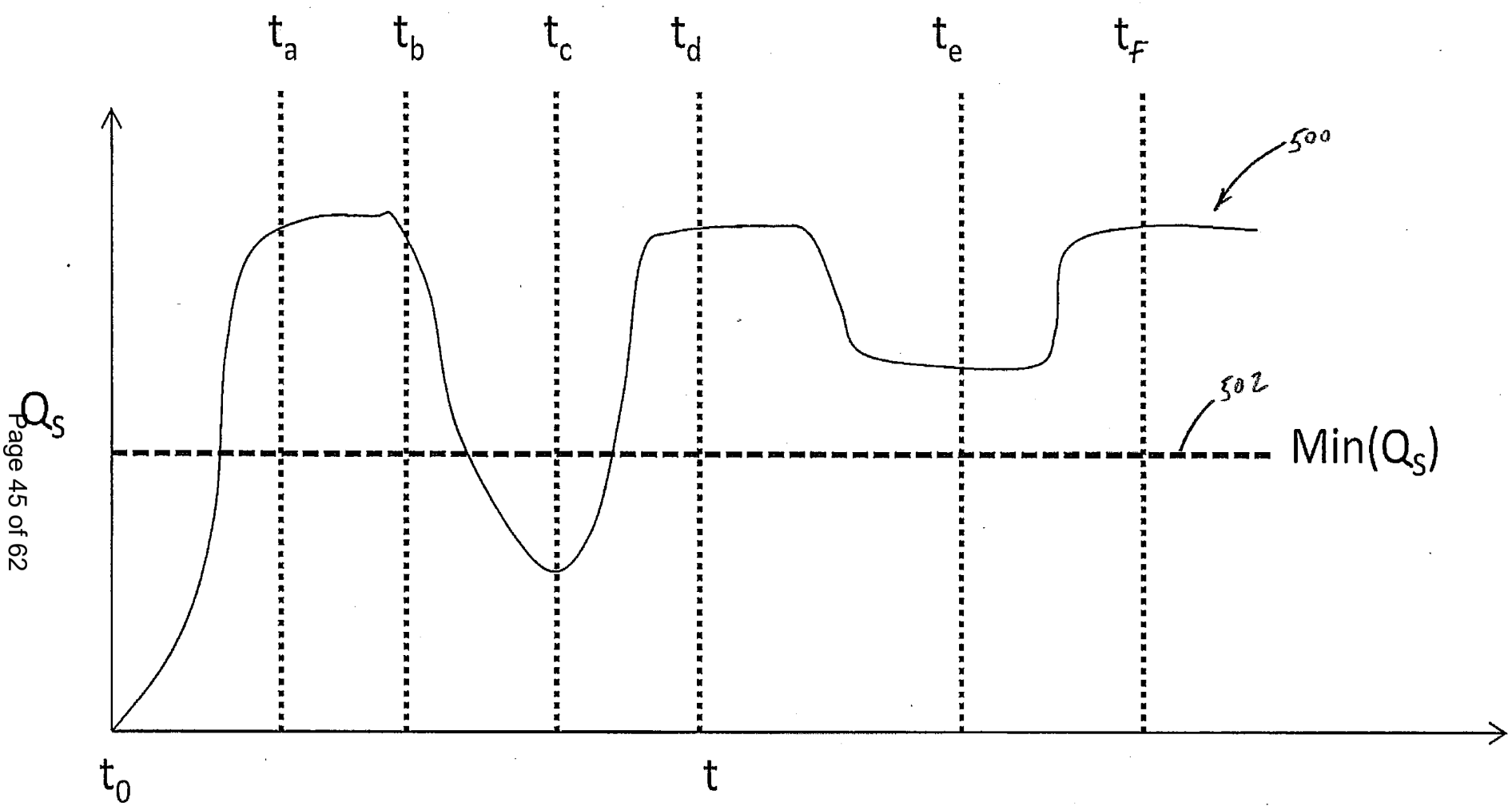



FIG. 14

## Process for generating assessments using high-quality biometric data

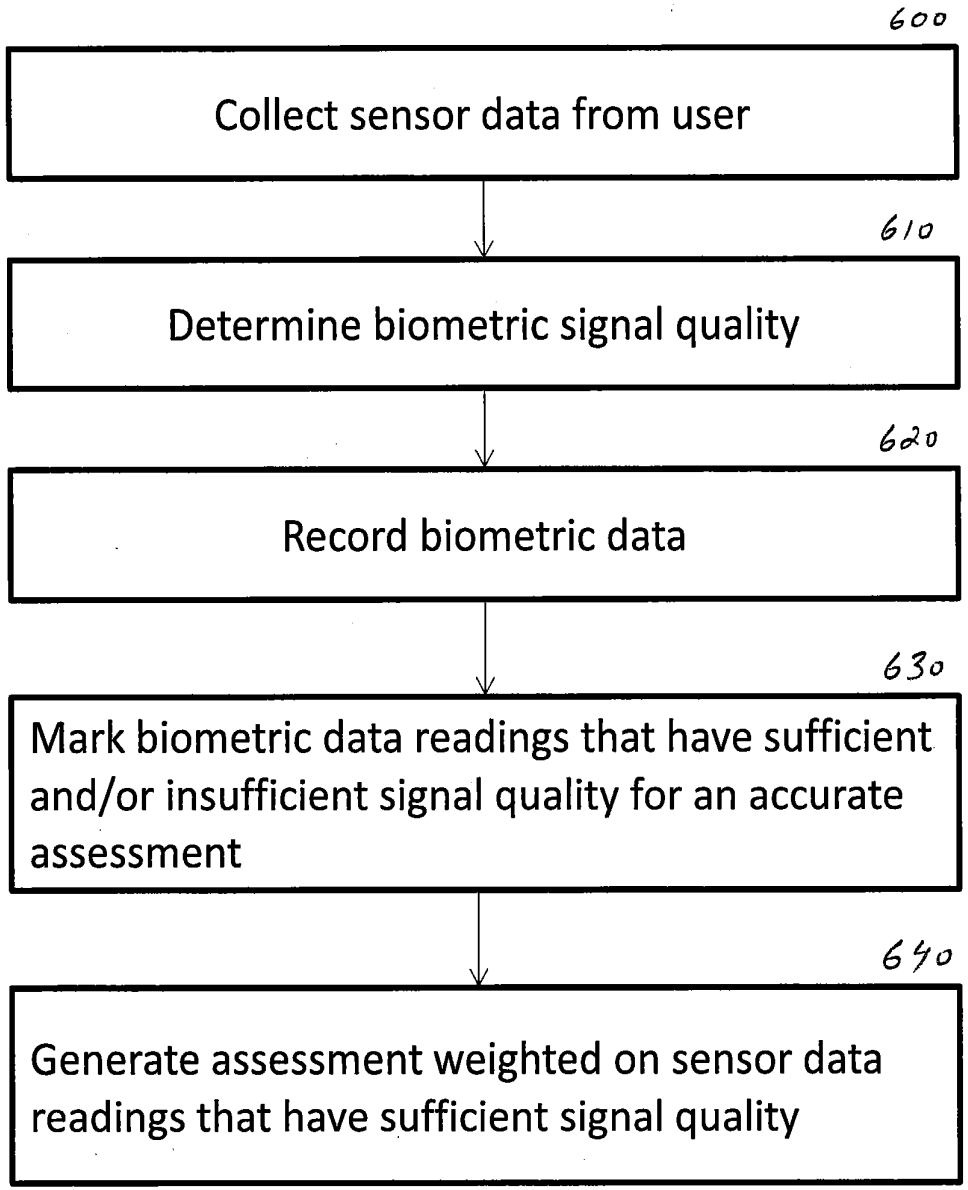



*Fig. 15*

## Example of marking unsatisfactory signal quality

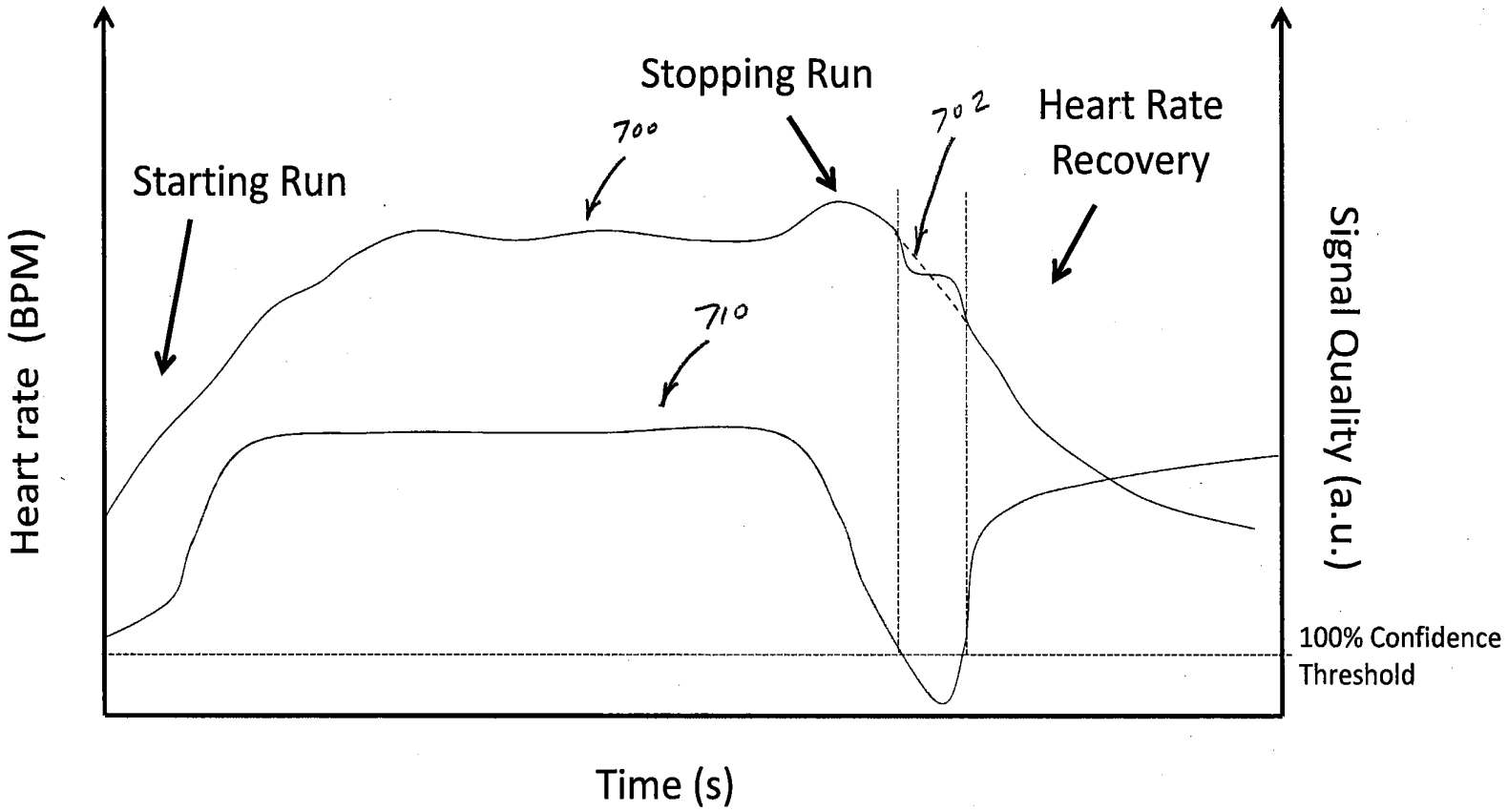



*Fig. 16*

## Example of marking unsatisfactory signal quality

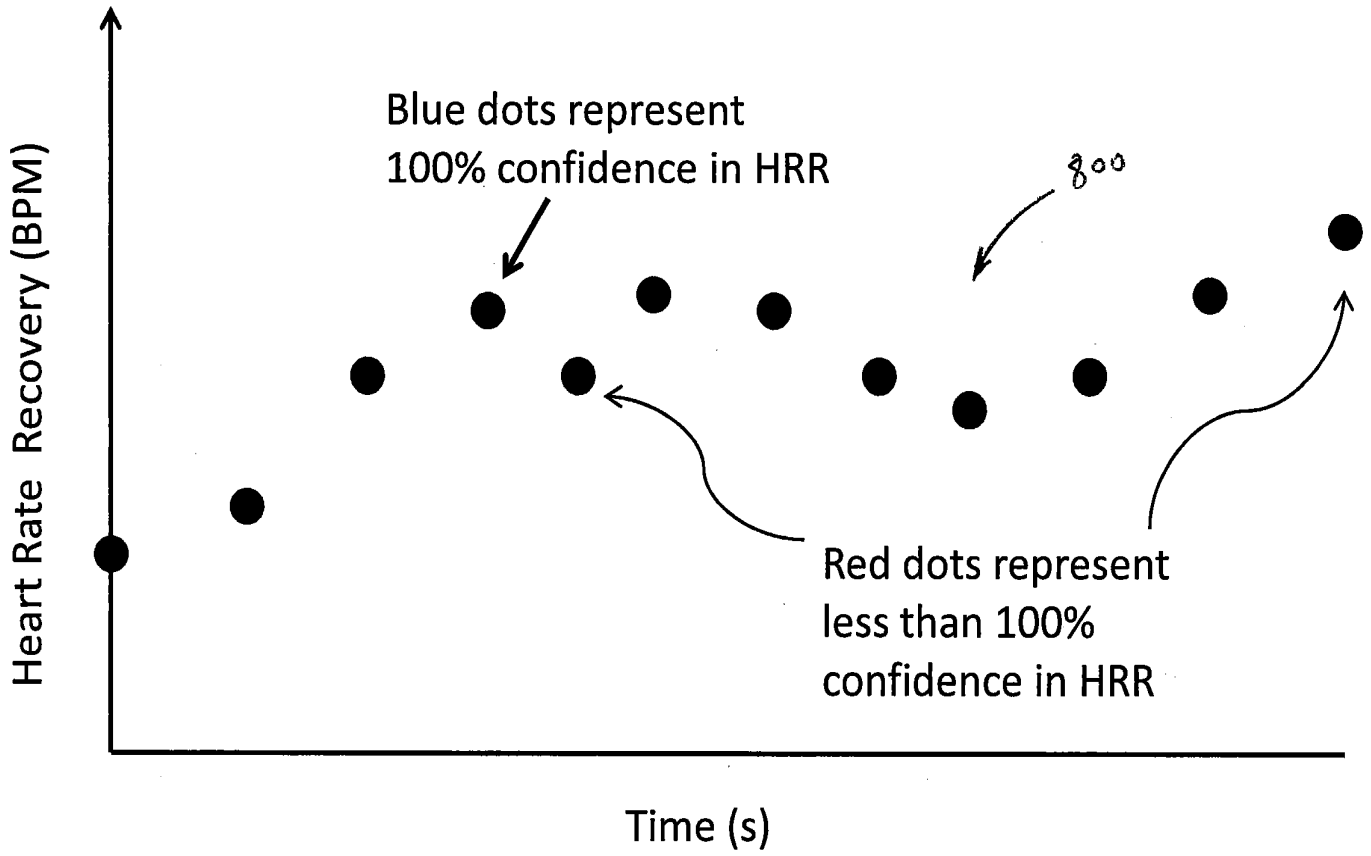



*Fig. 17*

## Process for generating assessments only when sensor is being worn

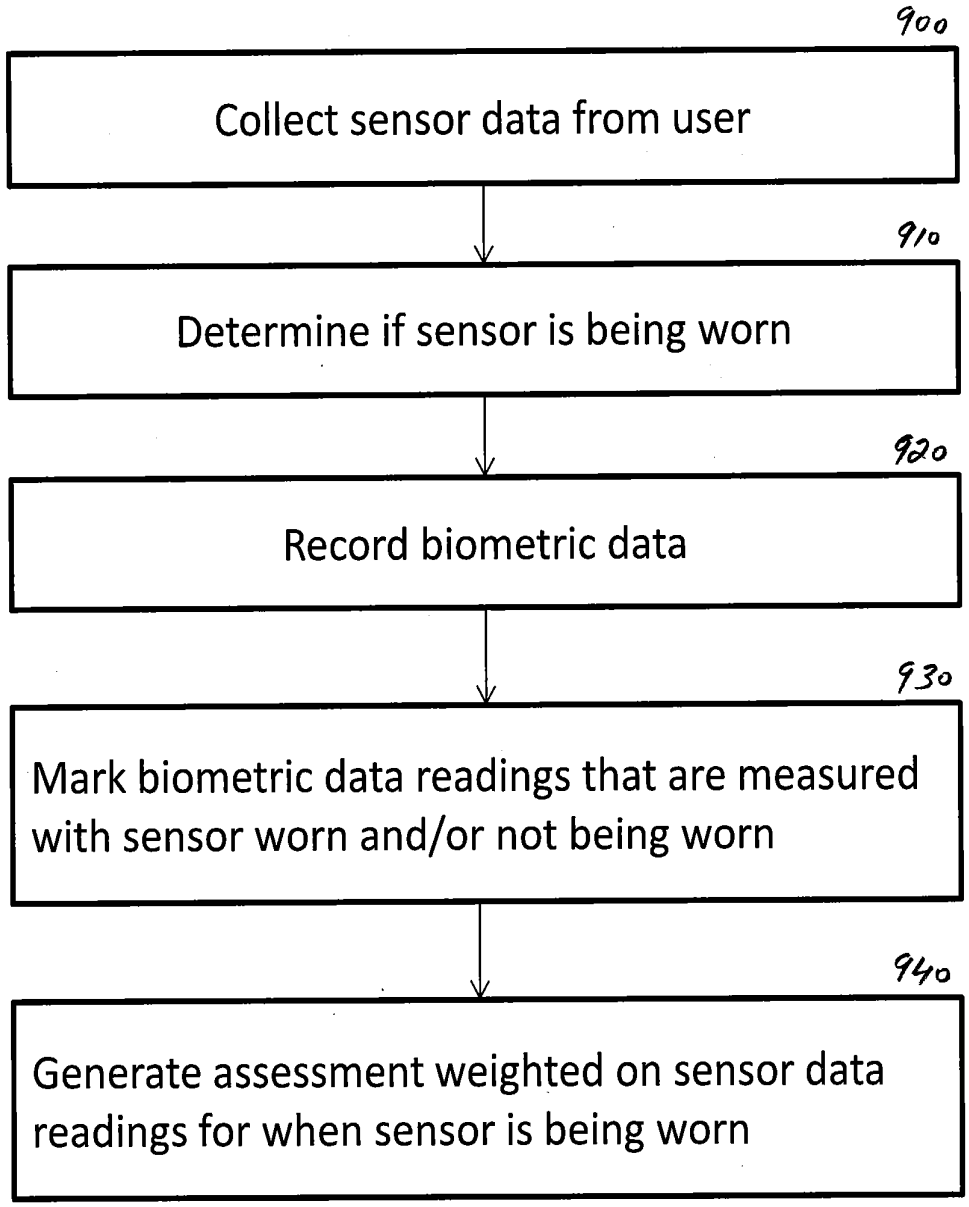



*Fig. 18*

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | |
| **Filing Date:** | |
| **Title of Invention:** | Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices |
| **First Named Inventor/Applicant Name:** | Steven Francis LeBoeuf |
| **Filer:** | Needham J. Boddie/Candi Riggs |
| **Attorney Docket Number:** | 9653-30PR2 |

Filed as Large Entity

**Filing Fees for Provisional**

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Basic Filing:** | | | | |
| Provisional Application Filing | 1005 | 1 | 260 | 260 |
| **Pages:** | | | | |
| **Claims:** | | | | |
| **Miscellaneous-Filing:** | | | | |
| **Petition:** | | | | |
| **Patent-Appeals-and-Interference:** | | | | |
| **Post-Allowance-and-Post-Issuance:** | | | | |

| Description | Fee Code | Quantity | Amount | Sub-Total in USD($) |
|---|---|---|---|---|
| **Extension-of-Time:** | | | | |
| **Miscellaneous:** | | | | |
| | | | **Total in USD ($)** | **260** |

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 21368138 |
| **Application Number:** | 62110655 |
| **International Application Number:** | |
| **Confirmation Number:** | 8090 |
| **Title of Invention:** | Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices |
| **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:** | 9653-30PR2 |
| **Receipt Date:** | 02-FEB-2015 |
| **Filing Date:** | |
| **Time Stamp:** | 11:06:48 |
| **Application Type:** | Provisional |

## Payment information:

| | |
|---|---|
| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | $260 |
| RAM confirmation Number | 9856 |
| Deposit Account | 500220 |
| Authorized User | |

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## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Transmittal of New Application | 9653-30PR2_Transmittal.pdf | 175494<br>af3a247d7e113dbfbba24f4a838ddad9ae391b01 | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 2 | | 9653-30PR2_Specification.pdf | 3456462<br>017404d9bec22775d7eb745daf7f46858775fabd | yes | 29 |

**Multipart Description/PDF files in .zip description**

| Document Description | Start | End |
|---|---|---|
| Specification | 1 | 25 |
| Claims | 26 | 28 |
| Abstract | 29 | 29 |

| | | | | | |
|---|---|---|---|---|---|
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 3 | Drawings-only black and white line drawings | 9653-30PR2_Drawings.pdf | 1241358<br>0b750f3541598d7bd3f6a8ad5412dd927118791c | no | 18 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 4 | Fee Worksheet (SB06) | fee-info.pdf | 30168<br>87c9e50b08888a8acf08033aced9817c95c20df9 | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | | **Total Files Size (in bytes):** | 4903482 | |

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

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Attorney Docket No. 9653-30PR2 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al. Confirmation No.: 8090
Application No.: 62/110,655
Filed: February 2, 2015
For: METHODS AND APPARATUS FOR IMPROVING SIGNAL QUALITY IN WEARABLE BIOMETRIC MONITORING DEVICES

Date: February 6, 2015

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

**REQUEST UNDER 37 C.F.R. 1.48**
**TO CORRECT ORDER OF INVENTORSHIP**

Dear Sir:

Pursuant to 37 C.F.R. 1.48(d), this is a Request to change the order of the inventors in the above-referenced provisional application. Applicants respectfully request that the order of the inventors be changed so that Michael Edward Aumer is the first inventor and Steven Francis LeBoeuf is second inventor. This request is being made without any deceptive intent.

Please charge the processing fee set forth in 37 C.F.R. 1.17(q) to Deposit Account No. 50-0220 in the amount of $50.00. The Commissioner also is authorized to charge any deficiency due, or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

Needham J. Boddie
Registration No. 40,519

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

**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 6, 2015.

Candi L. Riggs

# Electronic Patent Application Fee Transmittal

| | |
|---|---|
| **Application Number:** | 62110655 |
| **Filing Date:** | |
| **Title of Invention:** | Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices |
| **First Named Inventor/Applicant Name:** | Steven Francis LeBoeuf |
| **Filer:** | Needham J. Boddie/Candi Riggs |
| **Attorney Docket Number:** | 9653-30PR2 |

Filed as Large Entity

**Filing Fees for Provisional**

| 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($) |
|---|---|---|---|---|
| **Miscellaneous:** | | | | |
| Processing Fee for Provis. Applications | 1807 | 1 | 50 | 50 |
| | | **Total in USD ($)** | | **50** |

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 21424879 |
| **Application Number:** | 62110655 |
| **International Application Number:** | |
| **Confirmation Number:** | 8090 |
| **Title of Invention:** | Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices |
| **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:** | 9653-30PR2 |
| **Receipt Date:** | 06-FEB-2015 |
| **Filing Date:** | |
| **Time Stamp:** | 14:47:42 |
| **Application Type:** | Provisional |

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| Submitted with Payment | yes |
| Payment Type | Deposit Account |
| Payment was successfully received in RAM | $50 |
| RAM confirmation Number | 1163 |
| Deposit Account | 500220 |
| Authorized User | |

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## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Request under Rule 48 correcting inventorship | 9653-30PR2_RequesttoCorrectOrderofInventors.pdf | 80230<br>028f04ea3b2f4ea7900a8d5254c464f98c4da565 | no | 1 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 2 | Fee Worksheet (SB06) | fee-info.pdf | 30357<br>b9428955bbffe24e1a29c816592dd20e3adbf83d | no | 2 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| | | **Total Files Size (in bytes):** | 110587 | | |

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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.**

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

| APPLICATION NUMBER | FILING or 371(c) DATE | GRP ART UNIT | FIL FEE REC'D | ATTY.DOCKET.NO | TOT CLAIMS | IND CLAIMS |
|---|---|---|---|---|---|---|
| 62/110,655 | 02/02/2015 | | 260 | 9653-30PR2 | | |

**CONFIRMATION NO. 8090**

20792
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

**FILING RECEIPT**

*OC000000073426499*

Date Mailed: 02/13/2015

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. 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)**

Michael Edward Aumer, Raleigh, NC;
Steven Francis LeBoeuf, Raleigh, NC;

**Applicant(s)**

Michael Edward Aumer, Raleigh, NC;
Steven Francis LeBoeuf, Raleigh, NC;

**Power of Attorney:**
Needham Boddie II--40519

**If Required, Foreign Filing License Granted:** 02/13/2015
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/110,655**

**Projected Publication Date:** None, application is not eligible for pre-grant publication

**Non-Publication Request:** No

**Early Publication Request:** No

**Title**

Methods and Apparatus for Improving Signal Quality in Wearable Biometric Monitoring Devices

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

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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).

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