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

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 1 February 2007 (01.02.2007)

PCT

(10) International Publication Number WO 2007/013054 A1

(51) International Patent Classification: A61B 5/00 (2006.01)

(21) International Application Number:

PCT/IL2006/000505

(22) International Filing Date: 25 April 2006 (25.04.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 60/703,557 28 July 2005 (28.07.2005) U.

(71) Applicant and

(72) Inventor: SCHWARTZ, Boris [IL/IL]; 11 Haodem Street, 45350 Hod Hasharon (IL).

(74) Agents: SANFORD T. COLB & CO. et al.; P.O. Box 2273, 76122 Rehovot (IL).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

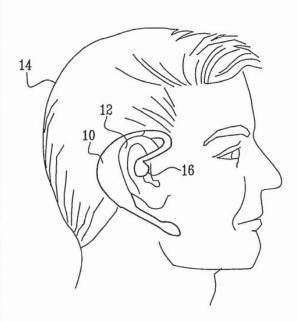
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

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

(54) Title: EAR-MOUNTED BIOSENSOR



(57) Abstract: A physiological monitoring device (10) includes a device housing (11) shaped to fit behind an ear (12) of a subject and a sensor (18, 28, 30) attached to the device housing so as to sense a physiological characteristic of the subject at a location behind the ear. An earphone speaker (16) extends from the device housing towards an ear canal of the subject and provides an audible communication to the subject responsively to the physiological characteristic.

Apple Inc. APL1037



EAR-MOUNTED BIOSENSOR

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application 60/703,557, filed on July 28, 2005, which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to health care and specifically to methods and systems for monitoring subject well-being.

10 BACKGROUND OF THE INVENTION

Two known indicators of physical and psychological stress are Galvanic Skin Response (GSR) and heart rate.

GSR (also known as electrodermal response, skin conductance response, or skin conductance level) is a measure of electrical conductivity of a subject's skin. GSR may be determined by applying a small voltage between two electrodes affixed to the skin and measuring the generated current. Often, GSR is measured at the tip of a subject's finger or on the palm of a hand. An example of a GSR sensor used in clinical settings is the Model V71-23 Isolated Skin Conductance Coupler, distributed by Coulbourne Instruments of Allentown, Pennsylvania.

Heart rate may be determined by photoplethysmography (PPG), which can also be used to measure variations in blood oxygen levels by pulse oximetry. Oximetry readings are generally made in terms of a percent of blood oxygen saturation (SpO₂). A PPG probe measures light transmitted through or reflected from arterial blood. In transmission PPG, light is generally transmitted through a thin appendage of the body. U.S. Patent 4,301,808 to Taus, for example, whose disclosure is incorporated herein by reference, describes the use of transmission PPG to measure the pulse rate of a subject during



25

physical exercise. Taus states that PPG readings be made through an appendage such as the ear, the nose septum, or the web between the forefinger and the thumb.

Reflective pulse oximetry measures light reflected from arteries beneath the surface of the skin. U.S. Patent 6,553,242 to Sarussi, whose disclosure is incorporated herein by reference, describes the use of reflective pulse oximetry to measure heart rate, as well as indications of apnea in sleeping infants. Sarussi identifies several means of affixing an oximetry sensor to a subject's body, including a wristband, an ankle band, a sock, and a headband for making measurements at the subject's forehead.

U.S. Patent 6,783,501 to Takahashi et al., whose disclosure is incorporated herein by reference, describes the use of pulse oximetry to measure heart rate from various locations on the head during exercise. Measurement locations described by Takahashi include the forehead and the ear canal. Heart rate feedback to the exerciser may be provided by an audio indication, which may be provided through an earphone, or by a visual indication, which may be provided on a screen attached to glasses worn by the exerciser.

U.S. Patent 6,760,610 to Tschupp et al., whose disclosure is incorporated herein by reference, describes the use of pulse oximetry to measure blood oxygenation in combination with a measurement of blood carbon dioxide levels.

U.S. Patent Publication 2005/0033131 to Chen et al., whose disclosure is incorporated herein by reference, describes an ear sensor assembly that supports an oximetry sensor in the ear concha, using an extension that clips onto the ear lobe.

Wearable medical devices that monitor an individual's well-being are available on the market. For



example, the SenseWear® Armband, distributed by Bodymedia of Pittsburgh, Pennsylvania, employs an accelerometer that records body movement, a temperature sensor that detects changes in skin temperature, and a GSR sensor that measures level of exertion during exercise.

Psychological stress among employees can have a significant impact on their job effectiveness and can lead to accidents, absenteeism, and employee turnover. According to an article by the American Institute of Stress, available at www.stress.org/job.htm and whose disclosure is incorporated herein by reference, workplace stress increases business costs in the U.S. by approximately \$300 billion per year. Workplace testing of employees for indications of well-being is known in the art. For example, U.S. Patent 6,352,516 to Pozos, et al., whose disclosure is incorporated herein by reference, describes a method for monitoring employee fatigue by measuring the force of fingers striking a keyboard.



SUMMARY OF THE INVENTION

Embodiments of the present invention provide apparatus and methods for monitoring one or more physiological parameters from a location behind the ear.

5 A sensor mounted to an earphone and positioned behind the ear is configured to sense the physiological parameters in a convenient, comfortable, and non-obtrusive manner.

Photoplethysmography (PPG) of arterial blood either in the scalp behind the ear or in the ear itself may be used to determine heart rate and/or oxygen saturation. Galvanic Skin Response (GSR) measurements may also be made from the location behind the ear.

The physiological parameters may be used to determine stress and other health indicators while an individual being monitored is performing activities in a non-medical setting, such as activities related to work or leisure. These indicators may be provided to the individual and/or to a health care institution, such as a remotely based hospital. The earphone to which the sensor is mounted may be utilized to provide an indication of the sensed parameters, as well as to provide additional functions that enhance the convenience of use.

There is therefore provided, in accordance with an embodiment of the present invention, a physiological monitoring device, including:

- a device housing shaped to fit behind an ear of a subject;
- a sensor attached to the device housing so as to sense a physiological characteristic of the subject at a location behind the ear; and
- an earphone speaker extending from the device housing towards an ear canal of the subject and operative to provide an audible communication to the subject responsively to the physiological characteristic.



30

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

