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(54) **FLASHING INDICATOR OF SWIMMER'S HEALTH**

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(60) Provisional application No. 62/658,651, filed on Apr. 17, 2018.

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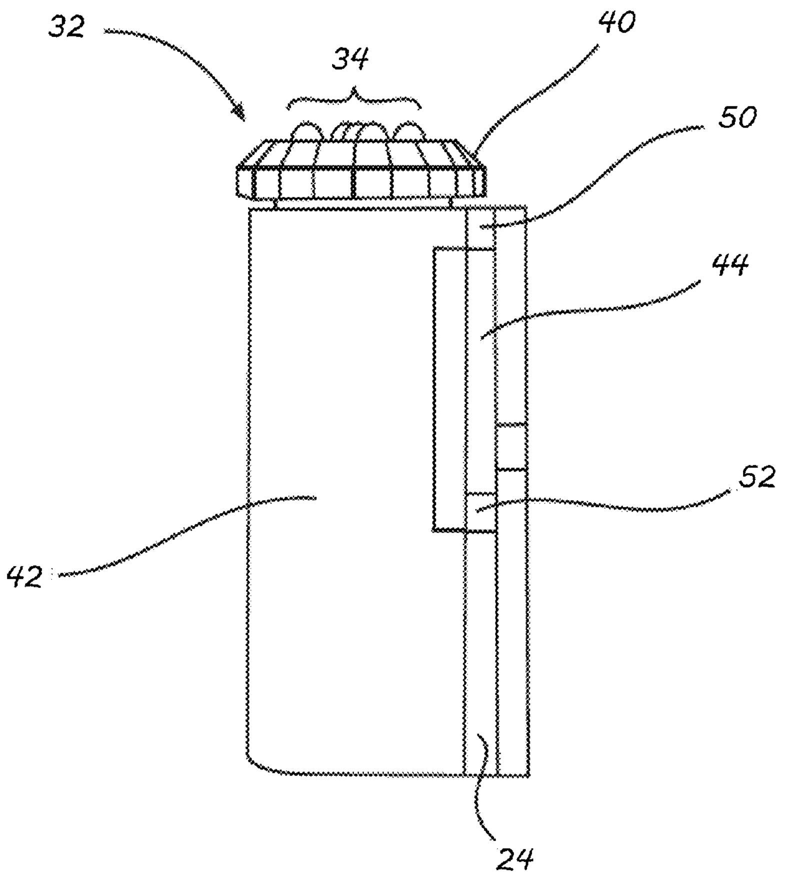
(57) **ABSTRACT**

A waterproof pulse oximeter sensor assembly configured to monitor vitals of a swimmer including a pulse oximeter sensor configured to evaluate conditions in a finger or a wrist of a swimmer and generate a pulse-ox signal in response thereto. A waterproof electronics compartment includes electronics configured to electrically receive the pulse-ox signal from the pulse oximeter sensor, and determine a heartbeat rate and/or a blood oxygen saturation level from the pulse-ox signal. The electronics generate an output signal that is based on the determined heartbeat rate and/or blood oxygen saturation level. An indicator proximate the electronics compartment is configured to receive the output signal and display an indication. A power source supplies electric power to the pulse oximeter sensor, electronics, and the indicator. The power source is recharged during use of the waterproof pulse oximeter sensor assembly by the swimmer.



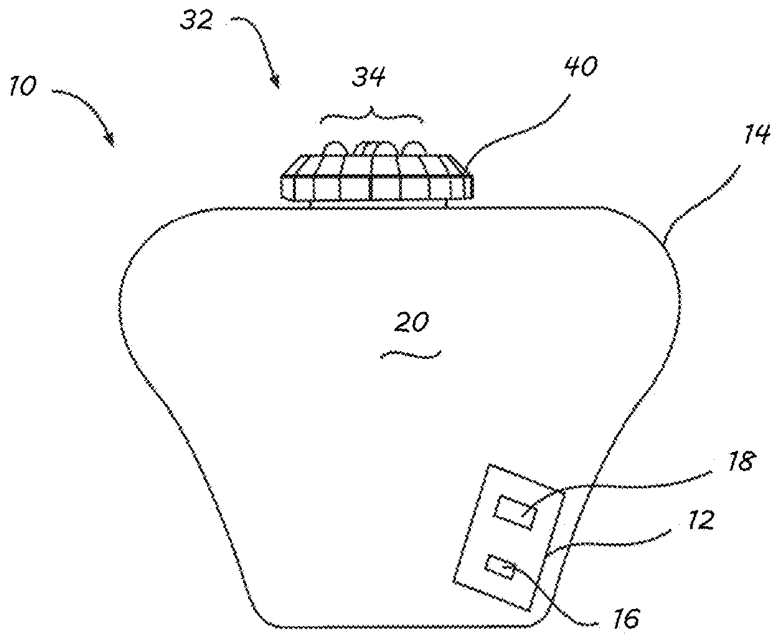


FIG. 1

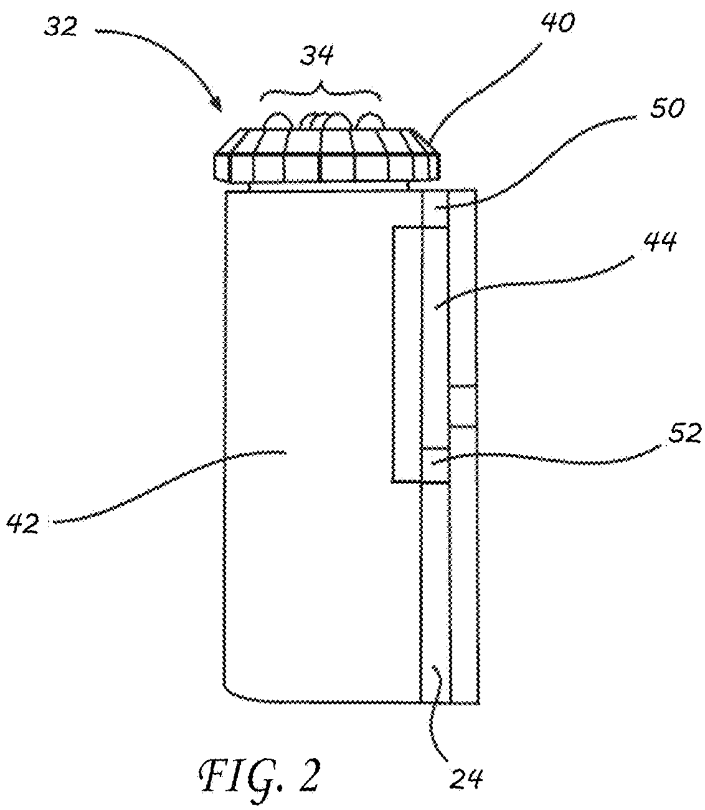


FIG. 2

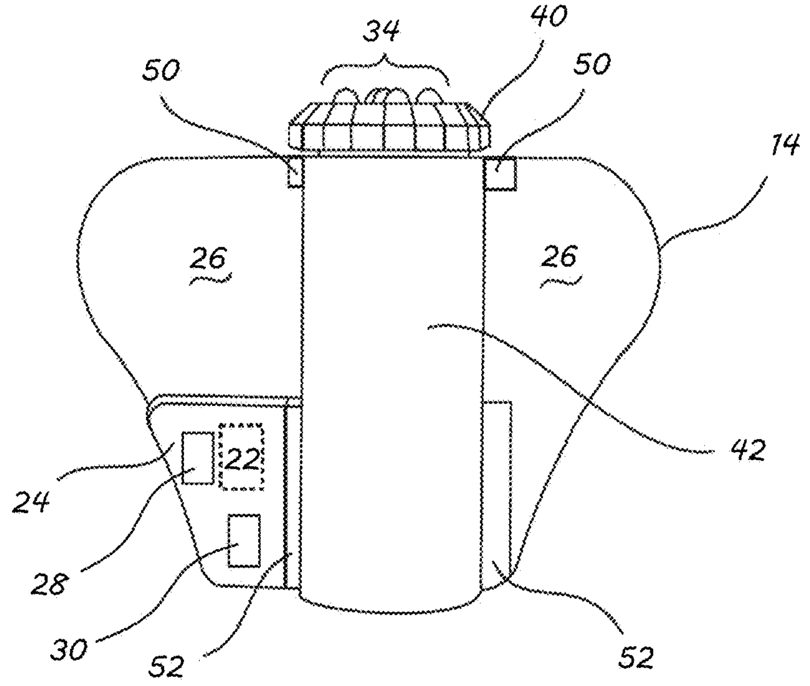


FIG. 3

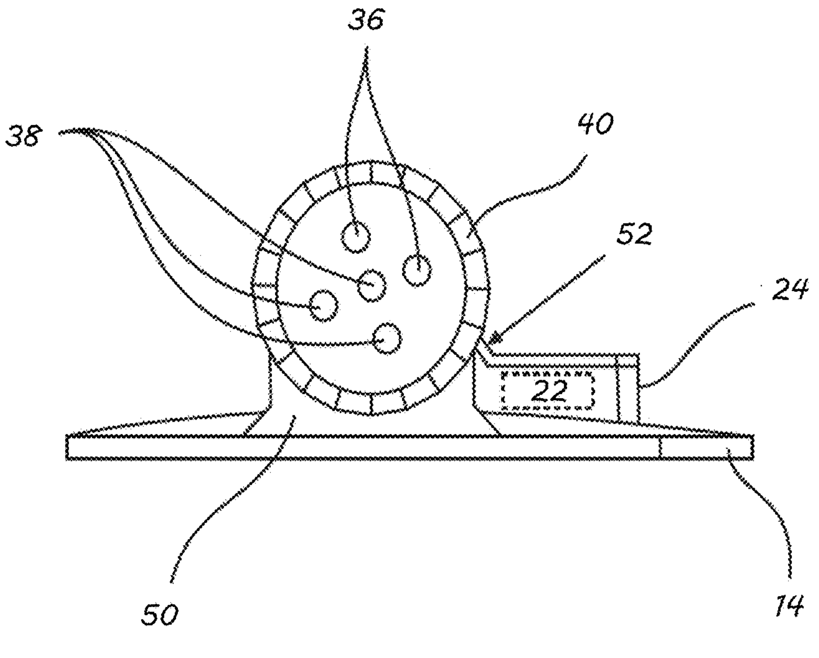


FIG. 4

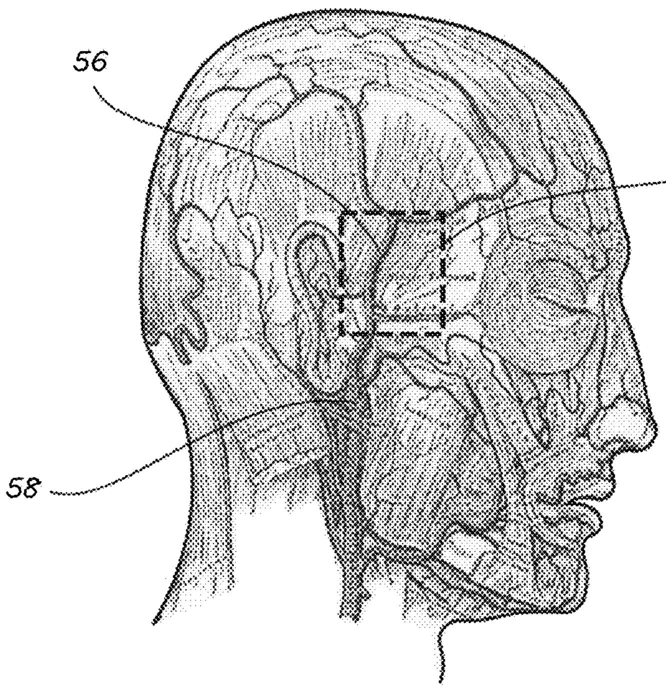


FIG. 5A

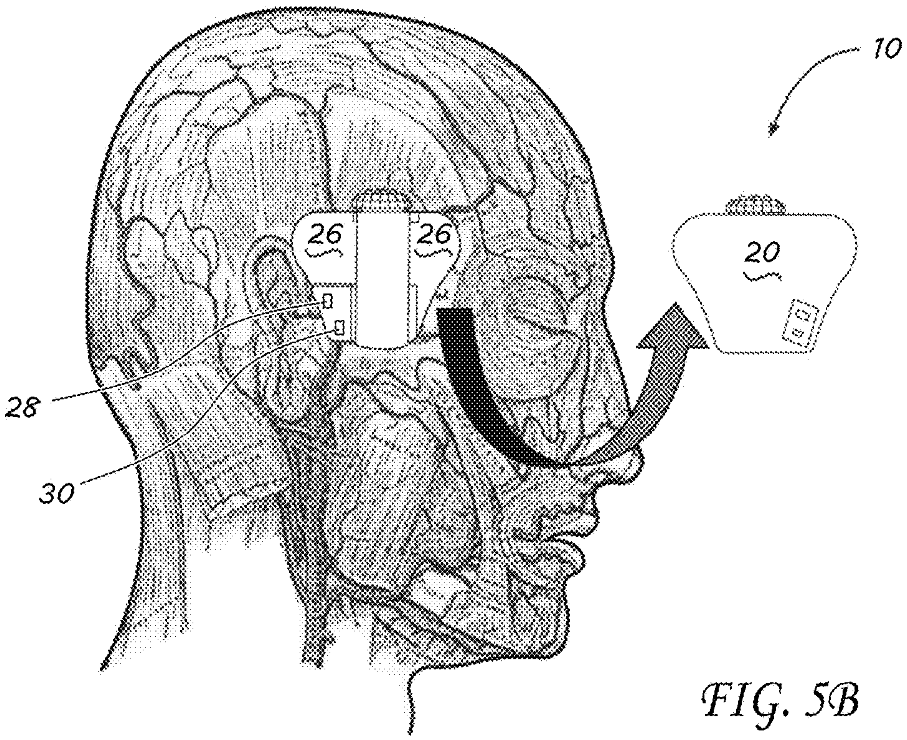


FIG. 5B

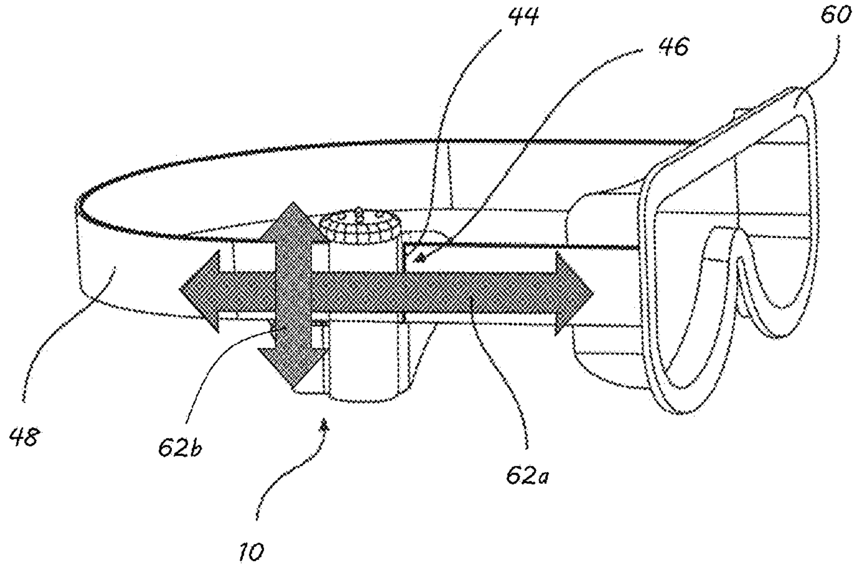


FIG. 6

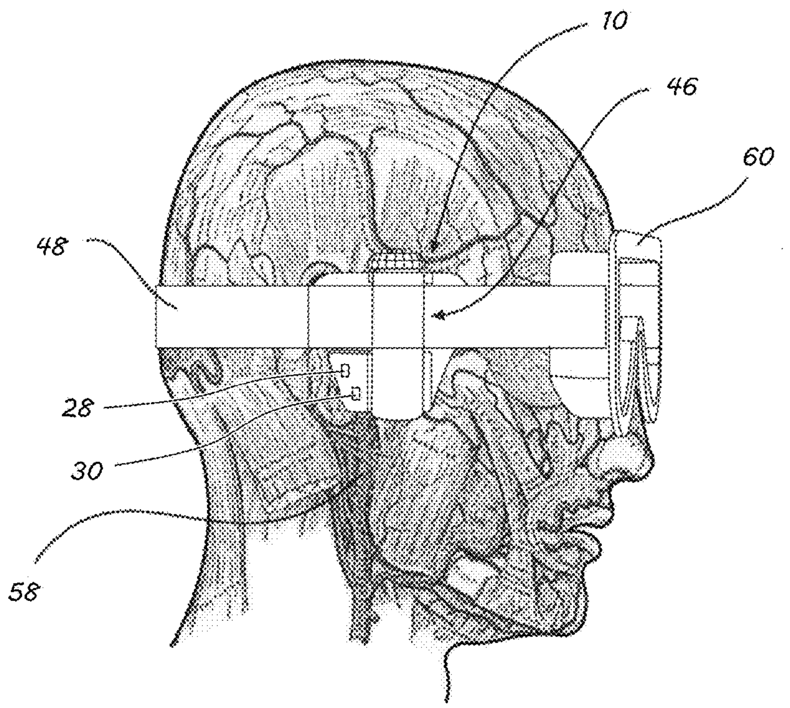


FIG. 7

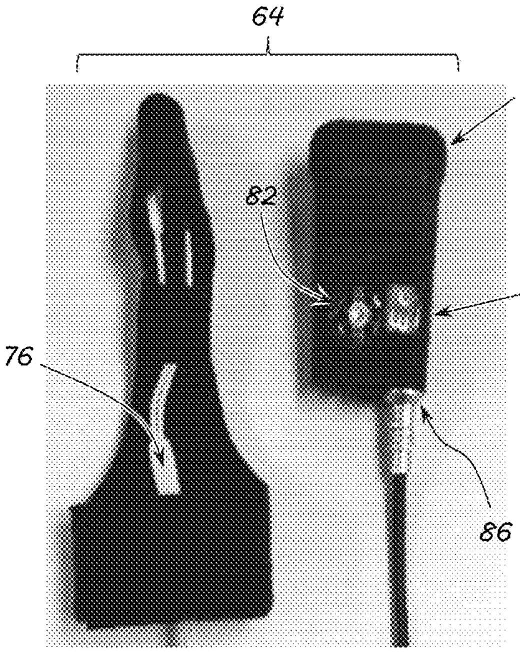


FIG. 8A

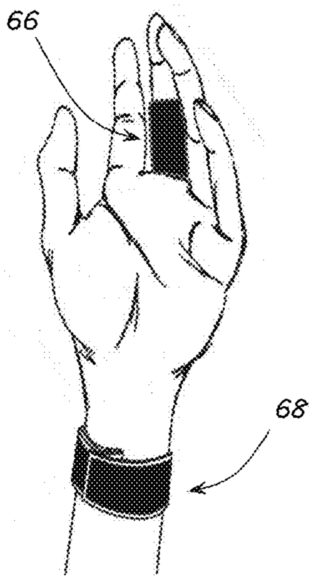


FIG. 8B

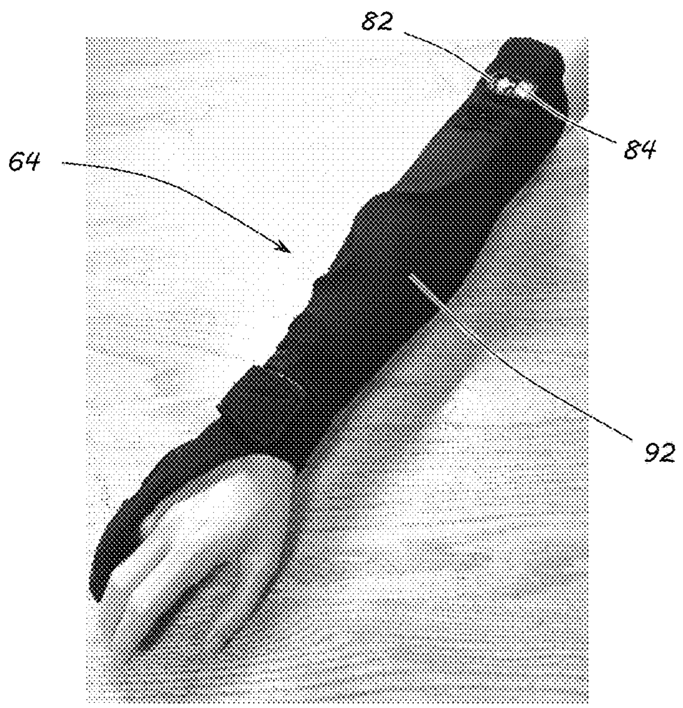


FIG. 8C

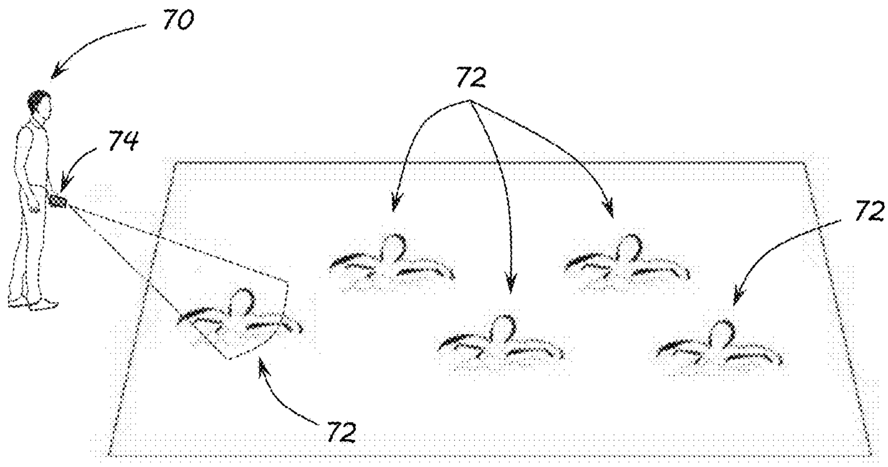


FIG. 9

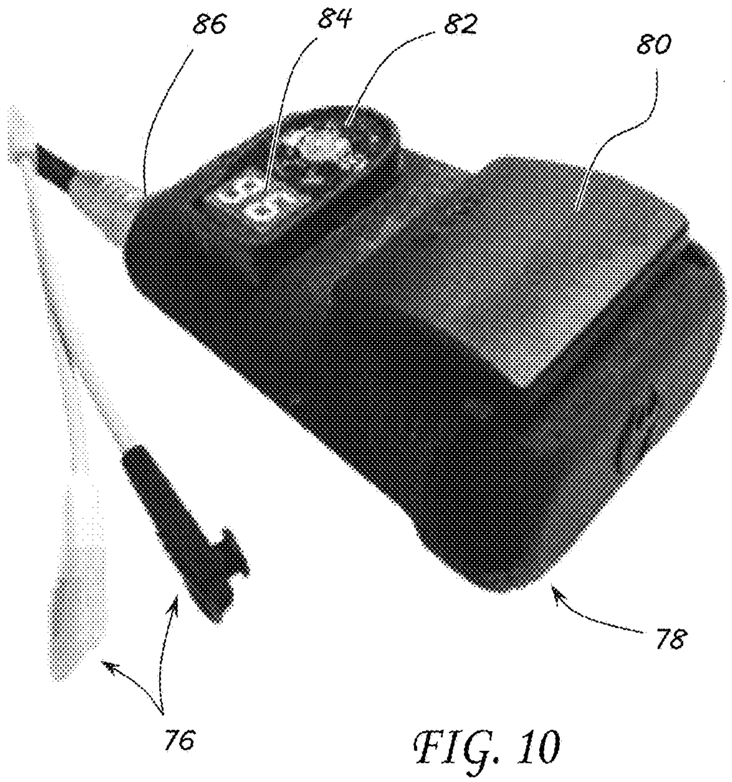


FIG. 10

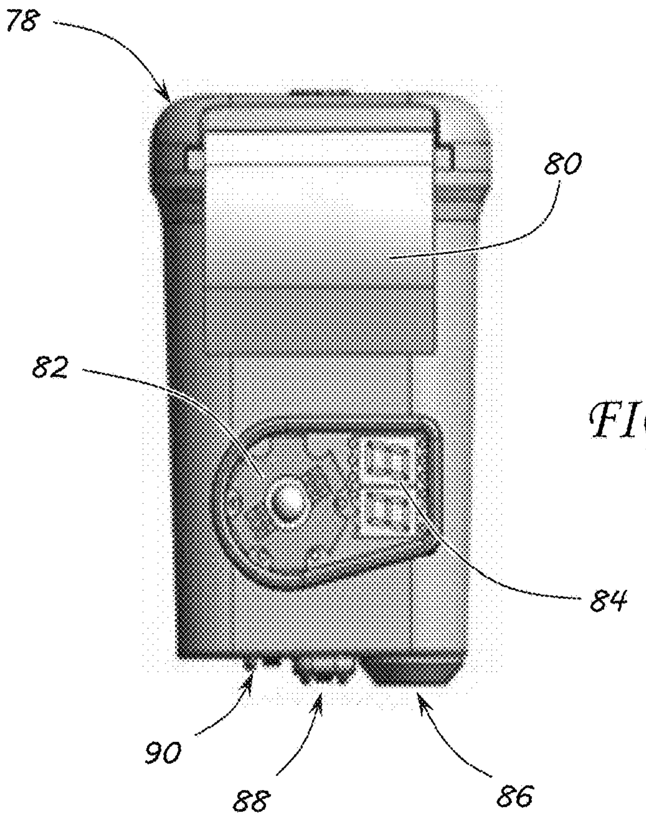


FIG. 11

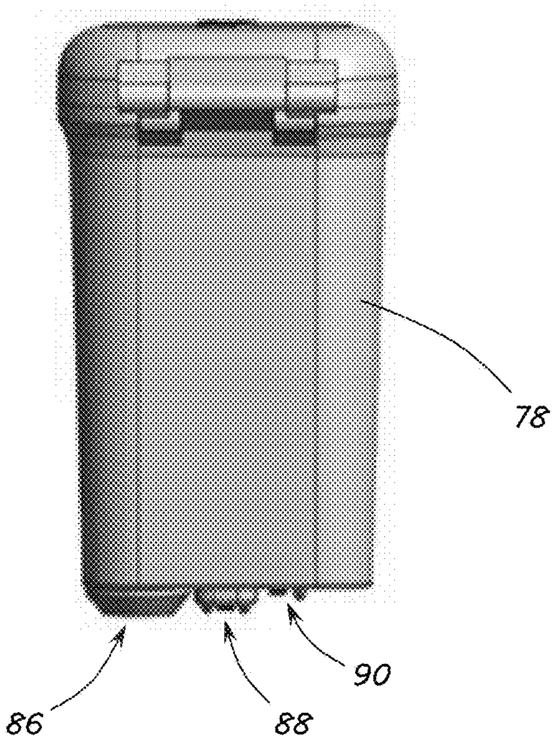


FIG. 12

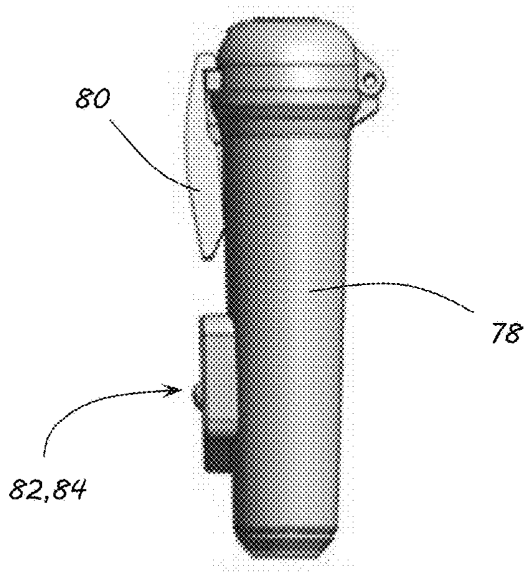


FIG. 13

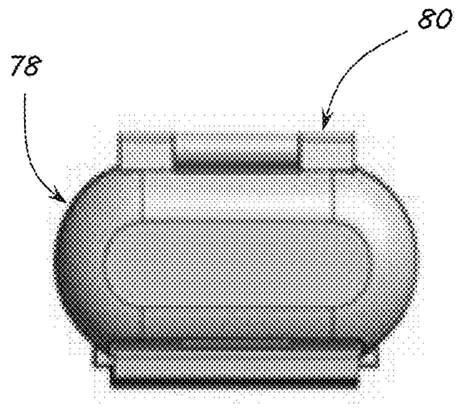


FIG. 14

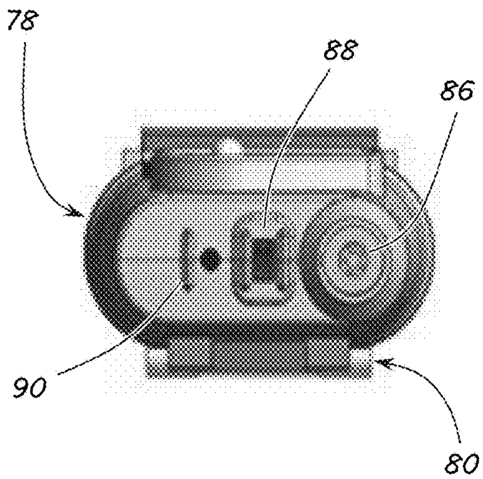


FIG. 15

FLASHING INDICATOR OF SWIMMER'S HEALTH

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. application Ser. No. 14/755,020, entitled "Pulse Oximeter Sensor Assembly and Methods of Using Same," filed on Jun. 22, 2015, the entirety of which is incorporated by reference herein. This application further claims the benefit of and priority to U.S. Provisional Application Ser. No. 62/658,651, entitled "Flashing Indicator of Swimmer's Health," filed on Apr. 17, 2018, the entirety of which is incorporated by reference herein.

RIGHTS OF THE GOVERNMENT

[0002] The invention described herein may be manufactured and used by or for the Government of the United States for all governmental purposes without the payment of any royalty.

BACKGROUND OF THE INVENTION

Field of the Invention

[0003] The present invention generally relates to the field of diagnostic instruments including wearable sensors, and more particularly to a waterproof pulse oximeter sensor assembly adapted to be positioned on a subject's hand or wrist and methods of using same.

Description of the Related Art

[0004] The U.S. Department of Defense trains service men and women who enter into specialized career fields such as combat control, pararescue, and other special operations positions in a variety of aquatic conditioning skills. The aquatic skills received enable military personnel to conduct operations around the world in and around water settings. However, prior to mastering these skills, basic recruits/students, hereinafter referred to as swimmers, are exposed to strenuous water sessions where swimmers are required to participate in both above and subsurface activities with and without breathing apparatuses. These activities are often accompanied, per design, by high stress and physically demanding exercises where a swimmer's heart rate is elevated and blood oxygen saturation is reduced. Current aquatic conditioning sessions maintain a safe swimmer-to-instructor ratio to help identify when swimmers are in need of assistance through verbal and/or visual observation of a swimmer's physical state (still moving). However, when training activities require challenging subsurface exercises, instructors could benefit from a device which could provide enhanced visual notification of a swimmer's physiological condition. Moreover, a device that monitors the well-being of a swimmer who is reaching their individual physiological thresholds can also assist in improving the safety of the training environment.

[0005] Pulse oximeter (or pulse-ox) assemblies include sensors that are configured to measure heart beat rate and/or the oxygen saturation of the blood, and are of particular importance in emergency medical situations as well as the monitoring of patients with respiratory or cardiac problems. Generally, pulse oximeters operate by directing light, such as in the red and/or infrared wavelength range, from one or more light emitting diodes (LEDs) toward the skin and blood vessels. In operation, the pulse-ox assembly emits light from the LED(s), and a photodiode collects the light reflected from the subject's body (reflectance pulse oximetry) or transmitted through the subject's body part (transmissive pulse oximetry). Light in the red wavelength range is absorbed at a different rate than the infrared light. Accordingly, the ratio of oxyhemoglobin and deoxyhemoglobin can be calculated from the respective amounts of reflected or transmitted light.

[0006] To reduce potential interference, contemporary pulse-ox sensors are generally configured to be worn on nonintrusive portions of the body such as wrists, fingers, or ear lobes. The measured heart rate and blood oxygen saturation of the subject is then reported on a local digital display or transmitted using wireless communication connections (e.g. bluetooth) to a remote display or system. This technology approach is practical for use in hospitals, home settings, and aviation environments; however, it does little to no assistance in aquatic settings. RF wireless communication is ineffective when submerged in water, which significantly attenuates the signal rendering the remote monitoring capability useless. Self-monitoring is not practical as swimmers will be engaged in other cognitive and physical activities and will typically push their limits to the point where they may become incapacitated. Therefore, a need exists for standoff monitoring that can be observed in both above and below water settings and provide a visual notification rather than the processing of digital information. Moreover, wearing sensors on one's fingertip or wrist by traditional means is generally cumbersome while swimming and may become detached through vigorous activities.

SUMMARY OF THE INVENTION

[0007] Embodiments of the invention address the need in the art and provide a waterproof pulse oximeter sensor assembly configured to monitor vitals of a swimmer. The waterproof pulse oximeter sensor assembly includes a pulse oximeter sensor configured to evaluate conditions in a finger or a wrist of a swimmer and to generate a pulse-ox signal in response thereto. A waterproof electronics compartment includes electronics that are configured to electrically receive the pulse-ox signal from the pulse oximeter sensor. The electronics are further configured to determine a heartbeat rate and/or a blood oxygen saturation level from the pulse-ox signal and generate an output signal that is based on the determined heartbeat rate and/or blood oxygen saturation level. An indicator is proximate the waterproof electronics compartment and configured to receive the output signal from the electronics and display an indication to an observer. The waterproof pulse oximeter sensor may also include a power source operable to supply electric power to the pulse oximeter sensor, electronics of the electronics compartment, and the indicator. The power source may be recharged during use of the waterproof pulse oximeter sensor assembly by the swimmer.

[0008] Some embodiments of the invention allow for wireless charging through magnetic capacitive induction. Internal to the housing of the electronics enclosure is a coiled antenna that can be tuned to for the purpose of wireless charging. A common practice is a swimmer "rest" by holding onto a pool's edge, boat platform, inner-tube, etc. while receiving instructions or awaiting their designated time to conduct aquatic tasks. These embodiments may leverage this "resting" state by incorporating induction charging that can be used to extend the initial battery state of charge.

[0009] Some embodiments of the invention allow for digital readout of SpO2/HR for real-time interrogating.

[0010] Some embodiments of the invention allow for on-demand occlusion of the overt/covert notification through a mechanical filter lens over the LED cluster IRIS lens. Swimmers are often required to participate in water sessions that are during the night-time or in a light-controlled facility to hone the swimmers skills. These embodiments may be equipped with a retractable IRIS lens that can limit the amount of light-energy emitting from its LED cluster to include closing it completely. Alternately, in some other embodiments, the brightness of the LED cluster may be directly adjusted from dim to bright via an on board voltage control.

[0011] Some embodiments of the invention allow for interchangeable and removable physiological sensors through a quick-disconnect interface. A benefit of this modular design is that health sensors continue to evolve producing higher fidelity/accuracy measurements thereby supporting various sensors (both transmissive, reflective, etc.). These embodiments can scale and be customized to the environments and conditions required for military operations, for example. Moreover, having a dynamically adjustable pull-force quick-disconnect enables these embodiments to remain secure but not create a potential risk to the swimmer in case of an entanglement situation. The orientation of the quick-disconnect interface promotes custom cable lengths and promotes in-line cable routing minimizing drag impact to the swimmer.

[0012] Some embodiments of the invention possess the ability to harvest kinetic, thermal deltas, and induction tuning to supply energy to its control circuitry. Kinetically, these embodiments may leverage electro-magnetic energy generation as the wearer exerts continuous movement through various swimming maneuvers and strokes. Thermally, these embodiments may leverage an array of thermoelectric generators arranged on one side to rest on the skin of the wearer and the other side exposed to the water. Water temperatures and fluid dynamics provide a constant thermal delta enabling energy harvesting. Lastly, using magnetic induction, these embodiments may be able to be remotely powered through induction tuned energy waves created in the aquatic environment, thereby affording continuous monitoring without the risk of power depletion.

[0013] Some embodiments of the invention may leverage a chemical reactive fuel cell that can harvest power from the water surrounding the embodiments. Micro-perforated inlets allow an absorption membrane to gather and store fluids that when exposed to the fuel-cell an electrical reaction occurs producing current and voltage that are stored in the rechargeable battery cells of these embodiments.

[0014] Some embodiments of the invention allow for programmable thresholds of swimmers' vitals. These embodiments can be configured to capture a swimmer's baseline vitals and can be programmed to alert via the LED notification cluster when a swimmer is outside of his/her "safe" programmed operational vital range.

[0015] Some embodiments of the invention are able to archive a swimmers vital history, sampled at a predefined interval, to be offloaded at the completion of a swimming session. This feature allows swimmers to monitor their conditioning as well as provide instructors with information on a swimmer's state during key elements/exercise within training regimes.

[0016] Some embodiments of the invention may wirelessly transmit a swimmer's real-time health vitals using a configurable microcontroller emitter that senses the swimmer's environment, dynamically adjusting the method of transmission. These embodiments possess a variety of communication emitters to include but not limited to Radio Frequency (Bluetooth, Ultra-Wide Band, WiFi, Zig-bee), Magnetic Induction, and Optical Free-Space Communication. The communication microcontroller can sense the receipt of its transmission and determine if switching to another medium is required to output the swimmer's vitals.

[0017] Some embodiments of the invention can give instructors an on-demand indicator of the swimmers' readiness status following strenuous activities. These embodiments may contain an optical receiver that allows an instructor to remotely interrogate ON/OFF and/or activate the on-board digital readout display and/or powers-on the notification signal indicating the swimmers' readiness level remotely.

[0018] Additional objects, advantages, and novel features of the invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following or may be learned by practice of the invention. The objects and advantages of the invention may be realized and attained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and, together with a general description of the invention given above, and the detailed description given below, serve to explain the invention.

[0020] FIG. **1** is a view of a subject-facing side of a pulse-ox sensor assembly, in accordance with an embodiment of the present invention;

[0021] FIG. **2** is a side view of the pulse-ox sensor assembly shown in FIG. **1**, in accordance with an embodiment of the present invention;

[0022] FIG. **3** is a view of an outward-facing side of the pulse-ox sensor assembly shown in FIG. **1**, in accordance with an embodiment of the present invention;

[0023] FIG. **4** is top view of the pulse-ox sensor assembly shown in FIG. **1**, in accordance with an embodiment of the present invention;

[0024] FIG. **5**A is a schematic showing the location of a temporal artery in a human subject;

[0025] FIG. **5**B is a schematic showing placement of the pulse-ox sensor assembly shown in FIG. **1** onto a subject's temporal region overlaying the temporal artery, in accordance with an embodiment of the present invention;

[0026] FIG. **6** is a perspective view of a pulse-ox sensor assembly, in accordance with another embodiment of the present invention;

[0027] FIG. **7** is a schematic showing placement of the pulse-ox sensor assembly shown in FIG. **6** onto a subject's temporal region, in accordance with another embodiment of the present invention;

[0028] FIGS. **8A-8C** illustrate a hand/arm mounted arrangement consistent with an embodiment of the invention;

[0029] FIG. **9** is a diagrammatic representation of an instructor remotely interrogating the hand/arm mounted arrangement of FIGS. **8A-8C**;

[0030] FIG. **10** is in isometric view of an electronic compartment of the hand/arm mounted arrangement of FIGS. **8A-8C**;

[0031] FIG. **11** is a front view of the electronics compartment of FIG. **10**;

[0032] FIG. **12** is a back view of the electronics compartment of FIG. **10**;

[0033] FIG. **13** is a side view of the electronics compartment of FIG. **10**;

[0034] FIG. **14** is a top view of the electronics compartment of FIG. **10**; and

[0035] FIG. **15** is a bottom view of the electronics compartment of FIG. **10**.

[0036] It should be understood that the appended drawings are not necessarily to scale, presenting a somewhat simplified representation of various features illustrative of the basic principles of the invention. The specific design features of the sequence of operations as disclosed herein, including, for example, specific dimensions, orientations, locations, and shapes of various illustrated components, will be determined in part by the particular intended application and use environment. Certain features of the illustrated embodiments have been enlarged or distorted relative to others to facilitate visualization and clear understanding. In particular, thin features may be thickened, for example, for clarity or illustration.

DETAILED DESCRIPTION OF THE INVENTION

[0037] Military personal who enter into specialized career fields such as combat control, pararescue, and other special operation forces and special tactics positions are required to master aquatic skills. Although at times, aquatic conditioning may prove to be too strenuous for swimmers and potentially necessitate medical intervention. The assemblies and methods described herein provide alerts when vital signs (e.g., SPO2 and/or HR) and core body temperature deteriorate to a predetermined threshold value prior to the need for medical intervention and thereby enable standoff monitoring of a swimmer's vitals and condition. Embodiments described herein provide an assembly and method for subsurface (underwater) and/or aquatic (within) monitoring of various vital signs (e.g., heart rate (HR), blood oxygen saturation (SPO2), core temperature, etc.) of a subject in an aquatic environment and providing the subject and/or others with external overt notifications. However, it should be further appreciated that the assemblies described herein may also be utilized in non-aqueous environments.

[0038] Thus, in accordance with embodiments of the present invention, a health status sensor assembly is provided that includes 1) a pulse-ox sensor, 2) an indicator device, 3) a processor, 4) a base layer, 5) a mounting assembly, 6) a temperature sensor, and 7) a pressure sensor. The pulse-ox sensor is configured to facilitate measuring a subject's heart beat rate, blood oxygen saturation level, or both. The indicator device provides a discernible signal to the subject or others, (e.g., communication via optical modulation to an underwater and/or above water receiver). The processor, which is coupled to the pulse-ox sensor, temperature sensor, pressure sensor, and/or the indicator device, includes control logic configured to receive an output signal from any of the sensors, determine the subject's heart beat rate, blood oxygen saturation level, core body temperature, water temperature, atmospheric pressure, and generate an output signal for the indicator device that is based on the subject's heart beat rate, blood oxygen saturation level, and/or core body temperature. The base layer is configured to conform to a temporal region of the subject's head and includes one surface adapted to face and contact the subject's skin, and a second surface adapted to face away from the subject's skin. The mounting assembly is configured to enable securing and/or maintaining the health status sensor assembly over the temporal region of the subject's head, which, relative to more distal extremities (e.g., fingers or wrists), is less prone to blood pooling. The health status sensor assembly may also include a power supply, which can include a chamber that is adapted to hold and maintain a battery in electrical communication with the pulse-ox sensor, temperature sensor, pressure sensor, the processor, and the indicator device.

[0039] With more detail and specificity, the foregoing exemplary components are further described with reference to FIGS. **1-4**, which provide complementary views of an exemplary embodiment. Referring to FIG. **1**, an exemplary health status sensor assembly **10** is provided with a pulse-ox sensor **12** disposed in a base layer **14**. The pulse-ox sensor **12** includes at least one light emitting diode (LED) **16** configured to emit light such as in the red and/or infrared range and at least one photodetector **18** configured to receive the light emitted by the at least one LED **16** and reflected by a subject's body (not shown) when in use and disposed proximate the body. The LED **16** and photodetector **18** cooperate to evaluate conditions observed in a region of the subject's skin, e.g., the temporal region. One exemplary pulse-ox sensor **12** is an 8000R Reflectance Sensor available from Nonin Medical, Inc. According to the depicted embodiment in FIG. **1**, the pulse-ox sensor **12** is adapted to fit within an opening formed in the base layer **14**. According to another embodiment, the pulse-ox sensor **12** may be embedded in the base layer **14**. In either arrangement, it is advantageous that the pulse-ox sensor **12** does not protrude too far above a subject-facing side **20** of the assembly **10** as to cause undue discomfort to the subject. In one embodiment, the subject-facing surface **20** of base layer **14** and the pulse-ox sensor **12** are substantially uniplanar. In yet another embodiment, the pulse-ox sensor **12** is within about 0.5 mm, about 1 mm, about 2 mm, about 3 mm, or about 4 mm of the subject-facing surface **20** of the base layer **14**. In yet another embodiment, base layer **14**, could have a two-axis slidable adjustment for the pulse-ox sensor **12** to accommodate custom fitting to the subject's temporal artery.

[0040] The pulse-ox sensor **12** is configured to electrically communicate with a processor **22**, which may be contained in and protected by an electronics compartment **24**. To permit continual use of the assembly **10** in a water environment, the electronic compartment **24** may provide a waterproof or water-resistant containment of the processor **22**, as well as any other water-sensitive electronic components. The electronics compartment **24** is preferably made of waterproof material. In other embodiments of the invention, the electronics compartment **24** may be made of materials that are merely water resistant. As used herein, "water resistant" refers to material that is capable, at least, of resisting or impeding the passage of liquid water by mass flow, capillary or wicking action. Thus, water resistant material may not prevent all passage of liquid water under pressure. "Water tight" refers to connections between components that are at least water resistant. As used herein, "waterproof" refers to the capability of withstanding immersion in water. Such immersion could be as little as splashing or dropping the assembly on or in water, or by submersion to a depth of about 10 cm, about 1 m, about 10 m, about 38 m, or about 100 m, in sea or freshwater. Waterproof material can range from gas proof to gas permeable, including such breathable fabrics and fabric coatings such as Gore-Tex®. The electronics compartment **24** may in certain applications be constructed to be not only waterproof, but also gas-proof, such that gases cannot escape or enter the sealed electronics compartment **24**. The assembly **10** may therefore be particularly useful to swimmers and divers. As shown in FIGS. **3** and **4**, the electronics compartment may be positioned on an outward-facing surface **26** of the base layer **14**.

[0041] The processor **22**, which is coupled to the pulse-ox sensor **12**, a temperature sensor **28**, a pressure sensor **30**, and an indicator device **32**, may include control logic configured to a) receive an output signal from the pulse-ox sensor **12**, b) determine the subject's heart beat rate, blood oxygen saturation level, or both, and c) generate an output signal for the indicator device **32** that is based on the subject's heart beat rate, blood oxygen saturation level, or both. The output signal may include data that provides numerical values of the measured vital signs, or simply designate if a threshold value for a vital sign has been crossed. The threshold value for a specific vital sign may be a value set within control logic of the processor **22** or it may be a value that is self-adjusting based on certain trials, exercises, routines, etc. For example, the threshold value may be based on one or more exercise routines (i.e., empirically derived), which can then be stored in memory, thereby permitting personalization of the threshold values for a given subject. The threshold value may also be based on multiple previous uses, which then updates the threshold value based on averaging the current use with the multiple previous uses.

[0042] In addition to the processor **22**, other electronic components that may be present in the electronic compartment **24** include, but are not limited to, a network interface, a data storage device, and/or electrical connections therebetween. When present, the network interface can be configured to communicate data by a protocol such as universal serial bus (USB), Wi-Fi, Bluetooth, IrDA, radio frequency, IEEE 802.11, IEEE 802.15, Zigbee, and/or free space optical (FSO) communication. When present, the data storage device can include local, network-accessible, removable/nonremovable, volatile/nonvolatile, and/or transitory/non-transitory memory, such as RAM, ROM, firmware and/or flash and can be further configured to store program instructions that, when implemented by the processor, are configured to communicate with the pulse-ox sensor **12** and specifically to operate the LED(s) **16** and photodetector(s) **18** so as to receive data/information based on light reflected from the patient's body when the pulse-ox is in use. One or more of the processor **22**, network interface, power supply, and data storage device can be configured to mount on a printed circuit board, each or all of which may be individually or collectively covered by waterproof or water-resistant materials. In some embodiments of the disclosed invention, substantially all electronic components may be encapsulated in an epoxy, urethane, silicone, resin, or the like, to seal against contamination ingress.

[0043] In an embodiment, the indicator device **32** may provide information relating to the absolute values of the measured vital signs. In another embodiment, the indicator device **32** may provide information as to the measured vital signs relative to the threshold value. In yet another embodiment, the indicator device **32** may provide information for both the absolute measurement and its relation to the threshold value. Accordingly, the indicator device **32** may provide the information visually, audibly, haptically, or a combination thereof, and may transmit the information for standoff monitoring. For example, the indicator device may include a light source, such as constant or flashing lights, one or more LEDs, or LCD displayed messages; a noise source, such as speakers that provide an audible tone; or a haptic device in contact with the subject that emits vibrating pulses; and/or a radiation transmitter. By way of further example, the indicator device **32** may be adapted to provide audible beeps through bone conductive transducers and tactile vibration along with visual alerts. Further, standoff notification alternatives can use a variety of frequencies to be picked up underwater and rebroadcasted through other protocols in pool settings. Moreover, each health status sensor assembly **10** may have a unique frequency output, or a common frequency with uniquely coded device identifiers, allowing for specific notification for individual swimmers.

[0044] In accordance with the embodiment shown in FIGS. **1-4**, the indicator device **32** may provide a visual notification through an LED array **34**, which may be a colored, multi-spectral LED cluster and may alert other subjects or standoff observers when the subject requires medical intervention, crosses a vital sign threshold, or is within a safe vital sign range. For example, the LED array **34** may comprise at least a first color indicator LED **36** and a second color indicator LED **38**. Additionally, the LED array, the output of which may be modulated, may provide a positive identification for swimmers above surface and sub-surface. Furthermore, the modulation of the LED array **34** may provide the means for free space optical (FSO) communication to off-board receivers transmitting the swimmers state. In accordance with an embodiment, the LED array **34** may be conveniently housed in a cap **40** of battery chamber **42**.

[0045] It will be readily apparent that any convenient portable power source (i.e., a battery) can be adapted to supply the electrical requirements for the health status sensor assembly **10**. In an embodiment, the battery is contained within a battery chamber **42**. To enable easy battery replacement, the battery chamber cap **40** and the battery chamber **42** may form a resealable, watertight connection (e.g., a screw cap with rubber O-ring). It should be appreciated that the form of the battery chamber **42** may modified or customized to accommodate virtually any battery shape. For example, as shown in FIG. **2**, the battery chamber **42** is formed to accommodate a cylindrical battery, such as a typical AA or AAA battery.

[0046] In accordance with another embodiment, the battery chamber **42** may be connected or joined to the base layer **14** in a manner that provides an aperture **44** between the two, which may serve as a mounting assembly **46** to accommodate a retaining strap (e.g., a goggle strap **48**, as shown in FIGS. **6** and **7**). For example, the battery chamber

42 may be connected to the base layer **14** by an upper support **50** and a lower support **52**, which thereby forms the aperture **44**. For the cylindrical battery chamber **42** shown in FIGS. **2-4**, the aperture-facing portion of the battery chamber **42** may be modified to convert the curved surface to a generally planar surface that is approximately parallel to the outward-facing surface **26** of the base layer **14**. Accordingly, the aperture **44** may be configured to accommodate or engage with a head band, a goggle strap, or an eye glass temple to hold and maintain the position of the pulse-ox sensor **12** over the temporal region **54**, and more specifically the temporal artery **56** (see FIGS. **5**A and **5**B). The temporal artery **56** is the smaller of two terminal branches (the other is the maxillary artery) that bifurcate superiorly from the external carotid artery **58** (see FIG. **5**A).

[0047] The base layer **14**, which includes the pulse-ox sensor **12** on the subject-facing surface **20**, helps to secure the assembly **10** flush to the subjects' temporal region and prevents the assembly **10** from rotating or being displaced during exercise (e.g., swimming) activities. In accordance with an embodiment, the base layer **14** is configured with a large surface area flare design, relative to the surface area of the pulse-ox sensor **12**. For example, a typical pulse-ox sensor **12** may have a surface area that is about 0.3 cm^2 to about 0.5 cm^2, and the base layer **14** may have a subject-facing surface area that is about 5×, about 6×, about 7×, about 8×, about 9×, about 10×, or more.

[0048] Additionally, the base layer **14** is configured to conform to a temporal region **54** of the subject's head. For example, the base layer **14** may be generally isosceles trapezoidal or "butterfly" in shape The location of the pulse-ox sensor **12** within the two-dimensional area of the subject-facing surface **20** of the base layer **14** need not be fixed to one specific area. However, placement of the pulse-ox sensor **12** centrally within the relatively larger surface area of the base layer **14** may require more adaptation to accommodate the ear tissue of the subject. While not shown, a blunted protuberance (e.g., an ear bud) may be projected from the subject-facing surface to facilitate indexing the pulse-ox sensor **12** over the temporal artery **56**. In conjunction with the foregoing, the ear bud may also provide a conduit for transmitting an audible signal from the processor to the subject.

[0049] The base layer **14** and other components that contact the subject's tissue (i.e., skin and/or hair) may be made of any suitable material, such as biocompatible materials. Flexible polymeric materials, such as polyethylene, polypropylene, fluoropolymers (e.g. polytetrafluoroethylene), polyurethane, or other similarly water resistant or waterproof materials, may be suitable for use. While latex materials are not specifically excluded, the use of latex may be avoided to prevent adverse reactions induced by latex allergies.

[0050] The aperture **44** may be configured to accommodate or engage with a head band, a goggle strap, or an eye glass temple to hold and maintain the position of the pulse-ox sensor **12** over the temporal region **54**. In addition to embodiments shown in FIGS. **2-4**, where the aperture-facing portion of the battery chamber **42** is shown modified to convert the curved surface to a generally planar surface that is approximately parallel to the base layer **14**, other configurations or devices may be use in the mounting assembly **46**. In an alternative embodiment (not shown), a clip or loop may be fixed to the outer-facing surface of the battery chamber **42**. In yet another embodiment (not shown), one or more clips or loops may be fixed to the outer-facing surface **26** of the base layer **14** that are laterally disposed from the battery chamber **42**. In any of the foregoing alternative embodiments, the clip(s) or loop(s) may be configured to accommodate or engage with a head band, a goggle strap, or an eye glass temple to hold and maintain the position of the pulse-ox sensor **12** over the temporal region **54**, and more specifically the temporal artery **56** (see FIGS. **5**A and **5**B). It should be further appreciated that other structures or materials may be used to connect the assembly **10** to a head band, a goggle strap, or an eye glass temple, such as hook and loop fasteners, snaps, clasps, stitching, or the like. In other words, the assembly **10** may be directly or indirectly connected to the head band, the goggle strap, or the eye glass temple.

[0051] As shown in FIGS. **6** and **7**, in accordance with another embodiment, the mounting assembly **46** may further include a set of goggles **60** and a goggle strap **48**. The goggle strap **48** passes through the aperture **44** formed between the battery chamber **42** and the base layer **14**. Once the subject dons the combined pulse-ox sensor assembly **10**, goggles **60**, and goggle strap **48**, the assembly **10** may be repositioned (as indicated by the bi-directional arrows **62***a*, **62***b*) to place the pulse-ox sensor **12** over the temporal artery **56**. Due to the frictional force between the goggle strap **48** and internal walls of the aperture **44**, as well as the stability provided to the assembly **10** by the relatively large surface area of the subject-facing surface **20**, the assembly **10** resists displacement during vigorous exercise, such as swimming.

[0052] The health status sensor assembly **10** may further include a pressure sensor (not shown), which is also in communication with the processor. In aqueous environments, the pressure sensor may provide an output signal to the processor indicating whether the subject's head is underwater, and optionally a depth of water above the subject's head. Accordingly, the processor may further include control logic configured to receive the output signal from the pressure sensor, determine a position of the subject's head in relation to a water surface as the depth from the water surface is directly proportional to the change in pressure. Then, a second output signal may be generated for the indicator device that is based on the position of the subject's head in relation to a water surface. For example, different colored lights in the LED array **34** of the indicator device **32** may be used to identify whether the subject's head is submerged. Additionally, the output of LED array **34** may be modulated to differentiate when the subject's head is above or below the water surface. Moreover the pressure sensor may be used to toggle predefined/customized power saving modes. For example, the LED array **34** and/or the pulse-ox sensor **12** may only be operational and powered once the subject is below the water surface.

[0053] In non-aqueous settings, the pressure sensor may be used as a component of an altimeter to provide information regarding absolute or changes in elevation. Additionally, global positioning system (GPS) receiver may also provide information about its location and elevation above sea level.

[0054] In accordance with an embodiment of the present invention, one purpose of the assembly **10** is to provide monitoring and assessing the physical state of active personnel. The assembly **10** described herein enables standoff monitoring of a subject's vital signs (e.g., SPO2 and HR) and provides visual alerts to observers monitoring the subject when vitals deteriorate to a predetermined threshold point prior to the need for medical intervention. For example, the assembly **10** enables determining if the subject's heart beat rate is greater than the predetermined threshold heart beat rate, determining if the subject's blood oxygen saturation level is less than the predetermined threshold blood oxygen saturation level, or both.

[0055] In aqueous environments, the assembly **10** is a waterproof device that monitors an subject's key physiological vitals, (e.g., HR and SPO2 levels), and emits a visual notification, (e.g., a continuous light, a flashing light, illuminating different colors, etc.), when one or more vital signs reach predefined thresholds to alert observers of a warning state that the subject may be experiencing. The assembly **10** can provide an earlier positive identification when the monitored subject needs assistance, when a subject needs requires additional recovery time from exercise, and enables standoff monitoring. Advantageously, notifications to standoff observers are passively invoked requiring no interaction from the subject swimmer to initiate.

[0056] Accordingly, another embodiment of the invention includes a method for monitoring and assessing a physical state of a subject is provided. The method includes positioning the pulse-ox sensor assembly **10** over the temporal region of the subject's head, wherein the pulse-ox sensor **12** is positioned over a portion of the temporal artery; obtaining the subject's heart beat rate, blood oxygen saturation level, or both; comparing the subject's heart beat rate to a predetermined threshold heart beat rate, and/or comparing the subject's blood oxygen saturation level to a predetermined threshold blood oxygen saturation level; and transmitting a signal to the indicator device **32** of the assembly **10** that indicates if the predetermined threshold heart beat rate and/or the predetermined threshold blood oxygen saturation level have been crossed. As noted above, the method and the assembly **10** described herein enables standoff monitoring of a subject's vital signs (e.g., SPO2 and HR) and provides visual alerts to observers monitoring the subject when vitals deteriorate to a predetermined threshold point prior to the need for medical intervention. Alternatively, audible alarms, vibrational devices, and/or radiation transmitters may also provide notification of a warning state to the monitored subject. Advantageously, notifications to standoff observers are passively invoked requiring no interaction from the monitored subject to initiate.

[0057] While the above embodiments of the assembly **10** significantly improve the current state-of-the-art for aquatic heart rate (HR) and blood-oxygen (SPO2) monitoring, continual design and refinement in form, fit, function identified further enhancements that are proving novel and are beneficial. The embodiments of the assembly **10** set out above actively measure the swimmer's blood profusion of the temporal artery and triggers an overt LED notification signal once a swimmer's vital levels reaches a predefined level. While this notification is useful for many applications, there is an additional need for enhanced monitoring and remote triggering of a swimmer-worn SPO2 monitor that provides real-time health data to remote observers.

[0058] An alternate embodiment of the invention may be positioned on a finger **66** or a wrist **68** of a swimmer using a hand/arm assembly **64** illustrated in FIGS. **8A-8C**. This hand/arm assembly **64** assists in providing a sub-surface aquatic (underwater) monitoring of heart rate and blood oxygen saturation of a swimmer with external overt notifications. This embodiment may also assist personnel who enter into specialized career fields such as combat control, pararescue, and other special operation forces and special tactics positions are required to master aquatic skills. At times, aquatic conditioning may prove to be too strenuous for swimmers and potentially result in the need for medical intervention. The hand/arm assembly **64** is a waterproof device that monitors an individual's key physiological vitals—heart rate, SPO2 levels, core body temperature—and emits a visual notification, flashing light, when vitals reach predefined thresholds to alert observers of a warning state a swimmer may be experiencing. These embodiments may also tie into pre-existing sensors to measure blood pressure through the use of a blood pressure "cuff" in a watch or arm band form factor and potentially measure blood glucose in vivo through the use of constant blood glucose sensors, among other types of vitals sensors. The hand/arm assembly **64** provides an earlier positive identification when swimmers need assistance or require additional recovery time from exercise, and provides standoff monitoring. Notifications are passively invoked requiring no interaction from the swimmer to initiate. Programmable thresholds of swimmers' vitals may be configured to capture a swimmer's baseline vitals. Then, additional levels may be programmed to alert via an LED cluster, for example, when a swimmer is outside of his/her "safe" programmed operational vital range.

[0059] As illustrated in FIG. **9** the hand/arm assembly **64** provides instructors **70** an on-demand indicator of the swimmers' **72** readiness status following strenuous activities. The hand/arm assembly **64** may contain an optical receiver **74** that may allow an instructor to remotely interrogate ON/OFF and/or activate an on-board digital readout display and/or powers-on the notification signal indicating the swimmers' **72** readiness level remotely.

[0060] A specific embodiment of the hand/arm assembly **64** may include eight overarching elements as illustrated in FIGS. **10-15**. These include a vital transmissive sensor **76**, an electronic compartment with USB port or the like for data downloads **78**, a securing clip **80**, a LED alert cluster **82**, a dual alphanumeric display **84**, a waterproof LEMO connector **86**, a power switch **88**, and a mode switch **90**.

[0061] Transmittance sensor **76** measures both oxygenated and deoxygenated hemoglobin through the use of red and infrared LEDs, similar to sensor **12** in assembly **10**, and electrically communicates those measurements to electronics in the electronic compartment **78**. The electronic compartment **78** may include digital microcontrollers, memory, communication drivers, and input/output electronics/protocols to process the data feed of the transmittance sensor **76**, to drive the LED cluster **82**, and to communicate with off-board systems similar to that of assembly **10** set out above, among other functions. Electronics in the electronic compartment **76** may also manage threshold levels, power, and may send control signals to the LED cluster **82** illuminating a series of LEDs, per the control signals, if a threshold is reached. The LED cluster **82** may contain a series of multi-colored visible and infrared LEDs for overt and covert visual notification in some embodiments.

[0062] The securing clip **80** secures a lid to the electronic compartment **78** against a rubber gasket maintaining waterproofing. LEMO Connector **86** is a waterproof connector that facilitates transmission of the signal from the transmittance sensor **76** to the electronics in the electronic compartment **78**. The dual alphanumeric display **84** may display the SpO2 data output received by the electronics in the electronics compartment **78** as well as other values or message codes. For example, the display may, alone or in conjunction with the LED alert cluster, be utilized indicating to the medical responder that a patient is in need of assistance. In some embodiments assembly **64** may include a waterproof speaker in addition to the LED cluster **82** for alerting a medical responder. An auditory alert can accompany the visual alert.

[0063] Some embodiments of assembly **64** may allow for on-demand occlusion of the overt/covert notification through a mechanical filter IRIS lens over the LED cluster **82**. Swimmers **72** are often required to participate in water sessions that are during the night-time or in a light-controlled facility to hone the swimmers skills. Some embodiments of assembly **64** may be equipped with a retractable IRIS lens that can limit the amount of light-energy emitting from its LED cluster to include closing it completely.

[0064] Assembly **64**, similar to assembly **10**, may also be battery powered. However, some embodiments of assembly **64** allow wireless charging through magnetic capacitive induction. Internal to the electronic compartment **78** is a coiled antenna that may be tuned for the purpose of wireless charging. A common practice is a swimmer **72** "rest" by holding onto a pool's edge, boat platform, inner-tube, etc. while receiving instructions or awaiting their designated time to conduct aquatic tasks. Assembly **64** leverages this "resting" state by incorporating induction charging that can extend the initial battery state of charge.

[0065] Additionally in some embodiments, assembly **64** may possess the ability to harvest kinetic, thermal deltas, and induction tuning to supply energy to its control circuitry or charge batteries. Kinetically, these embodiments may leverage electro-magnetic energy generation as the wearer exerts continuous movement through various swimming maneuvers and strokes. Thermally, these embodiments may leverage an array of thermoelectric generators arranged on one side to rest on the skin of the wearer and the other side exposed to the water. Water temperatures and fluid dynamics provide a constant thermal delta enabling energy harvesting. Lastly, using magnetic induction, these embodiments may be able to be remotely powered through induction tuned energy waves created in the aquatic environment, thereby affording continuous monitoring without the risk of power depletion.

[0066] Alternately, in some embodiments, assembly **64** may leverage a chemical reactive fuel cell that can harvest power from the water surrounding the assembly **64**. Micro-perforated inlets allow an absorption membrane to gather and store fluids that when exposed to the fuel-cell cause an electrical reaction producing current and voltage that may stored in rechargeable battery cells and used to power the device.

[0067] In an exemplary embodiment, the vital transmittance sensor **76** may be securely mounted to the base of the finger **66**, or the wrist **68**, with an attached data module and alert system. This may be accomplished, in some embodiment, with a sleeve **92** as illustrated in FIG. **8**C. Embodiments of assembly **64** provide for interchangeable and removable physiological sensors through a quick-disconnect interface. A benefit of this modular design is that health sensors continue to evolve producing higher fidelity/accuracy measurements thereby supporting various sensors (both transmissive, reflective, etc.). Embodiments may scale and be customized to the environments and conditions required for different sets of operations. Moreover, having a dynamically adjustable pull-force quick-disconnect enables these embodiments to remain secure but not create a potential risk to the swimmer in case of an entanglement situation. The orientation of the quick-disconnect interface promotes custom cable lengths and promotes an in-line design minimizing drag impact to the swimmer **72** wearing the assembly **64**.

[0068] Assembly **64** allows for digital readout of SpO2/HR/Core Temperature for real-time similar to assembly **10** above. In some embodiments, electronics in the electronic compartment **78** may be configured to archive a swimmers **72** vital history, sampled at a predefined interval, to be offloaded at the completion of a swimming session. This feature allows swimmers **72** to monitor their conditioning as well as provide instructors with information on a swimmer's **72** state during key elements/exercise within training regimes.

[0069] Embodiments of assembly **64** may also wirelessly transmit a swimmer's **72** real-time health vitals using a configurable microcontroller emitter that senses the swimmer's **72** environment, dynamically adjusting the method of transmission. These embodiments may possesses a variety of communication emitters to include but not limited to Radio Frequency (Bluetooth, Ultra-Wide Band, WiFi, Zigbee), Magnetic Induction, and Optical Free-Space Communication. The communication microcontroller can sense the receipt of its transmission and determine if switching to another medium is required to output the swimmer's **72** vitals.

[0070] Finally, power switch **88** turns the system on and off and mode switch **90** cycles the system through various sensor modes.

[0071] While the present invention has been illustrated by a description of one or more embodiments thereof and while these embodiments have been described in considerable detail, they are not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and method, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the scope of the general inventive concept.

What is claimed is:

1. A waterproof pulse oximeter sensor assembly configured to monitor vitals of a swimmer, the waterproof pulse oximeter sensor assembly comprising:

a pulse oximeter sensor configured to evaluate conditions in a finger or a wrist of a swimmer and to generate a pulse-ox signal in response thereto;

a waterproof electronics compartment comprising electronics configured to:

electrically receive the pulse-ox signal from the pulse oximeter sensor;

determine a heartbeat rate, a blood oxygen saturation level, a core body temperature or combinations thereof from the pulse-ox signal; and

generate an output signal that is based on the determined heartbeat rate, the blood oxygen saturation level, the core body temperature or a combination thereof;

an indicator proximate the waterproof electronics compartment configured to receive the output signal and display an indication; and

a power source operable to supply electric power to the pulse oximeter sensor, electronics of the electronics compartment, and the indicator,

wherein the power source is recharged during use of the waterproof pulse oximeter sensor assembly by the swimmer.

2. The waterproof pulse oximeter sensor assembly of claim 1, wherein the pulse oximeter sensor comprises at least one light emitting diode and at least one photodetector.

3. The waterproof pulse oximeter sensor assembly of claim 1, wherein the pulse oximeter sensor comprises interchangeable and removable physiological sensors through a quick-disconnect interface.

4. The waterproof pulse oximeter sensor assembly of claim 1, wherein the indicator comprises a light source, an alphanumeric display, or combinations thereof.

5. The waterproof pulse oximeter sensor assembly of claim 4, wherein the indicator further comprises a waterproof speaker.

6. The waterproof pulse oximeter sensor assembly of claim 4, wherein the alphanumeric display displays the blood oxygen saturation level data in the output signal.

7. The waterproof pulse oximeter sensor assembly of claim 1, further comprising:

a LED cluster IRIS lens; and

a mechanical filter lens over the LED cluster IRIS lens.

8. The waterproof pulse oximeter sensor assembly of claim 7, wherein the IRIS lens is a retractable IRIS lens configured to limit the amount of light-energy emitting from its LED cluster to include closing it completely

9. The waterproof pulse oximeter sensor assembly of claim 1, wherein the electronics of the electronics compartment comprise:

a processor configured to electrically receive the pulse-ox signal, determine the heartbeat rate, the blood oxygen saturation level, core body temperature or combinations thereof, and generate an output signal; and

a network interface configured to communicate data from the processor by a protocol selected from USB, Wi-Fi, Bluetooth, IrDA, radio frequency, IEEE 802.11, IEEE 802.15, Zigbee, Free Space Optical, or combinations thereof.

10. The waterproof pulse oximeter sensor assembly of claim 9, wherein the electronics of the electronics compartment further comprise:

a configurable microcontroller emitter that senses the swimmer's environment,

wherein the microcontroller can sense a receipt of its transmission and determine if switching to another medium is required to output the swimmer's vitals, and

wherein the medium is selected from a group comprising USB, Wi-Fi, Bluetooth, IrDA, radio frequency, IEEE 802.11, IEEE 802.15, Zigbee, Free Space Optical, and combinations thereof.

11. The waterproof pulse oximeter sensor assembly of claim 1, wherein the power source comprises a battery.

12. The waterproof pulse oximeter sensor assembly of claim 1, wherein the electronics of the electronics compartment comprise:

a coiled antenna configured for wireless charging,

wherein recharging the power source comprises magnetic capacitive induction charging using the coiled antenna and induction tuned energy waves created in an aquatic environment.

13. The waterproof pulse oximeter sensor assembly of claim 1, wherein the electronics of the electronics compartment comprise:

an array of thermoelectric generators arranged on one side to rest on a skin of the swimmer and the other side exposed to water,

wherein water temperatures and fluid dynamics provide a constant thermal delta to generate energy, and

wherein the power source is recharged from the generated energy.

14. The waterproof pulse oximeter sensor assembly of claim 1, wherein the electronics of the electronics compartment comprise:

a chemical reactive fuel cell comprising micro-perforated inlets allowing an absorption membrane to gather and store water,

wherein exposing the fuel-cell to water causes an electrical reaction producing current and voltage, and

wherein the power source is recharged from the produced current and voltage.

15. The waterproof pulse oximeter sensor assembly of claim 1, further comprising:

an optical receiver,

wherein the optical receiver is operable to receive commands to remotely interrogate ON/OFF, activate an on-board digital readout display, and powers-on a notification signal indicating the swimmer's readiness level.

16. A health status sensor assembly configured to monitor vitals of a swimmer, the health status sensor assembly comprising:

a waterproof housing configured to be positioned proximate to a temporal artery of the swimmer;

a temperature sensor operably coupled to the waterproof housing and configured to detect a water temperature, the temperature sensor being further configured to provide a temperature sensor output signal;

a pulse oximeter sensor operably coupled to the waterproof housing and configured to evaluate conditions in the temporal artery of the swimmer and to generate a pulse-ox signal in response thereto;

a pressure sensor operably coupled to the processor and configured to detect a change in pressure, the pressure sensor being further configured to provide a pressure sensor output signal; and

a processor in the waterproof housing and operably coupled to the pulse oximeter sensor, the temperature sensor, and the pressure sensor, wherein the processor includes control logic configured to:

receive the pulse-ox signal from the pulse oximeter sensor, the temperature sensor output signal from the temperature sensor, and the pressure sensor output signal from the pressure sensor,

determine a heartbeat rate, a blood oxygen saturation level, a core body temperature, or combinations thereof from the pulse-ox signal, determine an underwater depth in relation to the detected change in pressure,

generate an output signal that is based on the determined heartbeat rate, blood oxygen saturation level, the core body temperature, the underwater depth, the water temperature or a combination thereof, and

transmit the output signal to an indicator

17. The health status sensor assembly of claim **16**, further comprising:

an indicator operably coupled to the waterproof housing and configured to receive the output signal from the processor and, in response to the output signal is configured to transmit a visual signal, an audible signal, a sensory signal, or a combination thereof.

18. The health status sensor assembly of claim **17**, wherein the indicator is further configured to transmit the output signal at a set frequency for standoff monitoring.

19. The health status sensor assembly of claim **17**, wherein the indicator comprises a light source, a noise source, a haptic device, or combinations thereof.

20. The health status sensor assembly of claim **16**, further comprising:

a network interface in the waterproof housing configured to communicate data from the processor by a protocol selected from USB, Wi-Fi, Bluetooth, IrDA, radio frequency, IEEE 802.11, IEEE 802.15, Zigbee, Free Space Optical, or combinations thereof.

* * * * *

patsnap

专利名称(译)	游泳者健康的闪烁指示器
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摘要(译)

一种防水脉冲血氧计传感器组件，被配置为监测游泳者的生命体，包括脉冲血氧计传感器，该脉搏血氧计传感器被配置为评估游泳者的手指或手腕中的状况并响应于此产生脉冲血氧信号。防水电子隔间包括电子器件，其配置成从脉冲血氧计传感器电接收脉冲ox信号，并根据脉冲ox信号确定心跳速率和/或血氧饱和度。电子器件产生基于确定的心跳速率和/或血氧饱和度水平的输出信号。靠近电子隔间的指示器被配置为接收输出信号并显示指示。电源向脉冲血氧计传感器，电子设备和指示器提供电力。在游泳者使用防水脉冲血氧计传感器组件期间对电源进行再充电。