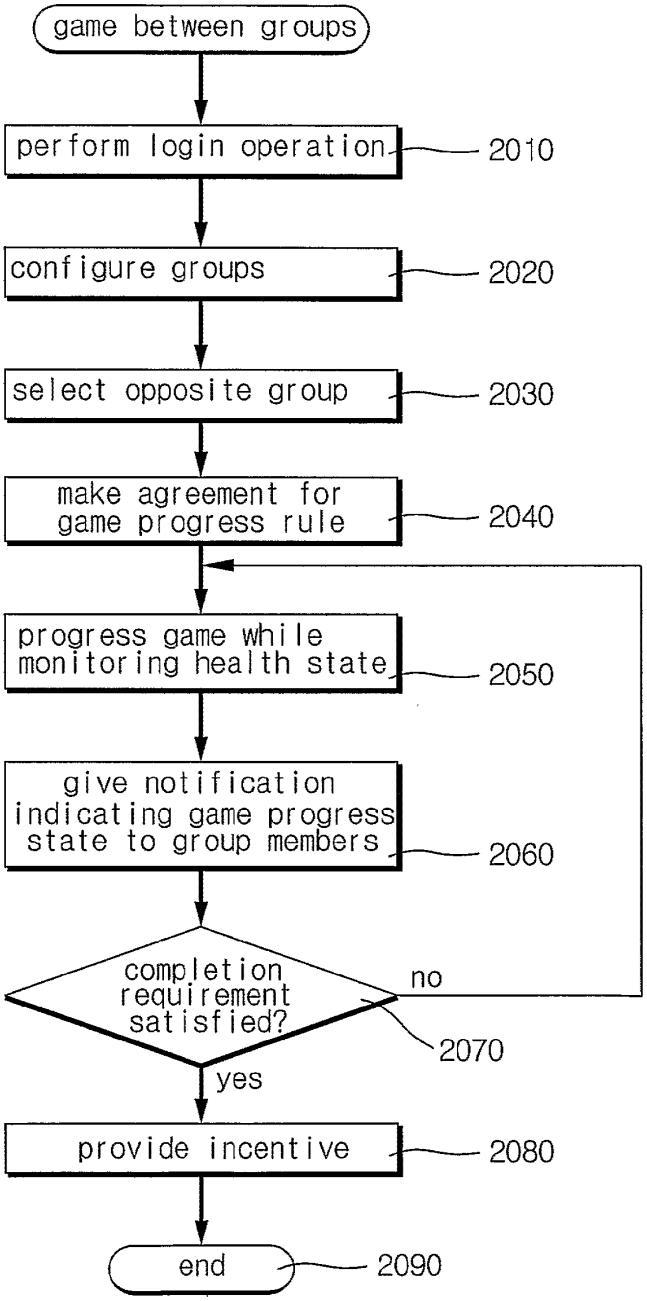
FIG.5



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International application No.
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR 2002-0009119 A (UZ DREAM Co., LTD.) 01 FEBUARY 2002 (Family one) * Whole Documents.	1 - 17
A	KR 2002-0069697 A (ELECTRONICS AND TELECOMMUNICATIONS RESEARCH INSTITUTE) 05 SEPTEMBER 2002 (Family None) * Whole Documents.	1 - 17
A	KR 2002-0091343 A (KIM DAE JOONG) 06 DECEMBER 2002 (Family None) * Whole Documents.	1 - 17
A	KR 2002-0091344 A (KIM DAE JOONG) 06 DECEMBER 2002 (Family None) * Whole Documents.	1 - 17
A	US 2002/0007286 A1 (NEC CORP.) 17 JANUARY 2002 (Family None) * Whole Documents.	1 - 17

☐ Further documents are listed in the continuation of Box C.

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(71) Applicant *(for all designated States except US)*: MEDOC LTD. [IL/IL]; P.O. Box 423, 30095 Ramat Yishai (IL).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: GAFNI, Ehud [IL/IL]; Ha'Oren Street 45, 30095 Ramat Yishai (IL). GAFNI, Edna [IL/IL]; Ha'Oren Street 45, 30095 Ramat Yishai (IL). TREYSTMAN, Alexander [IL/IL]; Ha'Oren Street 56A, 30095 Ramat Yishai (IL).

(74) Agents: FENSTER, Paul et al.; Fenster & Company Patent Attorneys, Ltd., P.O. Box 10256, 49002 Petach Tikva (IL).

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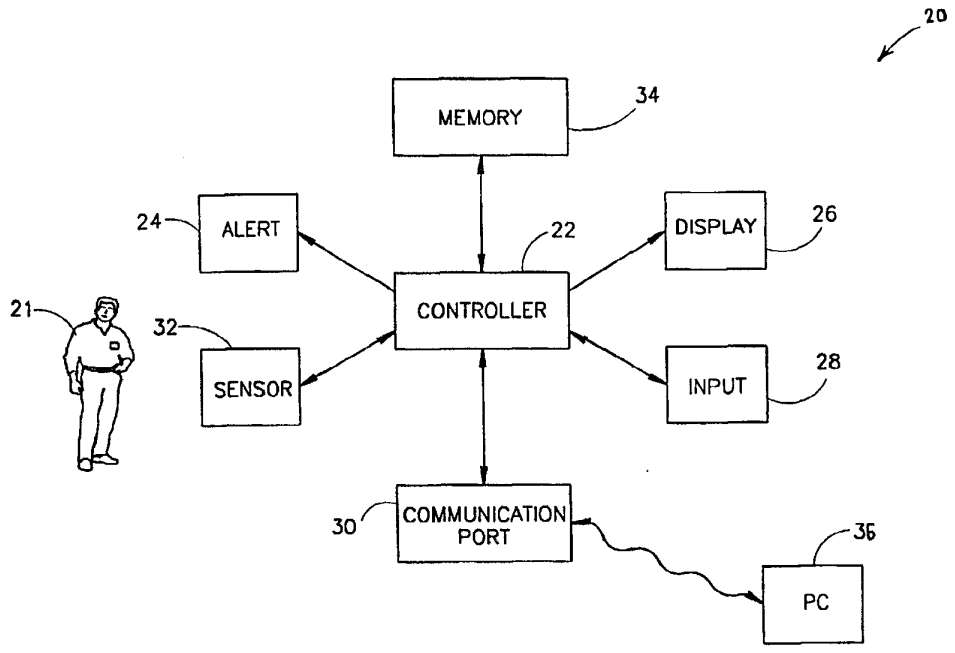

(57) Abstract

An ambulatory monitor (20) is used to increase patient compliancein medicine taking, reporting side effects, disease progress, symptoms, and/or the effect of treatment. The preferred embodiment includes the monitor (20), an alert generator (24), a controller (22), a display (26), a sensor/accelerometer (32), and a communication port (30) for the patient (21).

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AMBULATORY MONITOR

RELATED APPLICATIONS

This application claims the benefit under 119(e) of US provisional application 60/121,290, with like title and filed on February 22, 1999, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to ambulatory monitors, especially for tracking the progress of diseases and the effectiveness of medical treatments.

BACKGROUND OF THE INVENTION

Ambulatory patient monitors, also of types that automatically measure signals, are known. For example, one such device is described in U.S. Patent 4,354,375, the disclosure of which is incorporated herein by reference. U.S. Patent 5,293,879 and an article "Ambulatory Monitoring of Tremor and Other Movements Before and After Thalamotomy: A New Quantitative Technique", by EJW van Someren, WA van Gool, BFM Vonk, M Mirmiran, JD Speelman, DA Bosch and DF Swaab, in Journal of Neurological Sciences, 117 (1993) pp. 16-23, the disclosures of which are incorporated herein by reference, suggest using an ambulatory for monitoring Parkinson's disease. In the latter patent, it is suggested that the monitor automatically administer a pharmaceutical to a patient.

U.S. Patent 5,642,731, the disclosure of which is incorporated herein by reference, describes a portable device for reminding a patient to take medicine and for querying a patient (to some extent) regarding side effects. This patent describes a device that is large enough to hold one or more types of pills. A non-portable device for reminding a patient to take a blood test is described in U.S. Patent 5,442,728, the disclosure of which is incorporated herein by reference.

A disadvantage the pill-box device is that it must be carried around, as it is apparently too large to be worn. Consequently, patient compliance may be compromised, for example if the patient has no pockets in his apparel or if the patient is embarrassed or inconvenienced by carrying the pill-box around. If a patient does not carry the pill-box, he will not get any reminders, answer questions and/or otherwise be monitored.

SUMMARY OF THE INVENTION

An object of some preferred embodiments of the invention is to increase patient compliance in medicine taking and/or in reporting side effects, disease progress, symptoms and/or the effect of treatment. In a preferred embodiment of the invention, this increase in

compliance is achieved by providing the patient with a device that is worn, preferably a wristwatch-like device.

An object of some preferred embodiments of the invention is to increase a confidence level of a patient's subjective reports by providing objective data which can be compared with the subjective record of the patient.

An object of some preferred embodiments of the invention is to shorten pharmaceutical clinical trials and/or improve their credibility by enhancing the acquisition of patient data, especially with regard to side effects and treatment efficacy. In a preferred embodiment of the invention, data acquisition is enhanced by questioning the patient using focused queries. Preferably, the queries are structured and/or dependent on previous responses. Additionally or alternatively, the queries take into account data which is logged by an ambulatory monitor, either automatically or manually.

One aspect of some preferred embodiments of the invention relates to a patient querying device which is worn by the patient. In a preferred embodiment of the invention, the device is worn on a wrist, preferably having an exterior similar to a wrist-watch, possibly incorporating the functionality of a wristwatch. Alternatively, the device may be worn as a necklace and/or on a chain or cord around the neck. In a preferred embodiment of the invention, the device includes a display, which displays various information, including one or more of a query, a reminder, a time, processed and/or sensed data and/or an indication of a response by the patient. Alternatively or additionally, the queries, the patient responses and/or other information display use an auditory channel (for output and/or input).

An aspect of some preferred embodiments of the invention relates to a worn device which provides reminders to a patient, as well as querying the patient. In a preferred embodiment of the invention, the reminders include one or more of a reminder to take medicine, to eat, to drink, to be tested, to visit a doctor and/or fill out a form.

In some preferred embodiments of the invention, the device also monitors one or more physiological parameters of the patient, for example, movements, body position/posture, pulse rate, blood pressure, ECG, temperature and/or oxygenation level. Alternatively or additionally, environmental variables are monitored by the device, for example, ambient sounds, ambient temperature, ambient light levels and/or ambient air-pressure. Alternatively or additionally, to automatic monitoring, physiological parameters, ambient environmental conditions and/or patient activities may be logged manually, by a person entering them into the device. In some cases, the logging of data is initiated by a patient, in others, the device requests the data.

In a preferred embodiment of the invention, when the device queries the patient, the queries are responsive to the manually and/or automatically logged data, for example, to determine a relationship between a meal time and the effectiveness of a medicine or a side effect of the medicine. In a preferred embodiment of the invention, such querying is used during a clinical study of a medicine, to better classify, investigate and collect data about side-effects and/or medicine efficacy.

A differentiation should be noted between querying which is delayed and/or initiated responsive to a medicine taking time, expected blood level and/or other parameters which are a function of medicine metabolism and querying which delayed responsive to physiological processes, such as the circadian cycle, the menstrual cycle or the birth process.

In a preferred embodiment of the invention, an ambulatory monitor is used for one or more of disease progress monitoring, data collection for diagnosis, drug studies, drug schedule planning and/or treatment effectiveness determination. In a preferred embodiment of the invention, the data that is collected by the monitor is downloaded to a computer, on which the data may be analyzed by a technician and/or a physician.

One aspect of the invention relates to an ambulatory monitor being adapted for a particular disease. In one example, Parkinson's disease, the device may be provided with buttons having a size, shape and/or pressure response which is especially adapted for the use of Patients with Parkinson's disease. Alternatively or additionally, the logic of operation of the device is adapted to the disease, for example requiring confirmation for every input or requiring a longer press duration, to take into account a higher probability of a patient inadvertently pressing a wrong button. In another example, the monitor is adapted for pain monitoring, for example by including dedicated sensors; software for analyzing sensor results and displaying different queries and/or reminders; and/or faceplate marking.

An aspect of some preferred embodiments of the invention relates to using an ambulatory monitor for long term monitoring. In one preferred embodiment of the invention, the device monitors changes over a long period. In another example, the device provides reminders for infrequently occurring events, for example, a yearly checkup or a reminder to replace an implanted battery. In one example, suspected Alzheimer's disease is diagnosed, by periodically presenting questions to a patient, over a long period, so that degradation of mental and/or memory skills can be assessed.

An aspect of some preferred embodiments of the invention relates to coordination of an ambulatory monitor with other medical care. In one example, a reminder device which is worn by a health-care provider is synchronized with the ambulatory monitor, so that that health care

provider (for example a personal nurse) is reminded whenever the patient receives a medicine taking reminder. Thus, the patient can feel independent, while patient compliance is increased. Alternatively or additionally, one or more queries may be directed at the health-care provider, for example, to report on the patient's movements, activity state, mental alertness and/or mood. Such two coordinated monitors may also be useful where the patient does not answer queries at all, for example senile persons or babies. The two devices may be coordinated using wireless communication, for example, IR, Ultrasound or RF radiation. Alternatively or additionally, the devices are coordinated using a synchronized clock and suitable logic, so that one device is aware of the expected operation of the other device.

One aspect of some preferred embodiments of the invention relates to a method of data entry by a patient. In a preferred embodiment of the invention, the patent entered at least some of the data using an analog scale, for example, entering a pain level on a scale between 0 and 10. In a preferred embodiment of the invention, the data is entered by pressing a button to move a marker along a scale and releasing the button when the desired data value is displayed. This data entry method has the advantage of clear feedback to the patient regarding his input. In addition, if the patient has difficulty entering data, the absolute error may be expected to be small. Further, correcting such a data entry does not require erasing the data entry and reentering it, only correcting it, for example by moving the marker some more. In one embodiment of the invention, the analog scale is displayed with a varying resolution, so that there is a maximal resolution at about the marker. Alternatively or additionally, the speed of motion of the marker is a function of the duration of the button pressing. In some cases, information regarding the patient state and/or various physiological problems thereof may be determined by analyzing the act of data entry itself. Analog data entry, often provides more such data to be analyzed.

In a preferred embodiment of the invention, a patient may enter several types of data using an "analog" data input. Alternatively or additionally, some of the data entry may comprise selection from a list of discrete entries. Optionally, the physician sets the values of the ends of the analog scale and/or of the discrete choices. It is noted that using an Analog input device is known for patient studies. However, such a device is typically large (~10cm) and inconvenient to carry around. In addition, it is not practical to provide a patient with two or more such devices to entry multiple data types. Thus, comparison of changes in two such entered data types in an ambulatory patient was not a viable option.

An aspect of some preferred embodiments of the invention relates to data analysis of data acquired by the ambulatory monitor. One advantage of some monitors of the present

invention is synchronization between the patient query responses, medicine taking and other activities of the patient. In one example, a data analysis can be used to determine an average "time-to-ON" of a Parkinson's patient (i.e., the time period from the time the medication was taken until the patient switches from OFF to ON and feels an improvement in his motor abilities).

An aspect of some preferred embodiments of the invention relates to interconnecting an ambulatory monitor and external communication networks. In a preferred embodiment of the invention, the monitor can connect to a doctor's web site or to a pharmaceutical companies web site to upload patient data and/or responses to queries, and/or to download new programming, for example for detecting and/or avoiding newly discovered side effects or inter-drug interactions.

An aspect of some preferred embodiments of the invention relates to the determination of pain level from an analysis of automatically sensed movement and/or posture data. In a preferred embodiment of the invention, sudden onset of pain and/or high pain levels are identified when there is a sudden reduction in the amount of movement of an accelerometer. In another example, pain levels may be correlated with the patient's manner of walking: accelerations, gait profile, regularity of rhythm, step size, speed, way of starting and/or favoring of limbs (especially in lower back pain and limb injuries). In a preferred embodiment of the invention, the monitor learns to associate particular characteristics of features of the walk and/or movement profile with varying levels of pain. Alternatively or additionally, pain level may be determined by analyzing the temporal profile of the patient's posture and/or position, for example, walking straight, walking hunched, laying down, standing up or sleeping. Alternatively or additionally, such changes in motion are correlated with changes in a measured heart rate (which is expected to increase with pain).

There is therefore provided in accordance with a preferred embodiment of the invention, an ambulatory monitor, comprising:

a fastener for attaching said monitor to an ambulatory person to be monitored;

a display;

an input interface; and

a query generator which generates queries to said display and which receives answers to said queries using said input interface.

Preferably, the monitor comprises:

at least one sensor which generates a signal responsive to a sensed value; and

an automatic logger, which logs data responsive to said signal. Preferably, data comprises raw signal data from said sensor. Alternatively or additionally, said data comprises process signal data from said sensor. Alternatively or additionally, said at least one sensor comprises a physiologic sensor that senses a physiologic variable of said person. Alternatively or additionally, said at least one sensor comprises an environmental sensor that senses a parameter of an environment of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a motion of at least of a portion of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a change in posture of said person. Alternatively or additionally, said at least one sensor comprises a motion sensor that senses a change in body position of said person. Alternatively or additionally, said motion sensor comprises an accelerometer. Alternatively or additionally, said at least one sensor comprises at least two sensors, of different types. Alternatively or additionally, said at least one sensor comprises at least two sensors, which measure different parameters. Alternatively or additionally, said at least one sensor comprises at least two sensors, which are attached to different parts of said person. Alternatively or additionally, said at least one sensor comprises a sensor which is spatially separate from said monitor. Preferably, said sensor is a wireless sensor.

In a preferred embodiment of the invention, at least one of said queries is generated responsive to said logged data. Preferably, said query is generated at a delay responsive to said logged data. Preferably, said delay is responsive to a metabolism of a medication taken by said person. Alternatively or additionally, said delay is responsive to a physiological process of said person.

In a preferred embodiment of the invention, said monitor generates a medication schedule responsive to said logged data. Alternatively or additionally, said fastener comprises a wristband. Alternatively or additionally, said monitor is adapted to be worn around a neck. Alternatively or additionally, said display comprises a visual display. Alternatively or additionally, said display comprises an audio display.

In a preferred embodiment of the invention, the monitor comprises a reminder generator which provides said person with at least one reminder using said display. Preferably, said query generator generates at least one query responsive to a response of said person to said at least one reminder. Possibly, said response comprises not complying with said reminder. Alternatively or additionally, said at least one reminder comprises a reminder to eat. Alternatively or additionally, said at least one reminder comprises a reminder to drink. Alternatively or additionally, said at least one reminder comprises a reminder to take a certain

medication. Alternatively or additionally, said at least one reminder comprises a reminder for a medical checkup. Alternatively or additionally, said at least one reminder comprises a reminder for a medical test.

In a preferred embodiment of the invention, the monitor an alerter which calls attention of said person to said display.

In a preferred embodiment of the invention, said input interface is operative to receive unsolicited input from said person. Preferably, said input comprises an indication of a disease state. Alternatively or additionally, said input comprises an indication of a side effect. Alternatively or additionally, said input comprises an indication of an effect of said medicine. Alternatively or additionally, said input comprises an activity of the person. Alternatively or additionally, said query generator generates at least one query responsive to said input. Preferably, said query is generated at a delay responsive to said input. Preferably, said delay is responsive to a metabolism of a medication taken by said person. Alternatively or additionally, said delay is responsive to a physiological process of said person.

In a preferred embodiment of the invention, said monitor generates a treatment schedule responsive to said input. Preferably, said treatment schedule comprises a medication schedule.

In a preferred embodiment of the invention, said query generator generates at least one secondary query responsive to said person's response to said at least one query. Alternatively or additionally, said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to clinical testing of medical treatment. Alternatively or additionally, said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to selecting between two or more medication schedules.

In a preferred embodiment of the invention, said monitor is adapted for monitoring a particular health condition of said person. Preferably, said health condition comprises a chronic disease. Alternatively or additionally, said health condition comprises pain. Alternatively or additionally, said health condition comprises heart disease. Alternatively or additionally, said health condition comprises an anxiety disorder. Alternatively or additionally, said health condition comprises a depression disorder. Alternatively or additionally, said health condition comprises an ADD (Attention deficiency disorder). Alternatively or additionally, said health condition comprises a pulmonary difficulty. Alternatively or additionally, said health condition comprises diabetes. Alternatively or additionally, said health condition

comprises a progressive disease. Alternatively or additionally, said disease comprises Parkinson's disease. Alternatively, said health condition comprises a non-disease condition.

In a preferred embodiment of the invention, said monitor is adapted for tracking a health condition which is being modified using a medical treatment.

In a preferred embodiment of the invention, said monitor is synchronized with a second monitor, adapted to be worn by a second person and wherein said second monitor comprises an alerter which generates an alert to said second person responsive an operation at said monitor. Preferably, said operation comprises a reminder to take medicine. Alternatively or additionally, said monitor and said second monitor are synchronized using wireless communication therebetween. Alternatively or additionally, said monitor and said second monitor are synchronized using a common clock.

In a preferred embodiment of the invention, said input interface comprises at least one digital visual analog scale (DVAS) display. Preferably, said at least one DVAS comprises at least two DVASes.

In a preferred embodiment of the invention, said input interface comprises at least one menu selection interface. Alternatively or additionally, said input interface comprises an interface for entering at least two different types of data, each of said types of data having at least three possible values. Preferably, said query generator generates at least one query responsive to a relationship between said two types of entered data.

There is also provided in accordance with a preferred embodiment of the invention, a method of detecting a change in pain level, comprising:

tracking movements of at least a portion of a person; and

analyzing said tracked movements to identify changes in movement caused by a change in pain level. Preferably, said tracked movements comprises changes in posture. Alternatively or additionally, said tracked movements comprises changes in gait. Alternatively or additionally, said tracked movements comprises changes in a time profile of at least one body position.

There is also provided in accordance with a preferred embodiment of the invention, a method of data sensing, comprising:

automatically logging data of an ambulatory patient;

analyzing said data to determine at least one aspect of non-suitability of said logged data;

automatically querying said patient to provide data which improves said at least one aspect of non-suitability.

There is also provided in accordance with a preferred embodiment of the invention, a method of entering multi-state information, comprising:

displaying, on a worn device, a scale of values, including an indication of a particular value;

entering using said device a value, which entered value is indicated using said indication; and

storing said entered value, in said device, for later analysis.

Preferably, said display emulates a VAS (Visual analog scale). Alternatively or additionally, said entered value indicates a pain value. Alternatively or additionally, the method comprises repeating said displaying and said entering a plurality of times for a same type displayed scale. Alternatively or additionally, the method comprises repeating said displaying and said entering a plurality of times for a different type displayed scale.

There is also provided in accordance with a preferred embodiment of the invention, a monitor network comprising:

a first monitor, worn by a first person, which first monitor generates an alert to said first person; and

a second monitor, worn by a second person, synchronized with said first monitor, which generates an alert to said second person responsive to said first monitor. Preferably, said first and second monitors are synchronized using a common clock. Alternatively or additionally, said first and said second monitors are synchronized using at least one wireless transmission between them.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the following detailed description of the preferred embodiments of the invention and from the attached drawings, in which:

Fig. 1 is a block diagram of an ambulatory monitor, in accordance with a preferred embodiment of the invention;

Fig. 2A is a schematic illustration of a faceplate of an ambulatory monitor for Parkinson's disease, in accordance with a preferred embodiment of the invention;

Fig. 2B is a schematic illustration of a faceplate of an ambulatory monitor for pain management, in accordance with a preferred embodiment of the invention;

Fig. 2C is a schematic illustration of a faceplate of an ambulatory monitor for pain management, illustrating an alternative data entry mechanism, in accordance with a preferred embodiment of the invention;

Figs. 3A and 3B comprise an exemplary data display and analysis screen for a data analysis software in accordance with a preferred embodiment of the invention;

Fig. 4 is an exemplary flowchart for a querying logic in accordance with a preferred embodiment of the invention; and

Fig. 5 is a block diagram of a networking embodiment of an ambulatory monitor in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 is a block diagram of an ambulatory monitor 20 for a patient 21, in accordance with a preferred embodiment of the invention. Typically, monitor 20 includes an alert generator 24, for alerting patient 21 and an input 28 for receiving responses from patient 21. In a preferred embodiment of the invention, monitor 20 includes a display 26 (audio, visual or both) which is used to present alerts in greater detail and/or to query the patient. Preferably, monitor 20 includes a sensor 32, for example an accelerometer, for automatically logging data about movement, physiological and/or state environment of patient 21.

In a preferred embodiment of the invention, the operation of monitor 20 is coordinated using a controller 22. Logged data is preferably stored in a memory 34, for example a solid state memory or an electro-mechanical memory such as a magnetic tape.

In a preferred embodiment of the invention, monitor 20 can communication with other devices using a communication port 30, for example to download data to a personal computer 36.

In a preferred embodiment of the invention, monitor 20 is worn like a wristwatch, and is preferably designed to look like one, to reduce patient embarrassment.

In a preferred embodiment of the invention, monitor 20 is powered using a standard-type battery. Alternatively, monitor 20 is powered using a rechargeable battery. Alternatively or additionally, monitor 20 is powered using solar power or by the inertial power (from the movement of monitor 20). Preferably, when the battery is low, monitor 20 alerts the patient to download information and/or replace or recharge the battery. Alternatively, monitor 20 shuts down less critical functions or includes a backup power source, so that power is available for critical monitoring or reminder tasks and/or maintaining the integrity of recorded data. In a preferred embodiment of the invention, controller 22 conserves power by using a lower clock rate when no processing is required, for example, as compared to a higher clock rate when real-time data analysis is required.

Alert 24 is preferably used to remind patient 21 to perform a certain action, for example, taking medicine, testing a physiological parameter (such as glucose concentration in

the blood or blood pressure), perform a certain activity (such as eat, drink or exercise), respond to a presented query and/or fill out a clinical study form. In a preferred embodiment of the invention, alert 24 is an audio alert, for example a buzz or a verbal message. Alternatively or additionally, alert 24 utilizes a flashing light. Alternatively or additionally, alert 24 uses a vibration, for example by electrifying a piezoelectric element or a solenoid on the back of monitor 20, using an AC current. Alternatively or additionally, alert 24 can drive a small current through patient 21. Alternatively or additionally, alert 24 can send a wireless signal to a free-standing alert device, for example, a desk-top buzzer. In a preferred embodiment of the invention, display 26 is used to display a message that explains the alert. Alternatively or additionally, controller 22 monitors a patient's response to the alert, to determine if the alert was received. In some embodiments of the invention (for example as described below), monitor 20 can communicate with a doctor or a health-care professional to warn that the alert was not responded to.

In a preferred embodiment of the invention, the medicine is taken by patient 21 from a separate pill-box. Alternatively or additionally, the pill-box is controlled by monitor 20 to open at the time of the alert and/or to dispense a relevant pill. Such control may be time based or may be by wireless communication between the monitor and the pill-box(es). Alternatively or additionally, monitor 20 itself includes a storage for medicine which is to be taken by the patient. Alternatively or additionally, monitor 20 directly dispenses the medicine, for example by controlling a drug pump or a electrophoresis trans-dermal drug patch. Alternatively or additionally, for example for angina patients, when a patient feels pain, he indicates the pain sensation to monitor 20, which responds by providing a suitable medication by one of the above methods.

In a preferred embodiment of the invention, patient 21 can enter data to monitor 20 using input 28. In some cases, the data entry may be in response to a reminder or a query by monitor 20. For example, in response to a reminder to take medicine, a patient will enter an indication that the medicine was taken. In other cases, the data entry may be initiated by the patient. For example, a patient may enter meal times, a sudden feeling of pain or the onset of a side effect. In general, the entered data may comprises psychological data, physiological data, environmental conditions, explanations for automatically monitored events and/or commands which affect the operation of monitor 22.

In a preferred embodiment of the invention, sensor 32 is used to automatically monitor the patient. Preferably, the raw sensor data is stored. Alternatively or additionally, the data is compressed, preferably using a loss-less compression scheme. Alternatively or additionally,

the data is analyzed before being stored to identify features and/or interesting portions thereof, which features or portions are stored. Alternatively or additionally, the data is stored using a lossy compression scheme. Memory 34 on which the data is stored is preferably integral with monitor 20. Alternatively, memory 34 may be contained in a separate package, connected by wired or wireless communication means to monitor 20. In a preferred embodiment of the invention, the analysis and/or recording of sensor data for storage and/or feature extraction is responsive to previously acquired data, data entered by the patient and/or data which should have been entered by the patient but was not.

Alternatively or additionally, the acquisition of sensor data is made responsive to previously acquired data and/or data entered by a patient. In one example, data is logged only for times which appear to be relevant, for example, based on previously determined schedules and/or responsive to an event. In another example, gain, level and/or other characteristics of a sensors may be adjusted so that the sensor is optimally configured to sense expected data values. For example, a sensor may be configured to better detect tremors or to better detect gross movements, by modifying the sensor's gain..

In a preferred embodiment of the invention, data is downloaded from monitor 20 to computer 34. Alternatively or additionally, programming is uploaded from computer 34 to monitor 20. Alternatively or additionally, data, especially data useful for internal algorithms, may be uploaded from computer 34 to monitor 20.

In a preferred embodiment of the invention, the connection between communication port 30 and computer 34 uses standard networking hardware, for example, IR or RF networking or a serial cable. Alternatively, a dedicated communication protocol is used. Alternatively or additionally, port 30 is adapted to connect using an analog telephone line, the port possibly incorporating a modem. Possibly, port 30 is operative to generate an Internet connection, for example to a doctor's Web site. In some cases, port 30 may connect to a patient's personal computer which, itself connects to an Internet. Preferably, a special program is executed on the personal computer to communicate with the web site and/or to program the monitor. Possibly, the program may serve as an enhanced user interface to the monitor, for example to enter "requests" or to program in reminders, even when the personal computer is not connected to an Internet. Optionally, the program itself may be downloaded from the web site, for example as a Java applet. Possibly, the monitor itself is programmed in Java, so that it can be readily reprogrammed, e.g., from the Internet. In a preferred embodiment of the invention, the web site is that of a pharmaceutical company or of the manufacturer of the

monitor, thus allowing a patient to receive updates, for example, regarding his medicine, novel side effects and/or dosage limitations, in a direct manner.

Fig. 2A is a schematic illustration of a faceplate 40 of an ambulatory monitor for Parkinson's disease, in accordance with a preferred embodiment of the invention. In the exemplary embodiment shown, the monitor includes one or more band holders 42 for attaching a wristband to the monitor. Faceplate 40 preferably comprises a display 44, for example a dot-matrix LCD display, which can be used to display numbers (e.g., the time), short textual messages, icons, pictures, diagrams, symbols and/or images. A button 46 is used to indicate taking a meal. A button 48 is used to indicate taking of a medicine. In a preferred embodiment of the invention, monitor 20 generates an alert when it is time to take medicine, possibly also flashing a LED at or near the "medicine" button. When patient 21 takes the medicine, he presses the button and the flashing stops. Alternatively, in some cases the patient takes the medicine on his own and indicates this to the monitor, which then reschedules reminders for taking medicine.

A button 50 is used to indicate sleep and wake times. Buttons 52, 54 and 56 are preferably used to indicate a state of the Parkinson's disease, with button 54 allowing a patient to indicate an "OFF" state, button 56 allowing a patient to indicate an "ON" state and button 52 allowing the patient to indicate a state of dyskinesia. These indications may be additional or alternative to an automatic detection of these states by monitor 20, by analyzing reading from sensor 32. Preferably, these indications are used by monitor 20 to calibrate ranges for parameters which are associated with these disease conditions. Alternatively or additionally, monitor 20 learns to associate particular movement frequencies and/or other features of the sensor data with particular disease states, for example, for a particular patient, an "OFF" state may be characterized by a sudden, short, increase in motion in a particular frequency band, followed by a general depression of motion in all frequency bands. In a preferred embodiment of the invention, a "query" to a patient may consist of flashing LEDs (not shown) at or near the relevant buttons (e.g., one or more of ON, OFF, meal, sleep/wake, Dyskinesia and medicine). The patient responds to the query by pressing on one of the flashing buttons.

Two additional buttons 58 and 60 may be used for programming the monitor. In a preferred embodiment of the invention, an undo button 57 is provided to undo erroneous data entry.

In a preferred embodiment of the invention, all the buttons used share a similar logic and are activated by a single press. Alternatively, more complex and/or different logics may be used, for example to allow entry of more complex data or to better suit the special

circumstances of patient's having Parkinson's disease. In one example, a button-press may be accepted only if it was pressed for at least a predetermined threshold duration. In another example, every button press may require an acknowledgment, for example using a different button. In another example, only the relevant buttons are available for receiving input, for example, responsive to a current state of the monitor, patient input, sensor data or an outstanding alert. Alternatively or additionally, data entry may utilize speech recognition, preferably user dependent speech recognition, with a patient's speech pattern being uploaded using port 30. In some embodiments, data entry may use both speech (for the entry) and buttons (for the confirmation). Alternatively or additionally, speech sounds can be used for confirmation, for example, to confirm taking of medication, in response to a query.

In another example of a button logic one press on a button displays its state and a second press is required to change the state.

In a preferred embodiment of the invention, monitor 20 includes special logic that is specific for Parkinson's disease. Such logic is preferably dedicated to the disease process of Parkinson's and/or to the effects and/or side effects of particular medication. In one example, monitor 20 changes the schedule of medicine taking responsive to reported side effects or in order to correlate the "ON" state with the times at which a patient needs activity, for example, a physical therapy meeting. Thus, a patient and/or a doctor may be able to enter "requests" into monitor 20, either directly into the monitor or using programming from a computer. Such requests and/or other optimization aims may also be preprogrammed in to monitor 20. In a preferred embodiment of the invention, one or more of several variables are under control of the monitor to achieve such optimization, including: dosage, medication time, medication scheduling, temporal relationship between medication, meals, activities and/or other medical activities, such as physical therapy meetings.

In another example, monitor 20 determines if certain side effects are too severe or indicate a critical adverse reaction to a medication. In many cases, monitor 20 cannot make these determinations solely using logic and may thus query the patient for missing information. Alternatively, monitor 20 may request patient 21 to ask a doctor certain questions, report information and/or to connect the monitor to a communication line, for example, so the monitor can be updated and/or report to a supervising physician.

In a preferred embodiment of the invention, a severity of a side effect medicine efficacy and/or other "analog" information is entered using a DVAS (Digital Visual Analog Scale). In a standard VAS, a ruler with a (mechanically) movable marker is provided to the patient. The ruler shows a scale, for example, pain, and the marker is used to subjectively

select a pain level. Such a ruler is very bulky and usually does not automatically record data. Thus, patient compliance is a problem and using two such VASes is not practical. In a DVAS, the "VAS" is always available (e.g., on the wrist) and any number of DVASes can be programmed into a single monitor, so several variables may be entered using visual analog scales. Further, it is possible to visually and/or automatically compare the values entered on the several scales and/or data entered using other types of data input. A differentiated should be noted between entering "analog" data for data entry and entering data to set a control variable.

In a preferred embodiment of the invention, the data is displayed as a bar (filling an entire side of the display or only at the marker position) in a range of values. Such an indication can easily be corrected by moving the bar left or right. Further, it is possibly for the patient to control the resolution of his reply. For example, when in extreme pain, a patient may be satisfied with entering a large value (to indicate great pain), without taking the time to enter an exact value. In some embodiments of the invention, a rotatable control is provided to enter DVAS data, in others, a pair of buttons is designated {"Up", "Down"}.

Fig. 2B illustrates a faceplate 62 for a pain management application, using a DVAS for inputting pain severity. In this example, the DVAS comprises a lit triangle, with its apex at the "low" side and its base at the "high" side. Thus, although the horizontal dimension of the DVAS is reduced relative to that of a standard VAS, an added dimension, e.g., a vertical dimension, can partly or completely compensate for any loss in discernability. Alternatively or additionally, to shape, the DVAS may also be color encoded, for example, blue to red (e.g., blue = OK, red = severe pain).

Fig. 2C illustrates a faceplate 64 for a pain management application, wherein, pressing a button shows a menu (rolling) on the display, items from which menu are selected using the same or other buttons. In some embodiments, a menu may also include sub menus. Reference 66 indicates a complete list of possible selections in this menu.

In a preferred embodiment of the invention, the doctor can set up (using the communication port) the scale and/or format of the DVAS. Alternatively or additionally, the doctor can setup queries which are responsive to relationships between data entered using the DVASes and/or historical data.

In another example of a DVAS related query and/or activity, a doctor and/or patient can pre-set a goal, for example, a pain level. Once that pain level is reached, the medication may be stopped, switched with another medication and/or its schedule changed. In some cases,

an exact determination of a pain level may require querying the patient for more details, after he enters a VAS value.

As mentioned above, display 44 may be used for displaying one or more of queries, reminders, alerts and data input. Alternatively or additionally, display 44 is used for displaying a DVAS. Alternatively or additionally, display 44 may be used for graphically displaying logged data, for example data entered by a user or data which is automatically logged. In a preferred embodiment of the invention, such data is displayed textually and/or graphically, especially if showing a history of a variable, for example, variations of a pain level over time. Alternatively or additionally, display 44 may be used to display processed data and/or an analysis of data, for example in response to a patient request. Alternatively or additionally, display 44 may be used to provide the patient with instructions (visual and/or audio) on medication, healthful activities and/or using the monitor. Such instructions may be requested by the patient. Alternatively or additionally, such instructions are automatically generated when it is determined that the patient is not using the monitor in a correct fashion and/or is not using it enough.

Figs. 3A and 3B comprise an exemplary data display and analysis screen 70 for data analysis software in accordance with a preferred embodiment of the invention. As mentioned above, raw data and/or possibly partially analyzed data is preferably downloaded to a personal computer, on which a physician can perform additional analysis. In an exemplary embodiment, such analysis may include a display 72 showing ON and OFF state times, times medications were scheduled to be taken and time sat which medications were actually taken. A display 74 shown the ON duration as a percentage of waking hours. A display 76 shows the time to achieve an ON state after taking the first medication dose in the morning. A display 78 and a display 80 correspond to displays 74 and 76, but show long-term information, for example, monthly information. It is noted that the provision of better correlation between the sensor data, patient activities and/or patient reporting allows a better analysis of the data and confirms the usage of graphical display.

In a preferred embodiment of the invention, the data analysis program may initiate actions responsive to the downloaded data and/or its analysis, for example, to page a doctor or to send him e-mail. the conditions for performing such activities may be pre-set. Alternatively, the doctor may program them in, for example, via his Web site.

In other preferred embodiments of the invention, additional or alternative data processing techniques may be used. Preferably, data from monitor 20 and/or from the PC

processing program may be converted to a standard file format to be analyzed by standardized data processing programs, for example Excel or SAS.

One aspect of some preferred embodiments of the invention is scheduling of reminders and/or of queries. In a preferred embodiment of the invention, the scheduling can be a function of data which is entered by the user or analysis of automatically logged data, as well as a function of preset time and date schedules. As indicated above, scheduling and/or dosage of medicine taking can be preset or it can be a function of the effect and/or side effects that the medicine(s) (one or more types) is causing. The effects and/or side effects may be automatically detected, may be entered by a user or may be determined by correlating the user-entered information with the automatically sensed information.

In a preferred embodiment of the invention, queries may be scheduled to be at a preset time, for example, every 4 hours or every two days. Alternatively or additionally, queries may be scheduled to be delayed relative to events, for example one hour after eating or 15 minutes after achieving an ON state. In addition, more complex dependencies may be created, for example, 10 minutes after achieving an ON state if medication A was taken or 20 minutes after the ON state if medication B was taken. Possibly, a script programming language is provided for the physician to program when and under what circumstances queries are presented. Alternatively or additionally, a state machine representation may be provided, with certain states generating particular queries and certain responses (or monitored data) generating transitions to particular states.

Alternatively or additionally to queries being generated responsive to patient responses, a particular series of queries may be designed for particular situations, to better direct the queries to a patient. For example, if a patient enters that he has felt a side effect, a series of queries may be asked to determine the type, extent and/or other properties of the side effect. In addition, in some embodiments of the invention, data input to the monitor is limited so substantially only yes/no questions can be asked, requiring more questions to get the required information. The "tree" of questions may be dependent on the patient state, for example, with questions about fever being asked earlier on for medication A than for medication B. Additionally, a patient response or input may cause the scheduling of future questions. For example, if a patient complains about a headache, a follow-up question about the headache may be asked 1 hour later. Alternatively, a patient may be reminded in one hour to report again on side effects. Queries may also be used to present instructions to a patient, for example, to take aspirin for a headache or to see a doctor at once.

The scheduling of some events may be set to be at a delay after a different event (e.g., one hour after eating). In a preferred embodiment of the invention, one or more of three types of delays are provided: (a) simple time delays; (b) metabolic-related delays; and (c) physiologic process related delays. Metabolic related delays, which are responsive to the metabolizing of the medication by the patient, are typically used to make sure that a patient acts or is queried at a time when the effect of the medicine is expected to be maximal, minimal or at a steady state. Physiologic process related delays, which are responsive to the operation of the patient's body, are typically used to match the querying to what the patient's body is doing or is supposed to be doing. Examples of relevant physiologic processes (not only for Parkinson's) include, inflammation response, temperature adaptation, circadian rhythm, menstrual cycle and gestation process. Parameters of the metabolic process and of the physiological processes are typically patient dependent values which must be loaded for each patient. In some cases, an average value or a group value (e.g., based on age) may be sufficient.

Fig. 4 is an exemplary flowchart for a querying logic in accordance with a preferred embodiment of the invention. As can be appreciated, other flowcharts may be used for other embodiments of the invention. further, an particular flowchart may be individually tailored, for example, per patient, per disease and/or pre medication. In this example, a patient is reminded to take medication at 15:00. The medication may have a side effect of a headache, after it is absorbed by the body. In the sample flowchart, a patient is reminded to take the medicine if he did not indicate he had taken it. If he complains of no headaches or other side effects, an increase in dosage is considered (possibly dependent on the existing dosage not being effective enough, no reports of side effects over a period of time and a doctors agreement in advance). If there are persistent side effects, the dosage may be automatically reduced.

In a preferred embodiment of the invention, monitor 20 includes self testing and safety capabilities, for example, to determine if the sensors, memory and/or controller are working properly. Additionally or alternatively, the monitor checks that the patient behavior is within certain bounds, for example, that his movements are normal or that he is reasonably punctual with respect to medicine taking.

In a preferred embodiment of the invention, the logic of the monitor instigates actions, for example, suggesting to a patient that he call a doctor 20 if the duration of OFF states is increasing. Additionally or alternatively, the monitor may turn itself off, if it malfunctions. Additionally or alternatively, the monitor may initiate a call for help, for example if monitor 20 includes a wireless communication means.

In a preferred embodiment of the invention, the monitor logic includes a series of conditions, each of which, if met, may indicate a malfunction or problem of some sort. Additionally or alternatively, at least in some operational states, the monitor includes one or more functions which check correlation between data and/or analysis sources, for unreasonable discrepancies. In one example, the monitor checks for a significant discrepancy between disease states as inputted by a patient, for example an OFF state and movement detected by sensor 32 during the alleged OFF state. Additionally or alternatively, in monitors with two or more sensors, the outputs of the sensors may be cross-correlated.

In a preferred embodiment of the invention, the monitor includes one or more models of how the patient and/or medicine are expected to perform. In some preferred embodiments of the invention, these models may be used for planing medication and/or treatment schedules and/or presenting predictions to the patient. These models may be embodied using a neural network or using a state machine model. In one example, the monitor may generate an alert if a patient did not perform an expected activity, such as eat supper. The monitor will preferably alert the patient and ask if a data entry was missed. In another example, if a dose of medicine has no effect, the monitor will ask the patient if perhaps the medicine was not taken.

In a preferred embodiment of the invention, the model(s) are pre-set and/or programmed into the monitor, during a programming session. Additionally or alternatively, the model(s) for a particular patient and/or medicine regimen may be learned, for example, if they are embodied using a neural network or by learning parameters for a pre-set model. In one example, a model may model daily, weekly, monthly or yearly schedules of the patient and/or of his environment.

In a preferred embodiment of the invention, the monitor is used to track the effectiveness of certain medicines, for a particular patient. Possibly, a doctor can program such a monitor to alternate between different schedules so that the doctor can assess which schedule and/or medication has the best effect and/or the least side effects. Further, in some preferred embodiments of the invention, the monitor is used for clinical testing of drugs. As can be appreciated the automatic scheduling of queries and/or the dependency of some queries on logged data can be used to better determine side-effects and/or their causes and/or other parameters. Thus, a clinical study can obtain more effective information from the same number of test subjects, possibly in less time. Further, by correlating manual and automatic data entry, a higher confidence level in the data may be achieved.

Fig. 5 is a block diagram of a network embodiment of an ambulatory monitor in accordance with a preferred embodiment of the invention. A patient monitor 90 is preferably

networked with a health care provider monitor 92 and/or a base station 94. The network may be a real-time network, in which messages are transmitted in real-time between the elements of Fig. 5. In some embodiments base station 94 is required as a go between, in some embodiments base station 94 is used for back up or for remote reporting and in some cases no base station 94 is provided. Additionally or alternatively, the network may be an off-line network, in which synchronization is achieved by the elements sharing a common clock and being aware of the logic of the other elements. In this case, the monitors may be synchronized with each other periodically, possibly using base station 94 to perform the synchronization. In some cases, base station 94 (or monitor 92) may be utilized to perform some or all of the processing and/or data store for monitor 90. Preferably however, monitor 90 includes at least a limited storage and/or processing capability for when it is out of range of the base station.

In a preferred embodiment of the invention, a patient with a monitor 90 may not be trusted to comply with the instructions he receives from the monitor and/or to correctly (or at all) answer queries from the monitor. However, such a patient may still require a sense of autonomy, for example if the patient has "bad" days and "good" days. In a preferred embodiment of the invention, a monitor 92 is worn by the patient's health care provider (e.g., a live-in nurse). When the patient is reminded to take medication, the nurse is preferably also alerted, to check if the patient is complying. Additionally or alternatively, if the patient does not indicate that he has taken the medicine, it may be the nurse's monitor which sounds an alert, not the patient's (since he has already shown non-compliance). In some cases, a person other than the patient may respond to the alerts on the patient's monitor. In some cases, monitor 92 may be placed at a nurses station in a hospital.

In some embodiments of the invention, base station 94, patient monitor 90 and/or health care provider monitor 92 may be connected to a larger network, for example a hospital information center 96. Alternatively or additionally, they may be connected to a drug company center 98. Preferably, such complex network topologies utilize an Internet or direct dial-up, however, other available networking solutions may be used. In a preferred embodiment of the invention, patient monitor 90 uploads information to the hospital information system, to aid in diagnosis of the patient. Alternatively or additionally, the monitor downloads clinical information to be stored on monitor 90 or the patient's PC, to be used in programming the device, analyzing its results or for emergency healthcare providers. Preferably, the monitor includes a simple interface (for example a button and speech output) to allow an emergency medical practitioner to retrieve critical information (e.g., drugs ingested) from the patient.

The above description has focused mainly on using a monitor for Parkinson's disease. However, such a monitor may be useful for tracking other chronic conditions.

In one example, a pain monitor is provided, to monitor the changes in pain during the day and to aid in deciding on a suitable pain-reliever schedule. Alternatively, the monitor may be programmed to decide on a schedule. In a preferred embodiment of the invention, onset of pain may be automatically detected, by detecting changes in motion of the patient. In a preferred embodiment of the invention, one or more additional sensor may be provided, to back up the movement sensor, for example a heart rate sensor may be used to detect an increased heart rate on the onset of pain.

Alternatively or additionally, a pain level may be detected by analyzing characteristics of a patient's gait. For example, a correlation may be expected between step size, speed and/or accelerations, depending on the pain level. In particular, if the pain is affected by the walking, for example, back pain, leg pain or arm pain, it may be expected that one side of the body be favored, causing a marked effect on the rhythm of walking. Alternatively or additionally, the time spent in different postures may change, for example, more time standing or laying down (when in pain) and less time sitting. In some embodiments, a plurality of sensors may be provided on the body, to differentiate between the different postures (e.g., sitting is like standing, except for the knee-shoulder distance). Alternatively or additionally, one or more of the sensors may sense angle, relative or absolute position and/or velocity, rather than acceleration.

In a preferred embodiment of the invention, the monitor (and/or the data analysis programs on the personal computer) learns to associate certain features of the movements and/or postures with certain pain levels (or other disease states and/or symptoms). Preferably, this learning is accelerated by the patient entering a subjective input regarding the pain state. Preferably, the association is performed by the monitor. Alternatively or additionally, the association is performed by the patient's (or the doctor or drug company) computer, by analyzing data downloaded to it from the monitor.

Fib. 2B and 2C, referred to above, illustrate faceplates for a pain management application, in which buttons 50 and 46 are marked "down" and "up" respectively, buttons 48 and 52 are marked "sleep/wake" and "activity" respectively and buttons 54 and 46 are marked "medicine 1" and "medicine 2" respectively.

In a preferred embodiment of the invention, the monitor may include a microphone to detect ambient sounds. These sounds may be correlated with the patient's activities, for example, loud sounds may appear right before acceleration (subway). In another example,

these sounds may originate from the patient himself, for example coughing, sneezing and snoring, which activities it may be desired to monitor. This is another example where a person other than the wearer of the monitor may use the monitor to enter data (the patient's bed partner who is woken by the snoring). Sound analysis may be performed on-line or off-line, using automated processing and/or using a human operator.

In another preferred embodiment of the invention, a gastro-intestinal disease management monitor is provided, to track gastric reflux, irritable bowel syndrome, chronic constipation or diarrhea and/or other GI ailments. Preferably, an acoustic sensor is used to detect loud bowel sounds that travel through the body. In this context it is noted that, many bowel activities have a natural rhythm of, for example 20 minutes, to which the monitor is preferably attuned. Alternatively or additionally, a patient may enter an indication of a burning sensation. Alternatively or additionally, the monitor may query the patient at preset (or learned) times after the meal to see if any symptoms are being felt. Preferably, monitor 20 learns patterns of symptoms with and/or without medication, so that the queries are better timed to coincidence with the onset and/or decline of the symptoms.

Such a monitor as described herein above may also be used for other health-related applications. One advantage of some of the embodiments described herein, which advantage is useful for other health applications, is that the patient himself can be queried to supply missing, ambiguous and/or undetectable information. Thus, an ambulatory monitor can be used even if a sensor cannot guarantee high quality and/or complete information.

In one example, an ambulatory monitor is used to track hyperactivity and ADD (attention deficiency disorder) in children. A typically relevant sensor is an accelerometer, to determine the amount of movement and/or fidgeting. In order to differentiate between game playing and hyperactivity-related fidgeting. The child may be queried, for example as to whether he is playing a game (where movement is expected) or if he is at a lesson (where movement is not expected). Alternatively or additionally, a child can be queried directly or indirectly (using a simple test) to determine his attention span. In younger children, it may be advantageous to use icons or pictures, rather than textual messages.

Other examples of psychiatric disorders, such as anxiety and depression/mania are also characterized by significant swings in activity levels, body postures, shaking and/or other easily measured parameters. In addition, by querying the patient (or applying one or more psychiatric evaluation questions) it is possible to "measure" the mood of the patient. Thus, the efficiency of drugs, their interactions with events in the patient's life and/or the best timing for dispensing, may be determined with the help of an ambulatory monitor. Also, in an anxiety

embodiment, it may be advantageous to query the patient after an anxiety attack and medication taking, to determine the exact effect of medication. Preferably a scale having between 3-5 degrees of anxiety and/or a DVAS are used to input the anxiety level. The patient preferably reports the cause of the attach by selecting from a preset list of options. Possibly, if the cause is not on the list, the patient enters the cause using a voice recording and/or by selecting an option marked "other". Preferably, the doctor and/or patient will reprogram the monitor to include the missing cause(s).

An ambulatory monitor may be used for incontinence, for example for a patient to report incontinence events and their (possible) causes. Alternatively or additionally, the monitor may include a sensor, for example an implanted intra-bladder or intra-abdomen pressure sensor, to sense changes in pressure which might be related to incontinence. Alternatively or additionally, a sound sensor may be used to identify coughing. Alternatively or additionally, an accelerometer may be used to identify jumping and/or other potential incontinence causing events. Possibly, when such an even is detected, a patient may be queried whether there was an incontinence event and/or reminded to perform certain exercises to avoid such events.

In a blood-pressure embodiment, the monitor may periodically measure the patient's blood pressure and/or request the patient to measure his blood pressure. Possibly, such a monitor may also record movements and/or a heart rate, to detect blood-pressure affecting event. Alternatively or additionally, the monitor may query the patient when an increase in blood pressure is detected, for the reason.

In a pulmonary embodiment (e.g., emphysema, asthma) the monitor may include a sensor for example an electrical impedance sensor or an EMG sensor to detect breathing. Alternatively or additionally, the monitor may include an oxygenation sensor to detect actual blood oxygen level. Alternatively or additionally, the monitor may include a heart-rate sensor or an accelerometer to detect movements. Possibly, the monitor may periodically (or responsive to measured parameters) request that the patient use a spiro-graph to measure lung capacity and/or other pulmonary variables. Queries may be used to help the monitor differentiate between different activities and/or to better track the onset, decline and/or duration of breathing difficulty and/or the effect of medication or exercise.

In a diabetes example, a monitor may remind a patient to test his blood sugar and/or the monitor may control an insulin pump. Alternatively or additionally, the monitor tracks sweating, heart rate, dizziness (using an accelerometer) and/or other parameters, to detect

hypoglycemia. Preferably, the patient reports when he takes food and/or insulin, and the type of food or insulin taken.

In a heart disease example, the monitor can be used to detect ECG, while the patient is queried whether he feels an arrhythmia and/or its effects which is provisionally detected by the monitor.

Additionally or alternatively, such a monitor may be used to track disease (or health) states which have a known progression and/or a hoped-for effect of medication of other treatment. In one example, a monitor may be used to track the sensations of a cancer patient undergoing chemotherapy and/or radiation treatments. In an opposite example, a monitor may be provided to track a human gestation, for example to track embryonic movements and the activity of the mother. In a preferred embodiment of the invention, embryonic movements are detected by a pressure wave caused by the movement of the embryo and propagated through the body. It should be noted that some of the applications described herein can tolerate higher noise levels than is common in other medical applications. One possible reason is that in long term monitoring the statistical data may be more important than any single datum. Another possible reason is the ability to average very long runs of data. Another possible reason is the ability to correlate between sensors and between a sensor and a patient subjective input. Additionally or alternatively, a sensor, for example a Doppler sensor may be provided on the abdomen of the mother or inside the uterus or the vagina. Such a sensor may communicate by wire or wireless with the monitor. Additionally, other of the embodiments described herein may utilize a sensor additional or alternative to the accelerometer in the monitor, for example, a temperature sensor, a blood pressure sensor and an ECG sensor. Such a sensor may be connected by wired or wireless means to the monitor.

In another example a monitor is used to track the onset and/or progression of menopause, especially in order to control the side effects caused by hormonal medication. Preferably, a more exact dosage and/or schedule of dosing may be determined by analyzing the automatically logged and/or manually entered information. Alternatively or additionally, the dosage is determined responses to queries, which queries are used to asses the effect of medication.

In a preferred embodiment of the invention, the monitor is used to provide support to a patient experiencing a new condition. For example, a patient who is newly diagnosed with diabetes is not as experienced with the diabetic lifestyle. A worn monitor may assist such a patient in acclimating to the newly required lifestyle, while minimizing unhealthy mistakes. The assistance may include periodic queries regarding well being (to detect hypoglycemia) and

reminders after meals to take insulin. In another example, a leprosy patient (which are thankfully rare today) must perform a periodic scan of his extremities to insure that he has not incurred new damage, as the nerve endings are damaged by the disease. Preferably, the level of assistance changes in time, to reflect the knowledge gained by the patient and to reduce the annoyance caused by the monitor asking too many questions. A similar reducing level of assistance may be provided for instructions regarding using the monitor. As the user becomes more proficient, such instructions should cease.

In some embodiments, reminders may be for activities other than medication, for example, a reminder to eat, drink, get up (to avoid blood clots) and/or exercise. Additionally or alternatively, the reminders may be for long-term activities, for example monthly or yearly check-ups or calibration of the monitor.

The present invention has been described with reference to medical applications, where the need for precise information, patient feedback and/or patient compliance is especially critical, more so, when taking into account that the users are often ill and/or otherwise problematic. However, it is anticipated that such a monitor may be reprogrammed for other, non-medical applications. Thus, a dedicated electronic diary with a query mechanism may be provided. In one example, such a monitor may be used by an athlete on a tight training regimen. In another example, such a monitor may be worn by data samplers (for example for efficiency studies in industrial engineering) or by service providers, to remind them or activities they must perform and/or to query them. Possibly, at least some of the queries and/or reminders may be download in real-time from a controlling device, for example a base station which is in wireless communication with all the end stations and which may also be used to perform some or all of the processing and/or data storage.

In some application, such a monitor as described above may form a software component of a more complex electronic device which is worn, for example a cellular telephone or a wrist computer. In other applications, a multi-option monitor may be provided, which monitor can be used to track several disease states. Alternatively or additionally, such a monitor is adapted to a particular disease by programming. Possibly, the buttons include programmable displays, which display their function. Alternatively, a plurality of stickers are provided which may be pasted over or at the buttons to describe their function.

It will be appreciated that the above described apparatus and methods of ambulatory monitoring may be varied in many ways. In addition, a multiplicity of various features, both of methods and of devices, has been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a

particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. It should also be appreciated that many of the embodiments are described only as methods or only as apparatus. In addition, the scope of the invention includes methods of using, constructing, calibrating and/or maintaining the apparatus described herein. When used in the following claims, the terms "comprises", "comprising", "includes", "including" or the like mean "including but not limited to".

CLAIMS

1. An ambulatory monitor, comprising:

a fastener for attaching said monitor to an ambulatory person to be monitored;

a display;

an input interface; and

a query generator which generates queries to said display and which receives responses to said queries using said input interface.

2. A monitor according to claim 1, comprising:

at least one sensor which generates a signal responsive to a sensed value; and

an automatic logger, which logs data responsive to said signal.

3. A monitor according to claim 2, wherein said data comprises raw signal data from said sensor.

4. A monitor according to claim 2, wherein said data comprises process signal data from said sensor.

5. A monitor according to claim 2, wherein said at least one sensor comprises a physiologic sensor that senses a physiologic variable of said person.

6. A monitor according to claim 2, wherein said at least one sensor comprises an environmental sensor that senses a parameter of an environment of said person.

7. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a motion of at least a portion of said person.

8. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a change in posture of said person.

9. A monitor according to claim 2, wherein said at least one sensor comprises a motion sensor that senses a change in body position of said person.

10. A monitor according to claim 7, wherein said motion sensor comprises an accelerometer.

11. A monitor according to claim 2, wherein said at least one sensor comprises at least two sensors, of different types.

12. A monitor according to claim 2, wherein said at least one sensor comprises at least two sensors, which measure different parameters.

13. A monitor according to claim 2 wherein said at least one sensor comprises at least two sensors, which are attached to different parts of said person.

14. A monitor according to claim 2 wherein said at least one sensor comprises a sensor which is spatially separate from said monitor.

15. A monitor according to claim 14, wherein said sensor is a wireless sensor.

16. A monitor according to claim 2, wherein at least one of said queries is generated responsive to said logged data.

17. A monitor according to claim 16, wherein said at least one query is generated at a delay responsive to said logged data.

18. A monitor according to claim 17, wherein said delay is responsive to a metabolism of a medication taken by said person.

19. A monitor according to claim 17, wherein said delay is responsive to a physiological process of said person.

20. A monitor according to claim 2, wherein said monitor generates a medication schedule responsive to said logged data.

21. A monitor according to claim 1, wherein said fastener comprises a wristband.

22. A monitor according to claim 1, wherein said monitor is adapted to be worn around a neck.

23. A monitor according to claim 1, wherein said display comprises a visual display.

24. A monitor according to claim 1, wherein said display comprises an audio display.

25. A monitor according to any of claims 1-24, comprising a reminder generator which provides said person with at least one reminder using said display.

26. A monitor according to claim 25, wherein said query generator generates at least one query responsive to a response of said person to said at least one reminder.

27. A monitor according to claim 26, wherein said response comprises not complying with said reminder.

28. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to eat.

29. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to drink.

30. A monitor according to claim 25, wherein said at least one reminder comprises a reminder to take a certain medication.

31. A monitor according to claim 25, wherein said at least one reminder comprises a reminder for a medical checkup.

32. A monitor according to claim 25, wherein said at least one reminder comprises a reminder for a medical test.

33. A monitor according to any of claims 1-24, comprising an alerter which calls attention of said person to said display.

34. A monitor according to any of claims 1-24, wherein said input interface is operative to receive unsolicited input from said person.

35. A monitor according to claim 34, wherein said input comprises an indication of a disease state.

36. A monitor according to claim 34, wherein said input comprises an indication of a side effect.

37. A monitor according to claim 34, wherein said input comprises an indication of an effect of said medicine.

38. A monitor according to claim 34, wherein said input comprises an indication of an activity of the person.

39. A monitor according to claim 34, wherein said query generator generates at least one query responsive to said input.

40. A monitor according to claim 39, wherein said query is generated at a delay responsive to said input.

41. A monitor according to claim 40, wherein said delay is responsive to a metabolism of a medication taken by said person.

42. A monitor according to claim 40, wherein said delay is responsive to a physiological process of said person.

43. A monitor according to claim 34, wherein said monitor generates a treatment schedule responsive to said input.

44. A monitor according to claim 43, wherein said treatment schedule comprises a medication schedule.

45. A monitor according to any of claims 1-24, wherein said query generator generates at least one secondary query responsive to a person's response to at least one of said queries.

46. A monitor according to any of claims 1-24, wherein said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to clinical testing of medical treatment.

47. A monitor according to any of claims 1-24, wherein said query generator comprises a memory and wherein said memory has stored therein an indication of at least one query directed to selecting between two or more medication schedules.

48. A monitor according to any of claims 1-24, wherein said monitor is adapted for monitoring a particular health condition of said person.

49. A monitor according to claim 48, wherein said health condition comprises a chronic disease.

50. A monitor according to claim 48, wherein said health condition comprises pain.

51. A monitor according to claim 48, wherein said health condition comprises heart disease.

52. A monitor according to claim 48, wherein said health condition comprises an anxiety disorder.

53. A monitor according to claim 48, wherein said health condition comprises a depression disorder.

54. A monitor according to claim 48, wherein said health condition comprises an ADD (Attention Deficiency Disorder) condition.

55. A monitor according to claim 48, wherein said health condition comprises a pulmonary difficulty condition.

56. A monitor according to claim 48, wherein said health condition comprises diabetes.

57. A monitor according to claim 48, wherein said health condition comprises a progressive disease.

58. A monitor according to claim 57, wherein said disease comprises Parkinson's disease.

59. A monitor according to claim 48, wherein said health condition comprises a non-disease condition.

60. A monitor according to claim 48, wherein said monitor is adapted for tracking a health condition which is being modified using a medical treatment.

61. A monitor according to any of claims 1-24, wherein said monitor is synchronized with a second monitor, adapted to be worn by a second person and wherein said second monitor comprises an alerter which generates an alert to said second person, responsive to an operation at said monitor.

62. A monitor according to claim 61, wherein said operation comprises a reminder to take medicine.

63. A monitor according to claim 61, wherein said monitor and said second monitor are synchronized using wireless transmission therebetween.

64. A monitor according to claim 61, wherein said monitor and said second monitor are synchronized using a common clock.

65. A monitor according to any of claims 1-24, wherein said input interface comprises at least one digital visual analog scale (DVAS) display.

66. A monitor according to claim 65, wherein said at least one DVAS display comprises at least two DVAS displays.

67. A monitor according to any of claims 1-24, wherein said input interface comprises at least one menu selection interface.

68. A monitor according to any of claims 1-24, wherein said input interface comprises an interface for entering at least two different types of data, each of said types of data having at least three possible values.

69. A monitor according to claim 68, wherein said query generator generates at least one query responsive to a relationship between said two types of entered data.

70. A method of detecting a change in pain level, comprising:

tracking movements of at least a portion of a person; and

analyzing said tracked movements to identify changes in movement caused by a change in pain level.

71. A method according to claim 70, wherein said tracked movements comprise changes in posture.

72. A method according to claim 70, wherein said tracked movements comprise changes in gait.

73. A method according to claim 70, wherein said tracked movements comprise changes in a time profile of at least one body position.

74. A method of data sensing, comprising:

automatically logging data of an ambulatory patient;

analyzing said data to determine at least one aspect of non-suitability of said logged data;

automatically querying said patient to provide data which improves said at least one aspect of non-suitability.

75. A method of entering multi-state information, comprising:

displaying, on a donned device, a scale of values, including an indication of a particular value;

entering, using said device, a value, which entered value is indicated using said indication; and

storing said entered value, in said device, for later analysis.

76. A method according to claim 75, wherein said displaying emulates a VAS (Visual Analog Scale) display.

77. A method according to claim 75, wherein said entered value indicates a pain level.

78. A method according to any of claims 75-77, comprising repeating said displaying and said entering a plurality of times for a same type displayed scale.

79. A method according to any of claims 75-77, comprising repeating said displaying and said entering a plurality of times for a different type displayed scale.

80. A monitor network comprising:

a first monitor, worn by a first person, which first monitor generates an alert to said first person; and

a second monitor, worn by a second person, synchronized with said first monitor, which generates an alert to said second person responsive to said first monitor.

81. A network according to claim 80, wherein said first and second monitors are synchronized using a common clock.

82. A network according to claim 80 or claim 81, wherein said first and said second monitors are synchronized using at least one wireless transmission between them.

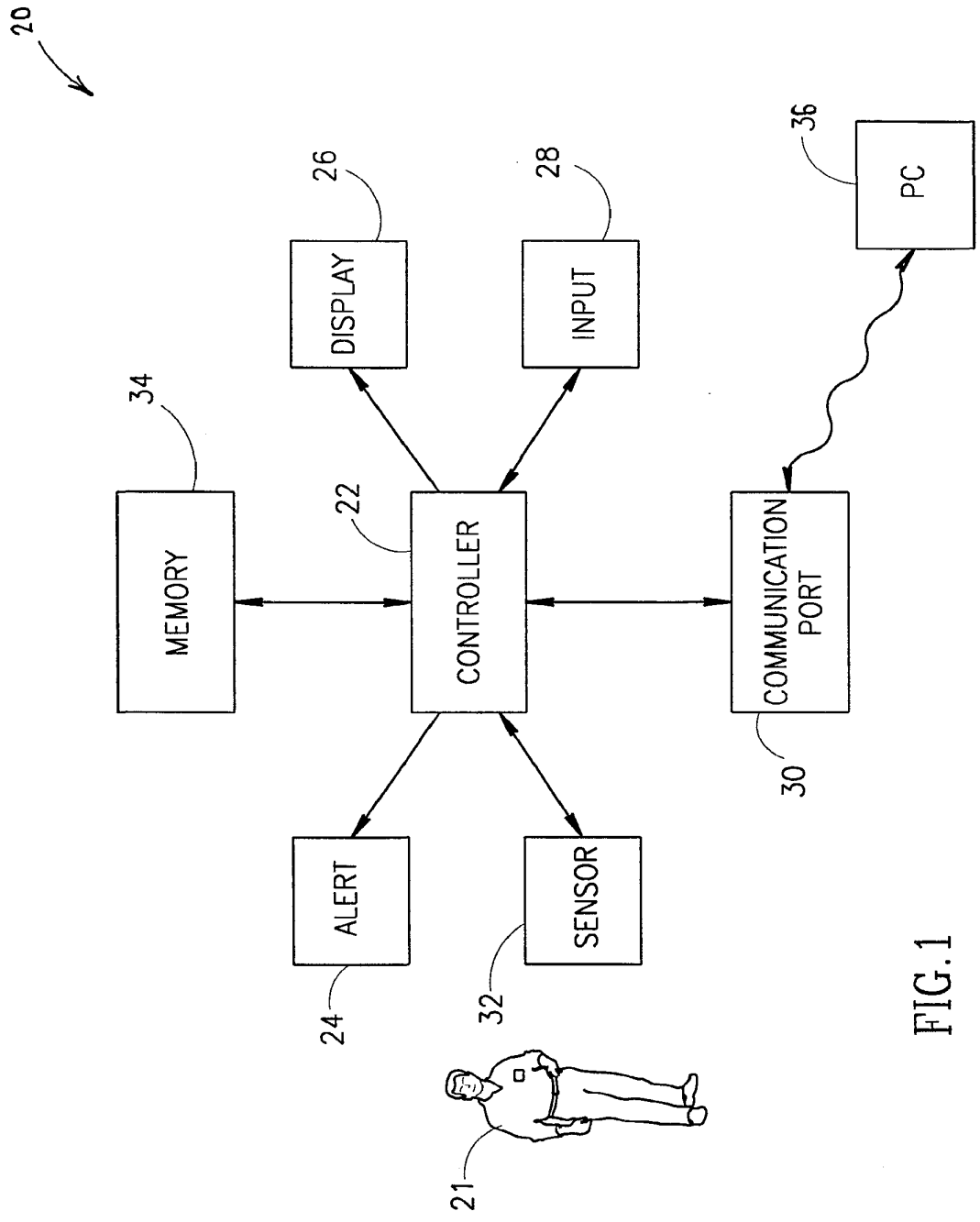
20
26
DISPLAY
28
INPUT
36
PC
34
MEMORY
22
CONTROLLER
COMMUNICATION PORT
30
ALERT
24
SENSOR
32
21

FIG.1

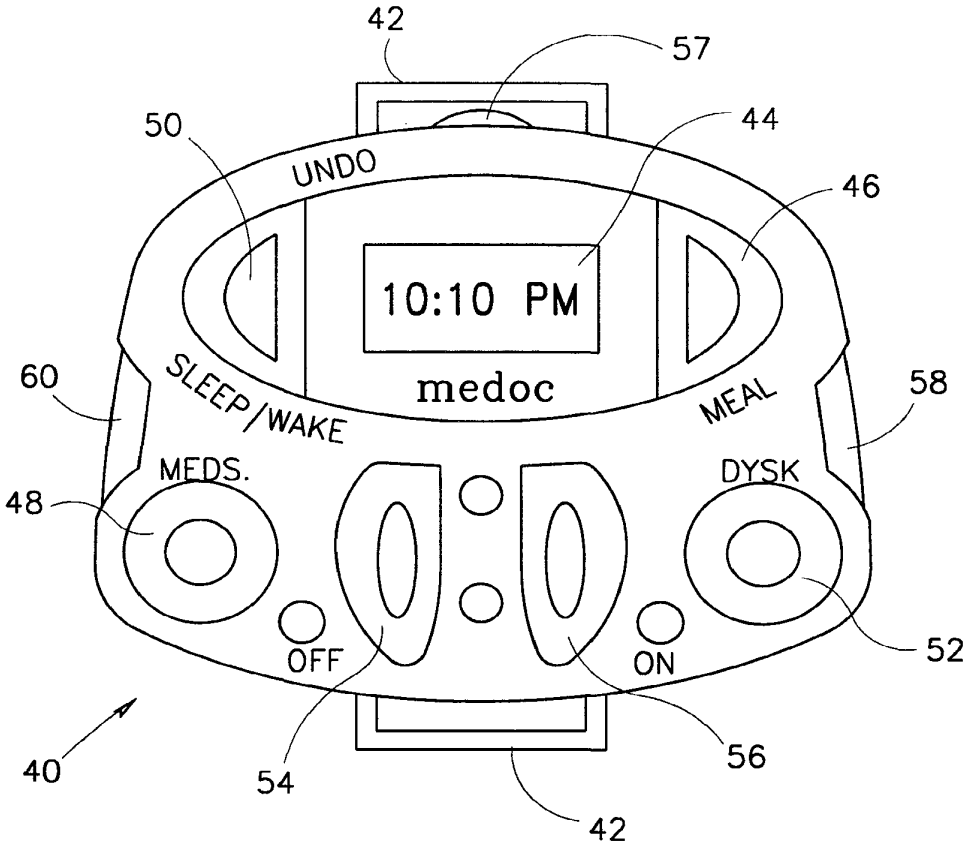
42
57
50
44
UNDO
46
10:10 PM
medoc
60
SLEEP/WAKE
MEAL
58
MEDS.
DYSK
48
OFF
ON
52
40
54
56
42

FIG.2A

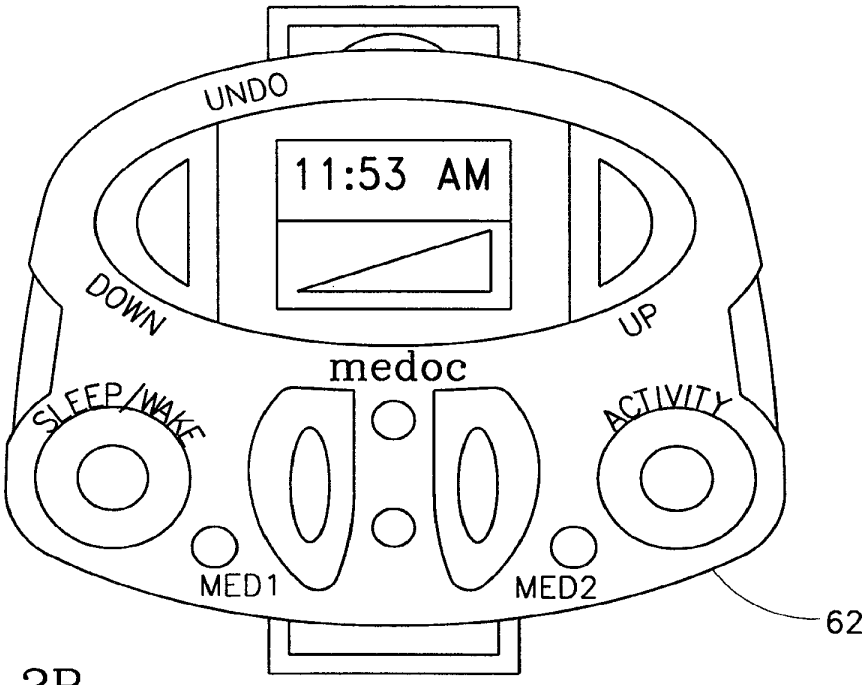
UNDO
11:53 AM
DOWN
UP
medoc
SLEEP/WAKE
ACTIVITY
MED1
MED2
62

FIG.2B

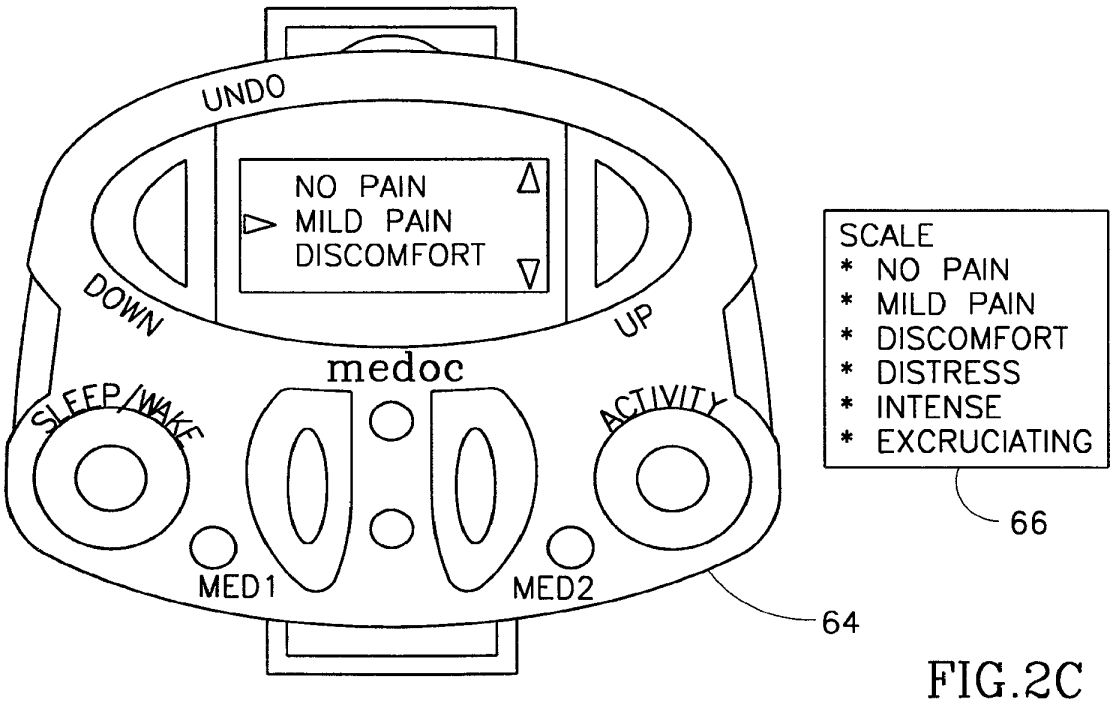
UNDO
NO PAIN
MILD PAIN
DISCOMFORT
DOWN
UP
medoc
SLEEP/WAKE
ACTIVITY
MED1
MED2
64
SCALE
* NO PAIN
* MILD PAIN
* DISCOMFORT
* DISTRESS
* INTENSE
* EXCRUCIATING
66

FIG.2C

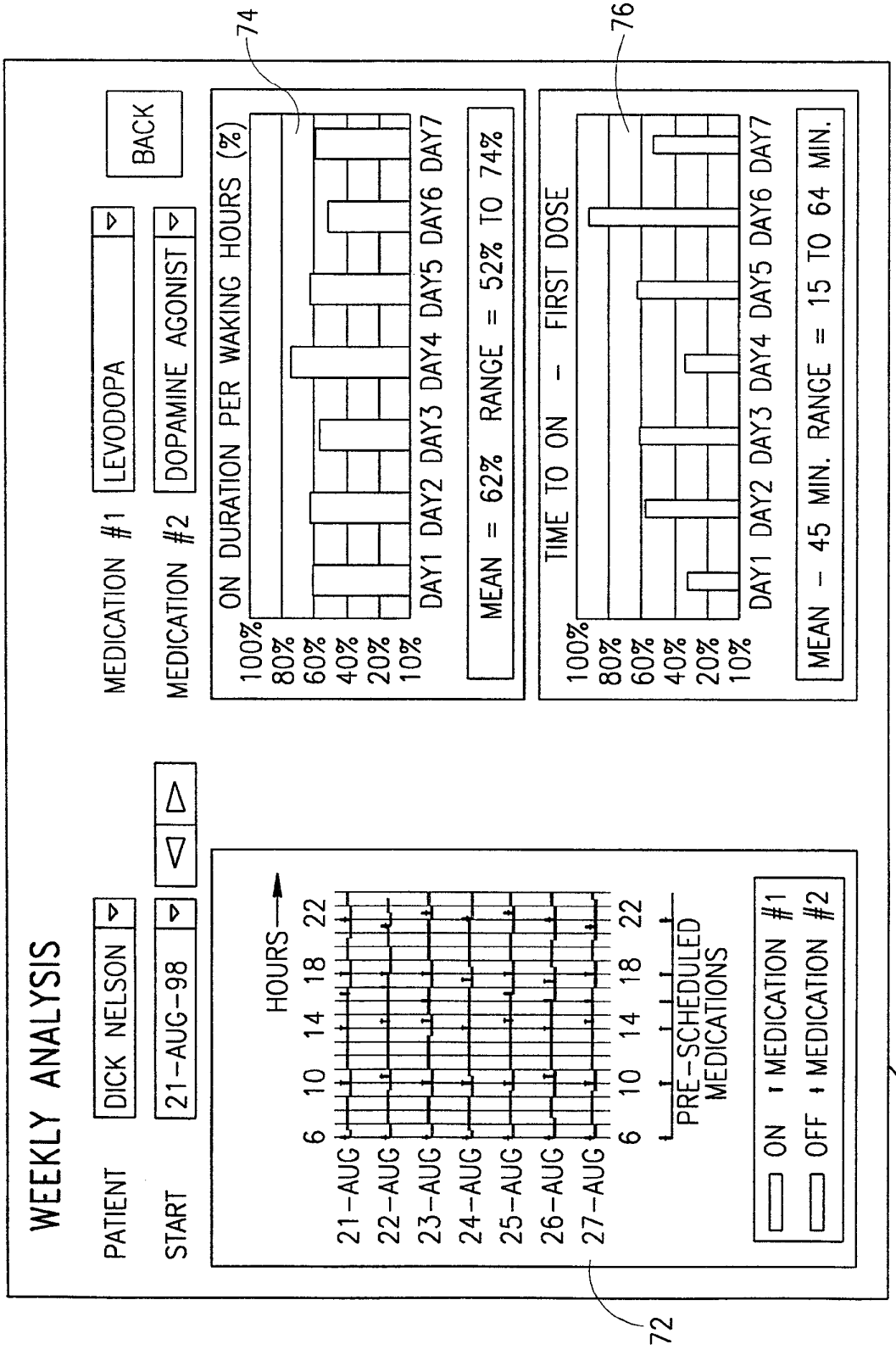
WEEKLY ANALYSIS
PATIENT
DICK NELSON
START
21-AUG-98
MEDICATION #1
LEVODOPA
MEDICATION #2
DOPAMINE AGONIST
BACK
74
ON DURATION PER WAKING HOURS (%)
100%
80%
60%
40%
20%
10%
DAY1 DAY2 DAY3 DAY4 DAY5 DAY6 DAY7
MEAN = 62% RANGE = 52% TO 74%
76
TIME TO ON - FIRST DOSE
100%
80%
60%
40%
20%
10%
DAY1 DAY2 DAY3 DAY4 DAY5 DAY6 DAY7
MEAN - 45 MIN. RANGE = 15 TO 64 MIN.
HOURS
6 10 14 18 22
21-AUG
22-AUG
23-AUG
24-AUG
25-AUG
26-AUG
27-AUG
PRE-SCHEDULED MEDICATIONS
ON : MEDICATION #1
OFF : MEDICATION #2
72
70

FIG.3A

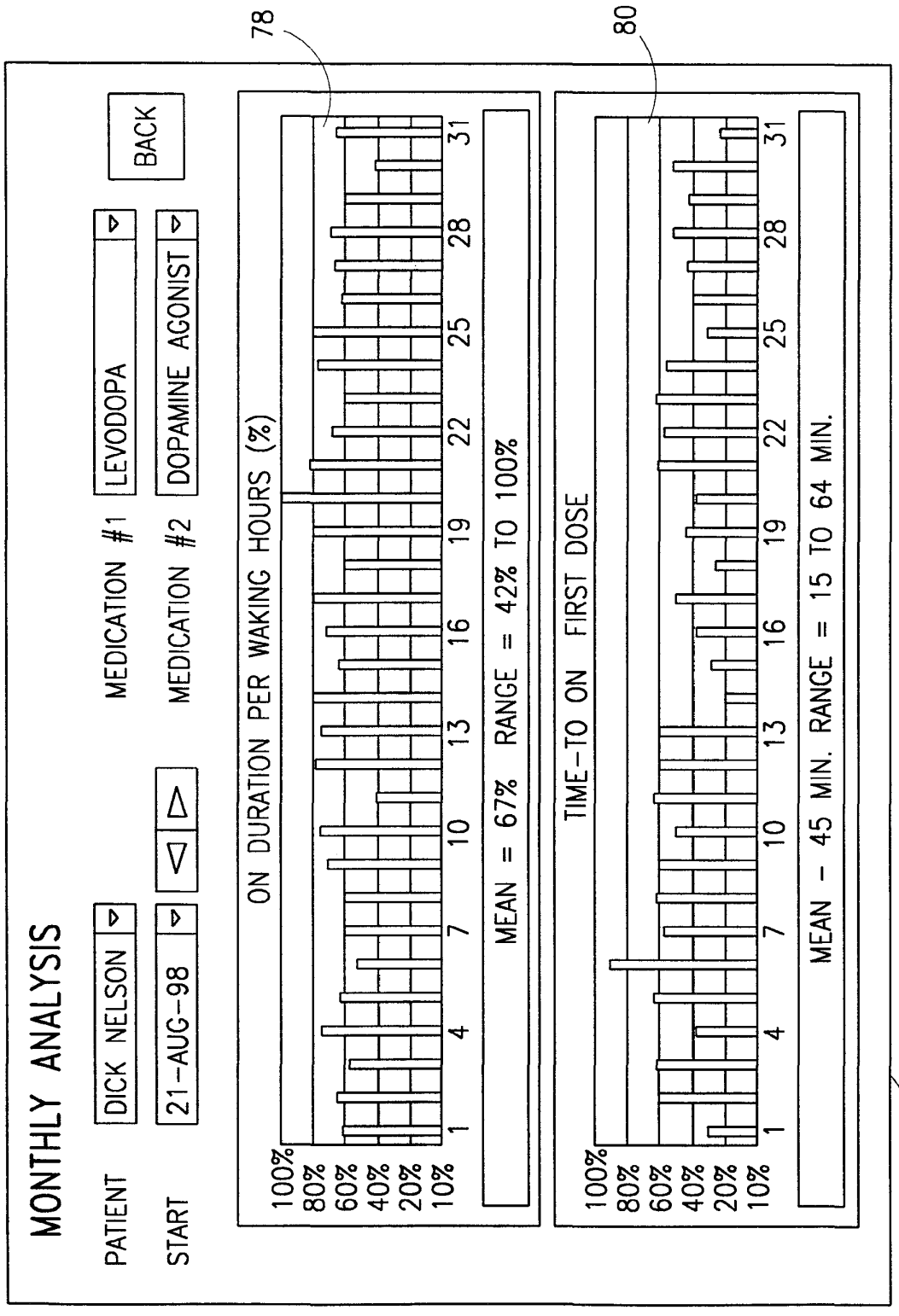
MONTHLY ANALYSIS
PATIENT
DICK NELSON
START
21-AUG-98
MEDICATION #1
LEVODOPA
MEDICATION #2
DOPAMINE AGONIST
BACK
78
ON DURATION PER WAKING HOURS (%)
100%
80%
60%
40%
20%
10%
1 4 7 10 13 16 19 22 25 28 31
MEAN = 67% RANGE = 42% TO 100%
80
TIME-TO ON FIRST DOSE
100%
80%
60%
40%
20%
10%
1 4 7 10 13 16 19 22 25 28 31
MEAN - 45 MIN. RANGE = 15 TO 64 MIN.
70

FIG.3B

6/7

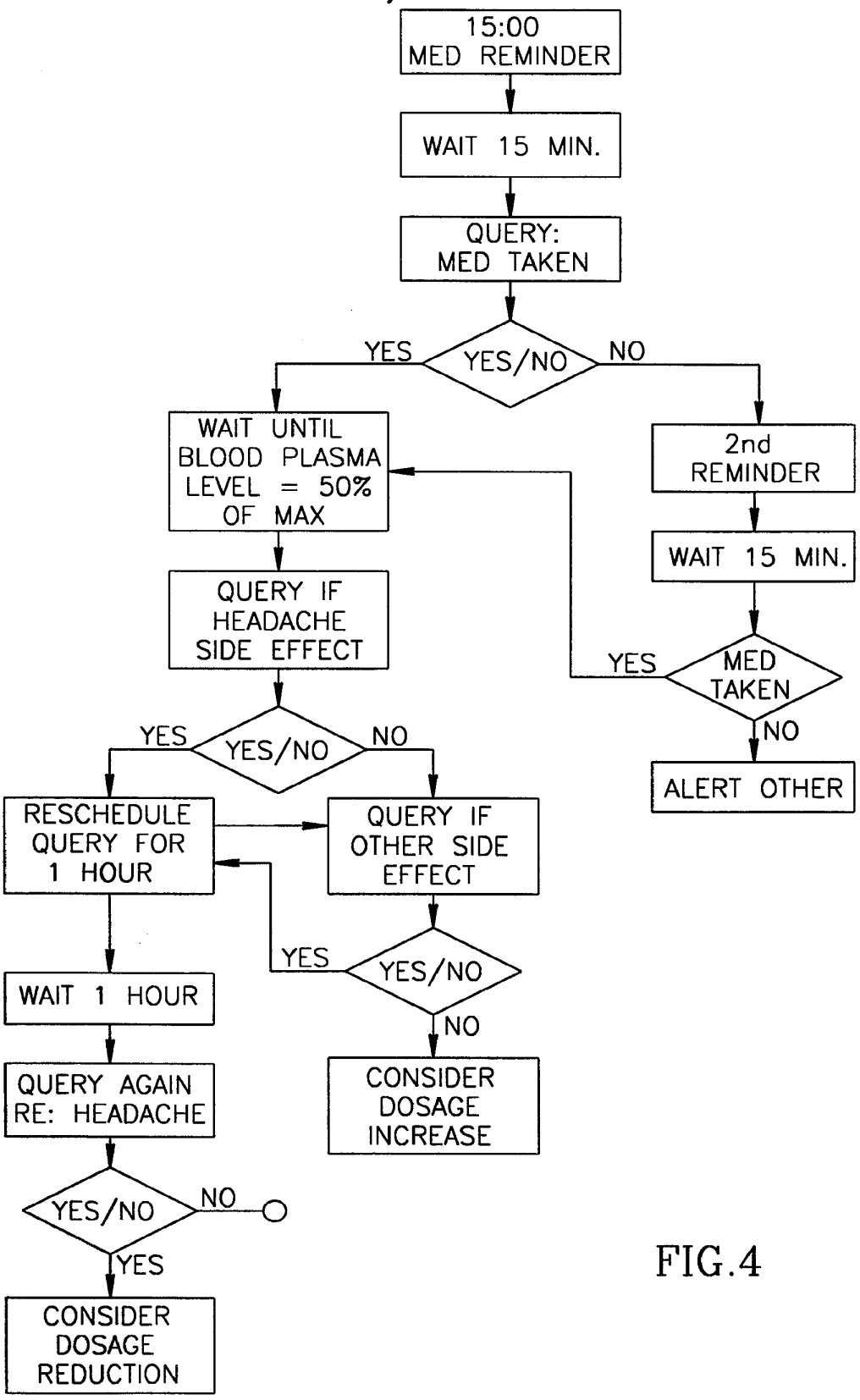
15:00
MED REMINDER
WAIT 15 MIN.
QUERY:
MED TAKEN
YES
YES/NO
NO
WAIT UNTIL
BLOOD PLASMA
LEVEL = 50%
OF MAX
2nd
REMINDER
WAIT 15 MIN.
QUERY IF
HEADACHE
SIDE EFFECT
YES
MED
TAKEN
NO
ALERT OTHER
YES
YES/NO
NO
RESCHEDULE
QUERY FOR
1 HOUR
QUERY IF
OTHER SIDE
EFFECT
YES
YES/NO
WAIT 1 HOUR
NO
QUERY AGAIN
RE: HEADACHE
CONSIDER
DOSAGE
INCREASE
YES/NO
NO
YES
CONSIDER
DOSAGE
REDUCTION

FIG.4

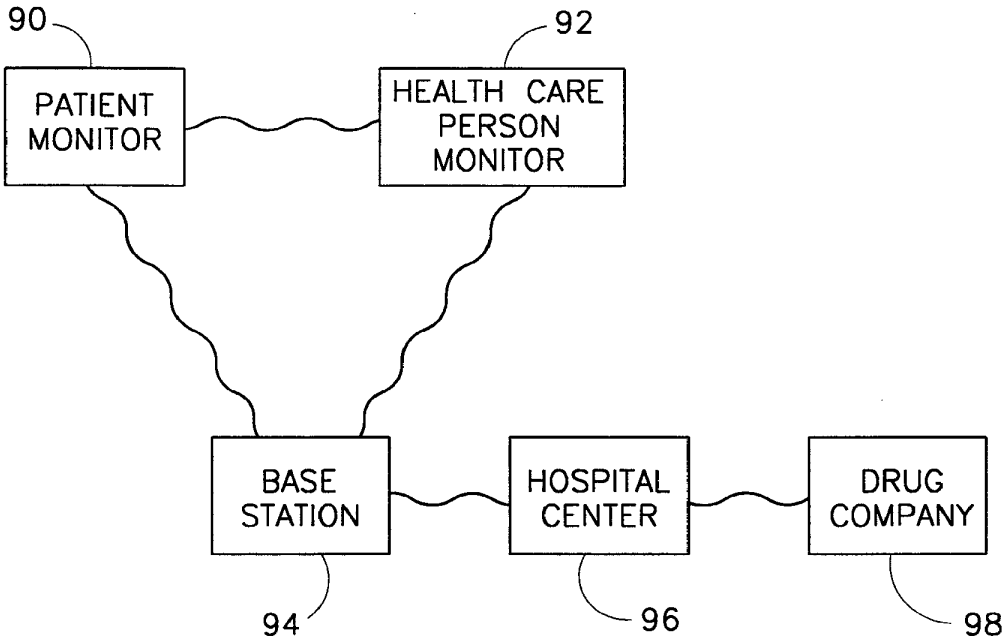
90
92
PATIENT MONITOR
HEALTH CARE PERSON MONITOR
BASE STATION
HOSPITAL CENTER
DRUG COMPANY
94
96
98

FIG.5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL00/00074

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/00
US CL :600/300
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/900, 903, 904; 600/300, 301, 500-504, 519, 522

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

NONE

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

WEST 1.2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,596,994 A (BRO) 28 January 1997, entire document.	1-5, 7, 11-60, 62-70, 73-79 --- 61, 80-82
Y	US 5,722,420 A (LEE) 03 March 1998, entire document.	1-5, 8-10, 71, 72
Y,E	US 6,030,342 A (AMANO et al.) 29 February 2000, entire document.	1-6, 10, 21, 23, 34, 38, 71, 72
Y	US 5,544,649 A (DAVID et al.) 13 August 1996, entire document.	1-5, 8-10, 71, 72

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

* Special categories of cited documents:

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

"E" earlier document published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 MAY 2000	26 JUL 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL ASTORINO Telephone No. (703) 306-9067

Form PCT/ISA/210 (second sheet) (July 1998)★

(12) UK Patent Application (19) GB (11) 2 411 719 (13) A

(43) Date of A Publication 07.09.2005

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(22) Date of Filing: 04.03.2004

(71) Applicant(s):
INOVA DESIGN LTD.
(Incorporated in the United Kingdom)
Catherine's Field, The Spinning Walk,
SHERE, Surrey, GU5 9HN, United Kingdom

(72) Inventor(s):
Leon Thomas Lee Marsh

(74) Agent and/or Address for Service:
Williams Powell
Morley House, 26-30 Holborn Viaduct,
LONDON, EC1A 2BP, United Kingdom

(51) INT CL[7]:
A61B 5/00 // G01K 13/00

(52) UK CL (Edition X):
G1A AAMT AAMX AA1 AG16 AG6 AR6

(56) Documents Cited:
GB 2357576 A **GB 2356052 A**
WO 1990/000366 A1 **US 6138079 A**

(58) Field of Search:
UK CL (Edition X) **G1A**
INT CL[7] **A61B, G01K, G06F**
Other:

(54) Abstract Title: **Hydration monitor**

(57) A hydration monitor includes a thermopile temperature sensor 65 for measuring a subject's core body temperature and a processor within a wristwatch 70. The processor is arranged to accept measurements of the subject's tympanic membrane from the temperature sensor 65 and calculate a hydration level in dependence on changes in the measured core body temperature. A method of measuring hydration is disclosed using change in core body temperature, a subjects weight and applying ambient temperature compensation.

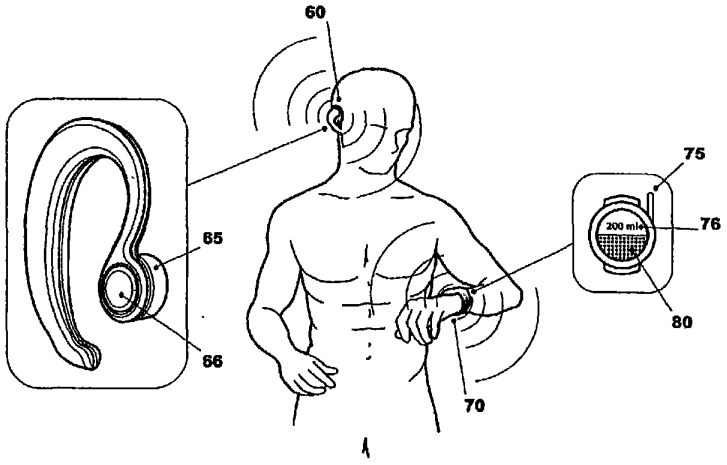

Figure 2

GB 2411719

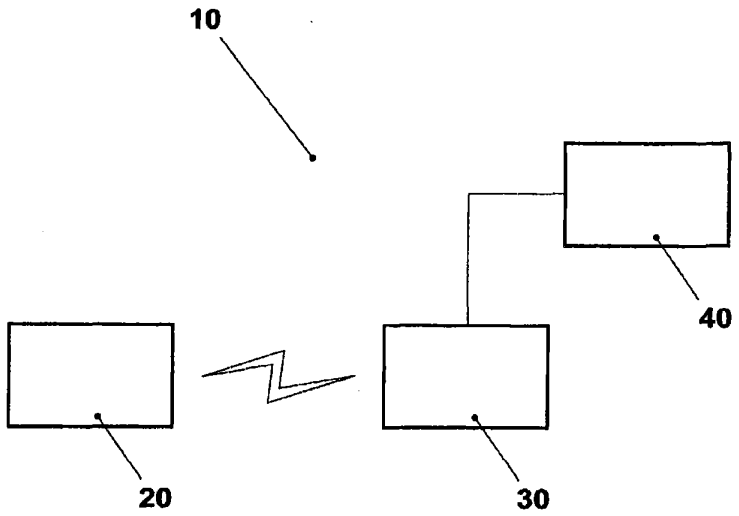

Figure 1

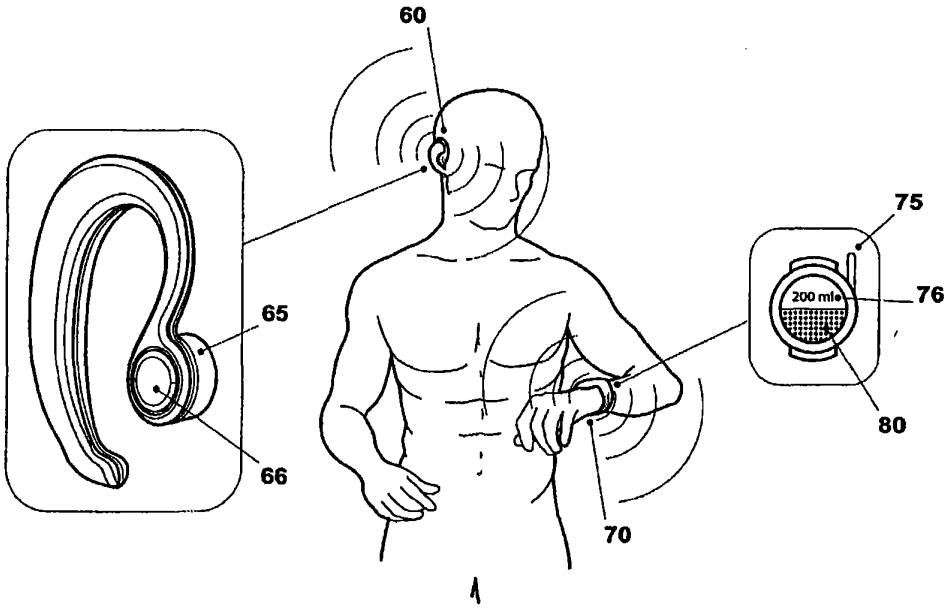

Figure 2

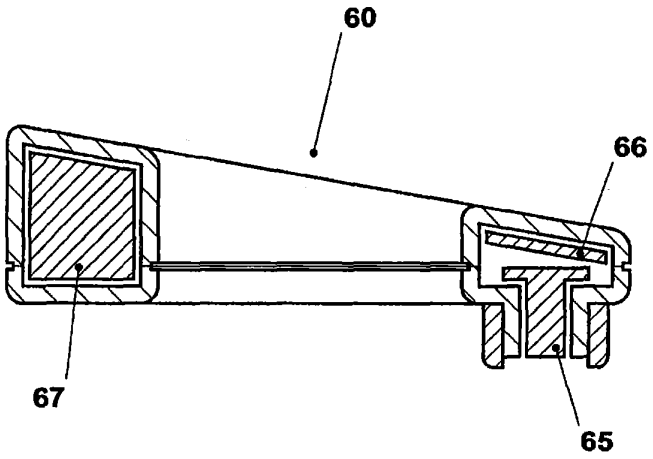

Figure 3

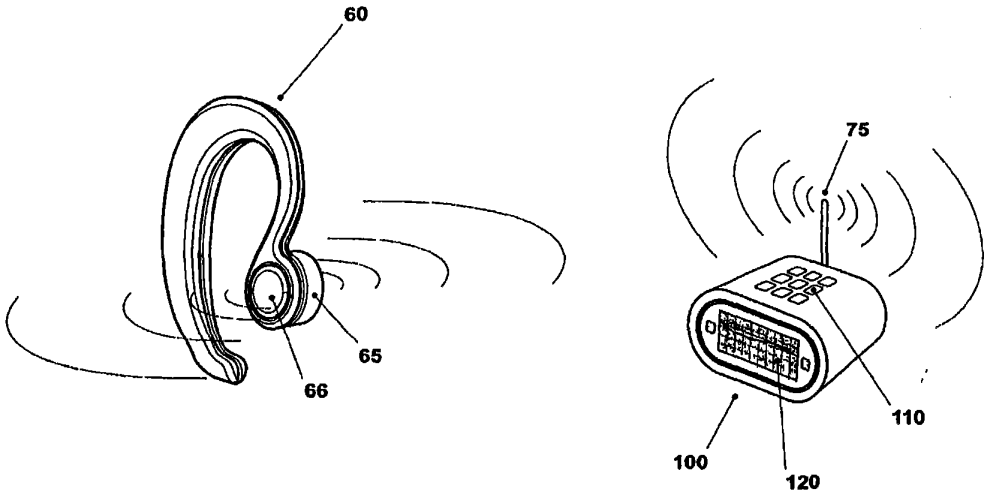

Figure 4

HYDRATION MONITOR

Field of the Invention

The present invention relates to a hydration monitor and in particular to a portable hydration monitor suitable for use during exercise.

Background to the Invention

In sport, particularly athletics, international competition is the ultimate challenge to the various regulatory systems of the body: physiological; biochemical; biomechanical and psychological. The body experiences a great challenge to accommodate the metabolic, thermal and other demands of intense exercise, where this challenge is greatest during endurance events in hot environments.

Since water serves the role of controlling most of the body's regulatory systems, the need for fluid intake during exercise is one of the main concerns, if not the primary concern, for the sportsperson in ensuring they can maintain their maximum sporting potential. The body's management of its *hydration* status is essential in its main roles of regulating body temperature; blood circulation, volume, viscosity and pressure; facilitating muscle movement and for removing waste.

A deficient level of hydration can lead to dehydration, a process referring to a loss of body water, from a state of hyperhydration (greater than normal body water content) to euhydration (normal body water content) or from euhydration downward to hypohydration (less than normal body water content).

In terms of performance, a subject who is just 2% dehydrated can see their performance drop by 20-30%, when compared to being in a state of euhydration. Put in context, this reduction in performance compares to the margin between winning gold and finishing outside of the medals, 7 seconds adrift, in the 1500m in the 2000 Sydney Olympics.

It is important, however, to emphasise that hydration is not the only factor that should be monitored in exercise. Other factors such as energy stores, levels of

electrolytes, fatigue, psychological factors and fitness (reduced fitness in elite athletes is due to insufficient recovery time to regain fitness after sustaining an injury) all have an effect on the performance of the sportsperson, and since the nature of sport is based around precision, an imbalance of any of these factors can lead to underachievement. In extreme cases, it has been known for a deficiency of electrolytes to be fatal, inducing a condition known as hyponatremia. The condition is often brought on through the dilution of sodium content in the blood, where the subject has consumed too much fluid without an adequate replacement of sodium.

It is the occasion where an athlete has the perfect balance of the above factors that they will perform at their lifetime best. A performance such as this requires the mind of the athlete to be in harmony with their body, an occurrence known simply as 'the zone'. It is an altered state of consciousness where the body and mind function automatically.

It is therefore desirable to be able to monitor hydration levels to achieve maximum possible performance. It is particularly desirable to be able to measure hydration levels during exercise to determine the quantity of liquid that should be taken on board to maintain, or reach, ideal hydration levels.

Current systems used for measuring hydration include osmometers and refractometers. Such systems are used by sporting bodies and clubs, although due to the size of the apparatus involved and the nature of the measurements taken, the systems can only be used before, during a stationary phase, or after an exercise is finished.

Osmometers work on the principle of either freezing point depression or vapour pressure (heating and cooling). Osmometers determine the number of water particles in a blood solution obtained from a subject by taking a blood sample. Another form of osmometry measures the concentration of water in a urine sample. In both cases, osmometry is not practical for use during exercise due to the need to collect blood or urine samples.

Refractometers measure the specific gravity of urine samples. By placing a drop of urine on the screen, the concentration of the urine is read off from a scale, the reading being determined by the refraction of light through the urine. The reading on the scale can then be converted into a number of milli-osmos per Kilogram. Again, it is not practical for use during exercise due to the need of a urine sample.

Although portable skin hydration monitors exist, such devices are designed for use in dermatology as a measure for skin moisture. Skin hydration monitors measure moisture levels in the corneocytes (dead skin cells) in the stratum corneum, the outer layers of the skin. In terms of body water, a normal moisture level in the stratum corneum could either be the result of, firstly, body euhydration or, secondly, sweating whilst in a dehydrated state. It therefore follows that skin hydration levels do not reflect body hydration. It is also not possible to determine the level and quantity of sweat, since the water in the stratum corneum reaches a maximum when the body is in a state of euhydration. Therefore it would not be possible to determine any excess sweat that evaporates or drips off the skin.

It has been suggested that blood flow monitors could be adapted to determine fluid status, through monitoring how peripheral blood flow varies during exercise to facilitate the dissipation of heat by the process of sweat and heat exchange. However, it is thought that this would not be a reliable method of monitoring hydration because sweat rates, and therefore blood flow rates, are greater in hot than in cold climates, even for the same level of dehydration. Peripheral blood flow fails to allow for other means of loosing fluid such as increased fluid exchange in cold climates between the environment and breath, where the environment draws moisture from the breath to try and equalise the two moisture levels.

It is understood from medical studies that for every 1% loss in body weight, due to dehydration, heart rates increase by about 7 beats per minute. From this, it may be possible to develop a heart rate monitor to calculate loss in hydration due to an increase in heart rate. However, it is not thought that such a monitor would be particularly accurate as heart rate increases could also be the result of other factors. For example, an increase in speed from one stride to the next would

cause an increase in heart rate, as would anxiety, hormone levels, caffeine intake and the (varying) temperature of the atmosphere.

Bio-electrical Impedance Analysis (BIA) is another technique that has been suggested for use in measuring hydration. BIA analyses the amounts of fat, muscle and water in the body. The measure of hydration is separated into intracellular and extra cellular fluid compartments. BIA works by sending a small current through electrodes attached to the skin, normally on the hand and the foot. The current is sent at two different levels, one that can penetrate the cells of the body and one that cannot. The difference between the two provides an indication of the hydration status, on the theory that fluid facilitates the conduction of current. Currently, BIA results are affected by numerous variables including body position; hydration status; consumption of food and beverages; ambient air and skin temperature; recent physical activity; and the conductance of anything in contact with the skin, other than the electrodes. Thus, BIA lacks the precision and accuracy necessary for hydration monitoring, and it is doubtful that it could ever be adapted for use to determine fluid levels during even gentle exercise.

The present invention seeks to provide means for monitoring hydration in the body during exercise. It was therefore important to understand whether or not the theories behind any existing products could be developed for use in the PHM.

Statement of Invention

According to an aspect of the present invention, there is provided a hydration monitor comprising a temperature sensor for measuring a subject's core body temperature and a processor, the processor being arranged to accept measurements from the temperature sensor and calculate a hydration level in dependence on changes in the measured core body temperature.

In a preferred embodiment of the present invention, a portable monitor is arranged to measure core body temperature non-invasively. Hydration is monitored in real-time device and measurements are output via a display to the user. In this manner, a user can see his or her hydration status during exercise. Through this, it is intended that dehydration is avoided and thus performance maximised.

The portable hydration monitor is particularly useful as it can be used to analyse an athlete's performance to ensure their maximum sporting potential and it can be used to guarantee that the level of hydration is always safe. Thus, severe dehydration can be avoided, something that can ultimately be a risk to health and even survival.

Many internal and external variables (including psychological variables) are relative to the core body temperature that is measured. In particular, by use of a hydration monitor according to an embodiment of the present invention, stitch and stomach discomfort should be prevented.

Embodiments of the present invention could be used by almost all sportsmen/women including the disabled. Embodiments of the present invention could be produced specifically for impact sports. In particular, the earpiece or other temperature sensor would be designed so it could not be damaged by impact or be forced into the ear by jostling/impact.

Preferably, the temperature sensor includes one or more air flow channels allowing the flow of ambient air around the ear canal. Preferably, the temperature sensor is designed to stabily fit within the subject's ear and maintain a constant position. For example, the temperature sensor may be mounted within a malleable rubber member or similar to allow it to adaptably fit within different sized ears of subjects. In another alternative, various sized ear pieces may be provided to permit a subject to select the most appropriate fit.

In a preferred embodiment, the portable hydration monitor includes an earpiece containing a thermopile to measure core body temperature via the tympanic membrane (eardrum) and a wristwatch or other visual and/or audible indicator module that provides the user with real-time feedback and informs the user of how much fluid they must drink to re-hydrate their body to a level of euhydration (normal).

Preferably, the two units communicate wirelessly.

The thermopile detects incident infrared radiation from the tympanic membrane and provides a voltage equivalent to the core body temperature of the subject. This is then fed into an algorithm and the result is output via the indicator module. Preferably, the result is the volume of fluid the subject should consume, in litres or ml to reach and/or maintain a level of euhydration.

Preferably, the monitor seeks to provide the athlete with a realistic accuracy of 0.5-1.0 %BWL (body weight lost in water).

This present invention seeks to provide a portable hydration monitor suitable for monitoring hydration status throughout an exercise, which in turn would educate athletes during training so that the regular and appropriate intake of fluids is automatic, and in competition they can concentrate solely on performing in 'the zone' (they may not be wearing the device during competition).

Various embodiments may eventually be produced to cater for the various needs of:

- athletes (and novice sports person);
- military personnel;
- hospital patients and
- normal public users

The hydration monitor may comprise an earpiece and a remote unit, the temperature sensor being positioned in the earpiece for measuring the core body temperature via the subject's tympanic membrane.

Preferably, the temperature sensor comprises a thermopile.

The earpiece may further comprises a transmitter, the remote unit including the processor, output means and a receiver, the earpiece being arranged to communicate measurements to the processor via the transmitter and receiver, the processor being arranged to provide an indication of the hydration level via the output means.

The transmitter and receiver may communicate wirelessly.

The transmitter and receiver may be transcievers.

The remote unit may comprise a selected one of:

a wristwatch, a personal digital organiser, a mobile telephone, a personal computer or medical diagnostic and/or monitoring apparatus.

The output means may include one or more of a display and a speaker.

The monitor may further comprise a memory for storing hydration level and/or core body temperature over time.

The processor may be arranged to determine a hydration level by the following formula:
[(core body temperature current - core body temperature normal) x subject's weight] / (factor of ambient compensation x 100).

The factor of ambient compensation may be between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject.

The hydration monitor may be arranged to operate repeatedly at predetermined time intervals.

The processor may be arranged to generate an alarm upon determination of a hydration level below a predetermined level.

According to another aspect of the present invention, there is provided a method of measuring hydration of a subject comprising the steps of:

measuring an initial core body temperature of the subject;

measuring a subsequent current core body temperature of the subject;

subtracting the initial core body temperature from the subsequent core body temperature;

multiplying by the subject's weight; and,

dividing by a factor of ambient compensation.

Preferably, the measurements are taken from the subject's tympanic membrane.

Brief Description of the Drawings

Embodiments of the present invention will now be described in detail, by way of example only with reference to the accompanying Figures, in which:

Figure 1 is a block diagram of a hydration monitoring system according to an embodiment of the present invention;

Figure 2 is a schematic diagram of a portable hydration monitor incorporating the system of Figure 1;

Figure 3 is a cross-sectional diagram of an earpiece of the monitor of Figure 2; and,

Figure 4 is a schematic diagram of another system according to an embodiment of the present invention.

Detailed Description

Figure 1 is a block diagram of a hydration monitoring system according to an embodiment of the present invention.

The hydration monitoring system 10 includes a temperature sensor 20, a processor 30 and a display 40.

The temperature sensor 20 is arranged to measure body temperature of a subject and communicate the measured temperature to the processor 30. Upon receipt of the measurement, the processor is arranged to calculate a body water level for the subject and output a corresponding hydration indication to the display 40.

Preferably, the temperature sensor 20 is arranged to measure temperature of a tympanic membrane within one of the subject's ears.

The calculation performed by the processor is carried out at regular intervals as follows:

[(core body temperature current - core body temperature normal) x weight] / (factor of ambient compensation x 100)

The normal core body temperature will have been determined and/or input into the device prior to use. The normal core body temperature is subtracted from the current core body temperature, multiplied by the weight of the subject in kg, (although could also be configured to accept pounds depending on user's preference) and then divided by the factor of ambient compensation. This is then either divided by one hundred to give a measurement in litres or alternatively multiplied by ten to give the measurement in millilitres.

The factor of ambient compensation is valued between 0.1 and 0.23 degrees centigrade, and refers to the increase in the subject's core body temperature for every percent loss of body weight, in temperate and hot climates respectively.

The measurement is the amount of liquid that the subject should drink to achieve euhydration (full hydration).

Figure 2 is a schematic diagram of a portable hydration monitor incorporating the system of Figure 1. Figure 3 is a cross-sectional diagram of an earpiece of the monitor of Figure 2.

The portable hydration monitor includes an earpiece 60 and a wristwatch 70.

The earpiece 60 includes a thermopile 65 positioned to measure core body temperature via the tympanic membrane when inserted into an ear of a subject and a transmitter 66 arranged to communicate temperature measurements to the wristwatch 70.

The transmitter and receiver could be transceivers to allow the two units to talk to each other for initialisation etc.

The wristwatch 70 includes a receiver 75 arranged to receive measurements from the earpiece, a processor to perform the calculations discussed above and a display 76 to provide the subject with feedback on their hydration status. Preferably, the display also informs the user of how much fluid they must drink to re-hydrate their body to a level of euhydration (normal). Preferably, the monitor operates on a substantially real-time basis.

In addition or as an alternative to the display 76, the wristwatch 70 may include an audible indicator 80 to provide the feedback and/or additional alerts. For example, hydration status and feedback may be provided via the display 76 and alerts may be provided via the audible indicator 80 when a predetermined level of dehydration is reached and/or immediate action is necessary.

Preferably, the transmitter 66 and receiver 75 communicate via a wireless data protocol such as BlueTooth ™ or another suitable wireless communication system. The earpiece 60 and wristwatch 70 both include one or more batteries to supply power. At least in the case of the earpiece 60, it is preferred that the battery 67 is rechargeable from within the earpiece via a suitable connection to a power-source or inductive coupling to a power-source. In order to conserve battery power, the transmitter 66 may establish a connection with the receiver only when it is provided with data to transmit. The earpiece 60 and/or wristwatch may include a sleep mode to further conserve power when not in use.

When inserted into a subject's ear canal, the thermopile 65 detects incident infrared radiation from the tympanic membrane and provides a voltage equivalent to the core body temperature of the subject. This is transmitted to the wristwatch and used by the processor to obtain a hydration indication for output via the display and/or audible indicator. Preferably, the result is the volume of fluid the subject should consume, in litres or ml.

Preferably, the wristwatch includes a memory and is connectable to a computer or other remote station, either via a wireless connection or via a docking station or other wired connection to enable the subject to store and subsequently download

core body temperature and/or hydration statistics and other relevant information for subsequent analysis.

If configured by the user, an alert can be set to sound periodically (for example, every minute) to indicate when the temperature is measured. The alert will preferably be generated in the earpiece but it could alternatively be generated from the wristwatch, or both. The alert is intended to remind the subject to look at the display and could also serve to indicate when the display is being updated. If ignored, and the subject becomes dehydrated, the device will sound an alarm, either in the earpiece or wristwatch or both when their hydration status falls below 2% of their level of euhydration.

Depending on the configuration of the wristwatch and earpiece, the user may be given a choice of a sound or vibration alert, or both.

It is understood from medical studies that for every 1% loss in body weight, due to dehydration, heart rates increase by about 7 beats per minute. From this, it may be possible to incorporate a heart monitor into embodiments of the present invention to provide more detailed information on hydration status. The heart rate monitor would be one of the many types currently available and would be arranged to communicate its measurements with the wristwatch in the same manner as the earpiece.

In addition, pressure detecting inserts could be included in an embodiment of the present invention. Such inserts would be inserted into shoes and arranged to measure weight by the pressure applied. This information could then be communicated to the wristwatch which could calculate a weight change due to fluid loss. This method is expected to be unreliable by itself as it is affected by balance distribution over the foot, for example running up or down slopes and speed changes. However, when used in combination with the temperature measurements from the earpiece and possibly the heart rate measurements from the heart rate monitor, accuracy could quite possibly be increased. As an alternative to inserts, a pressure sensor could be integrated into a treadmill or other weight measurement mechanisms could be used.

Various embodiments may eventually be produced to cater for the various needs of:

- athletes (and novice sportsperson);
- military personnel;
- hospital patients and
- normal public users

For example, whilst athletes may be interested in actual numeric levels, the public users may prefer an indicator in the form of a traffic light or similar (for example, green = hydration normal, amber = a little dehydrated, red = very dehydrated). Similarly, hospital patients themselves may not care about hydration levels - the output data could be passed to medical staff for analysis and determination of treatment or it may be fed into a control system for a fluid drip so that the fluid intake for a patient could be automatically adjusted. Some embodiments may include a memory and connection/transmission system so that data can be recorded over time and uploaded onto a computer for more detailed analysis of performance. An example embodiment of the present invention that may be used by medical personnel or trainers of sportsmen is shown in Figure 4 in which the wristwatch is replaced by a base station 100. As the base station need not be portable, it can include a larger display 120 and/or more powerful speaker 110 and a receiver having a greater reception radius to allow the subject to move further from it and still be in contact. The base station could be used as well as a wristwatch so both the sportsman and the trainer is able to see hydration levels – indeed, they may even be provided different types of information depending on their needs.

The device could also be used to prevent athletes reaching their 'ceiling temperature' and having to stop running in, for example, an ultra endurance event where the athlete is performing at their peak for several hours. An indication of extreme temperature would allow the athlete to reduce their speed and continue running instead of having to walk to cool down. This would apply even if there was no water available. Therefore by using the device they don't lose valuable time, and reduce the risk of damaging their body.

The device could also be used to determine cardiac changes in the body, particularly central blood volume, heart rate, stroke volume (these are relative to body water). This will help to prevent a reduction in cardiac output which will reduce the athletes performance, as described below:

In a preferred embodiment, the calculation used to determine hydration status may take account of fat percentage of body weight. This will address discrepancies in use where a subject has a large percentage of fat for body weight. Since fat contains little or no water, the device may not give accurate results for someone with a large percentage of fat content, as for that of a slender person (the slender person will no doubt have a greater percentage of water in their body than the fatter person).

Other factors that may be taken into account during the calculation may include the temperature of the surrounding environment. The magnitude of core temperature elevation can range from 0.1 to 0.23°C for every percent of body weight lost, and is greater during exercise in hot, as opposed to temperate climates.

CLAIMS

1. A hydration monitor comprising a temperature sensor for measuring a subject's core body temperature and a processor, the processor being arranged to accept measurements from the temperature sensor and calculate a hydration level in dependence on changes in the measured core body temperature.

2. A hydration monitor as claimed in claim 1, comprising an earpiece and a remote unit, the temperature sensor being positioned in the earpiece for measuring the core body temperature via the subject's tympanic membrane.

3. A hydration monitor as claimed in claim 2, wherein the temperature sensor comprises a thermopile.

4. A hydration monitor as claimed in claim 2 or 3, wherein the earpiece further comprises a transmitter, the remote unit including the processor, output means and a receiver, the earpiece being arranged to communicate measurements to the processor via the transmitter and receiver, the processor being arranged to provide an indication of the hydration level via the output means.

5. A hydration monitor as claimed in claim 4, wherein the transmitter and reciever communicate wirelessly.

6. A hydration monitor as claimed in claim 4 or 5, wherein the transmitter and receiver are transcievers.

7. A hydration monitor as claimed in any of claims 4 to 6, wherein the remote unit comprises a selected one of:

a wristwatch, a personal digital organiser, a mobile telephone, a personal computer or medical diagnostic and/or monitoring apparatus.

8. A hydration monitor as claimed in any of claims 4 to 7, wherein the output means includes one or more of a display and a speaker.

9. A hydration monitor as claimed in any preceding claim, further comprising a memory for storing hydration level and/or core body temperature over time.

10. A hydration monitor as claimed in any preceding claim, wherein the processor is arranged to determine a hydration level by the following formula: [(core body temperature current - core body temperature normal) x subject's weight] / (factor of ambient compensation x 100).

11. A hydration monitor as claimed in claim 10, wherein the factor of ambient compensation is between 0.1 and 0.23 and is determined in dependence on the temperature of the environment surrounding the subject.

12. A hydration monitor as claimed in any preceding claim arranged to operate repeatedly at predetermined time intervals.

13. A hydration monitor as claimed in any preceding claim, wherein the processor is arranged to generate an alarm upon determination of a hydration level below a predetermined level.

14. A method of measuring hydration of a subject comprising the steps of:
measuring an initial core body temperature of the subject;
measuring a subsequent current core body temperature of the subject;
subtracting the initial core body temperature from the subsequent core body temperature;
multiplying by the subject's weight; and,
dividing by a factor of ambient compensation.

15. A method as claimed in claim 14, wherein the measurements are taken from the subject's tympanic membrane.

16. A hydration monitor as herein described and as illustrated in the accompanying drawings.

17. A method as herein described and as illustrated in the accompanying drawings.

Application No: GB0404961.5 **Examiner:** Robert Price

Claims searched: 1-15 **Date of search:** 7 January 2005

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-	US6138079 A (PUTNAM) See col 1 lines 36-42 and figures 1 & 3
A	-	WO90/00366 A1 (McCARTHY) See page 2 lines 27-33
A	-	GB2357576 A (DRACO) See page 1 lines 16-20
A	-	GB2356052 A (DRACO) See page 3 lines 6-13

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[X] :

G1A

Worldwide search of patent documents classified in the following areas of the IPC[07]

A61B; G01K; G06F

The following online and other databases have been used in the preparation of this search report

EPODOC, JAPIO, WPI

Espacenet

Bibliographic data: JP2003159221 (A) — 2003-06-03

METHOD FOR DETERMINING FEMALE SKIN CONDITIONS

No documents available for this priority number.

Inventor(s): OKABE MIYUKI ± (OKABE MIYUKI)

Applicant(s): SHISEIDO CO LTD ± (SHISEIDO CO LTD)

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Priority number(s): JP20020263885 20020910 ; JP20010279178 20010914

Abstract of JP2003159221 (A)

PROBLEM TO BE SOLVED: To provide a method for objectively determining the skin condition of a subject not depending on the findings by an observer, but based on the data obtained from the subject. ;
SOLUTION: This method is characterized in that subjects to be determined are classified into a plurality of groups on the basis of the severity of their complains, the high or low degrees of a negative sensation index of and a pattern of a circadian rhythm, and their skin conditions are determined by using an attribute of the respective groups as an index. ; COPYRIGHT: (C)2003,JPO

分類	MDQによる感覚閾数	食の補助指数	サーカディアンリズム	CS指標時値 (単mol/ml)
A	小	低	規則	11～20
B	中	中	中途覚醒	8～9
C	大	高	消失	2～5

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(71)出願人　000001959
株式会社資生堂
東京都中央区銀座７丁目５番５号
(72)発明者　岡部　みゆき
東京都品川区西五反田３－９－１　株式会社資生堂ビューティーサイエンス研究所内
(74)代理人　100066644
弁理士　竹内　裕

Ｆターム(参考)　4C038 VB22

(54)【発明の名称】　女性の肌状態の判定方法

(57)【要約】
【課題】　観察者の知見に依らず、被判定者から得たデータに基づいて被判定者の肌状態を客観的に判定することを課題とする。
【解決手段】　被判定者の該当愁訴数の強弱、負の情動指数の高低、サーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする。

分類	MDQによる該当愁訴数	負の情動指数	サーカディアンリズム	CS起床時値(Pmol/ml)
A	小	低	現出	14～20
B	中	中	やや消失	8～9
C	大	高	消失	2～5

【特許請求の範囲】
【請求項１】被判定者の該当愁訴数の強弱に基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする女性の肌状態の判定方法。
【請求項２】被判定者の負の情動指数の高低に基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする女性の肌状態の判定方法。
【請求項３】被判定者のサーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする女性の肌状態の判定方法。
【請求項４】被判定者の該当愁訴数の強弱、負の情動指数の高低及びサーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする女性の肌状態の判定方法。
【請求項５】複数の集合群は、愁訴数の強弱に基づいて少なくとも３つの群に区分されていることを特徴とする請求項１記載の女性の肌状態の判定方法。
【請求項６】複数の集合群は、負の情動指数の高低に基づいて少なくとも３つの群に区分されていることを特徴とする請求項２記載の女性の肌状態の判定方法。
【請求項７】複数の集合群は、サーカディアンリズムのパターンに基づいて少なくとも３つの群に区分されていることを特徴とする請求項３記載の女性の肌状態の判定方法。
【請求項８】複数の集合群は、愁訴数の強弱、負の情動指数の高低及びサーカディアンリズムのパターンに基づいて少なくとも３つの群にそれぞれ区分され、各群は互いに対応した関係で配列され、各群の属性要素の集積を指標として肌状態を判定するようにしたことを特徴とする請求項４記載の女性の肌状態の判定方法。
【請求項９】肌状態に変化のあると判定される集合群に属することとなった被判定者に、クラリセージ油などを用いた処置を施すことにより、被判定者に肌状態の改善をもたらすことを特徴とする女性の肌状態の改善方法。
【請求項１０】肌状態に変化のあると判定される集合群に属することとなった被判定者に、肌状態の改善を目的とした処置を施すために使用されることを特徴とするクラリセージ油。
【発明の詳細な説明】
【０００１】
【発明の属する分野】この発明は、女性の肌状態の判定方法に関する。
【０００２】
【従来の技術】従来、女性の７０％以上に月経周期に伴い様々な症状を呈する月経前症候群（ＰＭＳ）と呼ばれる症状が存在することが知られている。月経前症候群の発生には心理学的要因や社会学的要因などの要因が相互に関わっており、各人の発生要因を的確に捉えることは困難であるが、その症状には不安や憂鬱などの精神的症状や、腹痛やむくみなどの身体的症状がある。
【０００３】また、肌状態の判定に際しては、皮膚の表面を拡大鏡等を用いて観察し、観察者が自己の知見に基づいて肌状態を判定する手法が採られている。しかし、月経前症候群の身体的症状の一つである肌において生ずる症状に着目し、月経周期と連関させて肌状態を判定する方法は、従来行われていない。
【０００４】
【発明が解決しようとする課題】この発明は、観察者の知見に依らず、被判定者から得たデータに基づいて被判定者の肌状態を客観的に判定することを課題とする。
【０００５】
【課題を解決するための手段】上記課題を解決するためにこの発明が採った手段は、被判定者の該当愁訴数の強弱、負の情動指数の高低、サーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする。
【０００６】また、複数の集合群は、愁訴数の強弱、負の情動指数の高低、サーカディアンリズムのパターンに基づいて少なくとも３つの群に区分されていることを特徴とする。
【０００７】また、複数の集合群は、愁訴数の強弱、負の情動指数の高低及びサーカディアンリズムのパターンに基づいて少なくとも３つの群にそれぞれ区分され、各群は互いに対応した関係で配列され、各群の属性要素の集積を指標として肌状態を判定するようにしたことを特徴とする。
【０００８】また、肌状態に変化のあると判定される集合群に属することとなった被判定者に、所要の処置を施すことにより、被判定者に肌状態の改善をもたらし、また、その処置にはクラリセージ油などを用いることを特徴とする。
【０００９】
【発明の実施の形態】この発明の好ましい実施の形態を、以下に詳細に説明する。この発明は、(i)被判定者の該当愁訴数の強弱、(ii)負の情動指数の高低、(iii)サーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定することを特徴とする。まず、被判定者の該当愁訴数とは、月経前症候群（ＰＭＳ）の発症の程度を調査する月経随伴症状質問紙（ＭＤＱ）などにより被判定者にアンケート形式で愁訴について質問し、そのうち該当すると回答された愁訴の合計数である。なお、該回答は即時的回答であることが望ましい。また、負の情動指数とは、調査時の被判定者の心理状態を調査する情動及び覚醒に関する質問紙により被判

定者にアンケート形式で質問し、後に述べる各質問項目のうちの「負の情動」と呼ばれる項目に該当した合計数である。また「サーカディアンリズム」は、後述の通り唾液中コルチゾール数値の経時的なグラフから把握されるものであるが、かかる唾液中コルチゾール（ＣＳ）は、様々なストレス状態の研究に用いられるいわゆるストレスホルモンの一つであり、月経前症候群による心理状態をストレス状態に近似した心理状態として捉えて、本発明の要素として用いるものである。

【００１０】また、この発明は上記判定を行った結果、肌状態に変化のある（肌荒れ状態にある）と判定される集合群に属することとなった被判定者に、クラリセージ油などを用いた処置を施すことにより、被判定者の肌状態の改善をもたらすことを特徴とする。

【００１１】

【実施例】この発明に係る肌状態の判定方法は、(ｉ)被判定者の該当愁訴数の強弱、(ii)負の情動指数の高低、(iii)サーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態を判定するものであるが、複数の集合群は三群であることが好ましく、ここでは被判定者をＡ，Ｂ，Ｃの三群に分けてその肌状態を判定する。以下各評価項目について詳細に説明する。

【００１２】前記(ｉ)のＭＤＱによる被判定者の該当愁訴数の調査は月経の前・中・後の計３回行い、その質問内容は、以下に示す８の愁訴群に分類される各愁訴の有無を問うものである。まず第１群の「痛み」に分類される愁訴としては、肩や首がこったり、筋肉が痛くなる、頭が痛い、下腹部が痛い、腰が痛い、疲れやすい、体が痛い、等である。第２群の「集中力の低下」に分類される愁訴としては、眠れない、もの忘れしやすい、考えがまとまらない、判断力が鈍る、集中力が低下する、気が散る、指を切ったり皿を割ったり失敗が多くなる、動作がぎこちなくなる、等である。第３群の「自律神経失調」に分類される愁訴としては、めまいがしたり、ボーッとなったりする、冷や汗が出る、吐き気がする、顔が火照る、等である。第４群の「行動の変化」に分類される愁訴としては、勉強や仕事への根気がなくなる、居眠りをしたり、ふとんから起き出せなくなる、人との付き合いを避けたくなる、出不精になる、勉強や仕事の能率が低下する、等である。第５群の「水分貯留」に分類される愁訴としては、体重が増えてくる、肌が荒れたり、吹き出物が出たりする、お乳が痛い、腹部・乳房・足にむくみがある、等である。第６群の「否定的情緒」に属する愁訴としては、ちょっとしたことで泣いたり、泣きたくなる、さびしくなる、不安になる、落ち着かない、いらいらしたり、怒りっぽい、気分が変わりやすかったり、動揺する、憂鬱になる、緊張しやすくなる、等である。第７群の「気分の高揚」に分類される愁訴としては、やさしい気分になる、素直になる、興奮しやすい、満たされた気持ちになる、活動的になる、等である。第８群の「コントロール」に分類される愁訴としては、息苦しい、胸が締め付けられる感じ、耳鳴りがする、動揺する、手足がしびれる、ぼやけて見えたり、目がかすむ、等である。

【００１３】前記(ii)の情動及び覚醒に関する質問紙による負の情動指数の調査は、１日計５回、起床時、１０時、１１時４０分、１４時、１６時に行い、好ましくは各月経周期ごとに調査を行う。なお、被判定者が月経期、卵胞期、排卵期、黄体期のいずれの月経周期に属しているかについては、月経周期の判定法として従来知られている基礎体温と女性ホルモン測定による判定法を用いて判定するのが好ましい。該質問紙による質問内容は、以下に示す覚醒に関する４項目と情動に関する５項目に分類される心理状態の有無を問うものである。まず覚醒の第１項目「エネルギー覚醒＋」に分類される心理状態としては、機敏な、活動的な、気力に満ちた、エネルギッシュな、等である。覚醒の第２項目「エネルギー覚醒－」に分類される心理状態としては、無気力な、生気がない、気分ののらない、等である。覚醒の第３項目「緊張覚醒＋」に分類される心理状態としては、緊張した、気が休まらない、落ち着かない、等である、覚醒の第４項目「緊張覚醒－」に分類される心理状態としては、くつろいだ、落ち着いた、ゆったりした、等である。情動の第１項目「恐怖」に分類される心理状態としては、こわい、おびえている、不安な、びくびくしている、等である。情動の第２項目「怒り」に分類される心理状態としては、腹が立っている、いらいらしている、不機嫌な、気が立っている、等である。情動の第３項目「悲しみ」に分類される心理状態としては、落ち込んでいる、気が滅入った、ふさいでいる、悲しい、等である。情動の第４項目「嫌悪」に分類されている心理状態としては、うんざりした、不快な、嫌悪感がある、嫌な、等である。情動の第５項目「喜び」に分類される心理状態としては、楽しい、さわやかな、快い、満ち足りた、等である。このうち、情動の第１～４項目「恐怖」「怒り」「悲しみ」「嫌悪」を「負の情動」といい、本発明ではこの「負の情動」に該当した指数を評価の際に用いる。

【００１４】前記(iii)のサーカディアンリズムに関する唾液中コルチゾール（ＣＳ）濃度の数値の測定は、前記(ii)の情動及び覚醒に関する質問紙による負の情動指数の調査と同様、１日計５回、起床時、１０時、１１時４０分、１４時、１６時に測定し、測定方法はＲＩＡ法又はＨＰＬＣ法を用いることが好ましい。

【００１５】図１は起床時、１０時、１１時４０分、１４時、１６時に一日計５回測定した被判定者の唾液中コルチゾール（ＣＳ）濃度の数値をグラフ化したものの例である。図１で示したグラフは起床時に一番高い数値を示し、時間の経過に従って数値が低くなっている。この

時間の経過に伴う唾液中コルチゾール濃度の数値の減少を「サーカディアンリズム」という。図2～4は、各月経周期における起床時、10時、11時40分、14時、16時に一日計5回測定した被判定者の唾液中コルチゾール（CS）濃度の数値をグラフ化したものの例である。図2のグラフにおいては、いずれの月経周期においても、時間の経過に伴い唾液中コルチゾール濃度の数値が減少する「サーカディアンリズム」が明確に現れていることが理解できる。これに対し、図3の各グラフにおいては、いずれかの月経周期、例えば本グラフでは月経期、卵胞期において、サーカディアンリズムが崩れており、更に図4の各グラフにおいてはいずれの月経周期においてもサーカディアンリズムが現れていないことが理解できる。なお、月経周期については被判定者の基礎体温又は女性ホルモンを測定することにより判別する。

【0016】ここで上記(i)被判定者の該当愁訴数の強弱、(ii)負の情動指数の高低、(iii)サーカディアンリズムのパターンにより、被判定者をA，B，Cの三群に分ける。図5を参照して、上述のMDQにより該当した愁訴が少なく、負の情動指数が低く、月経周期のいずれの時期においても図2に見られるようなサーカディアンリズムが明確に現出している（目安としてCS起床時値14～20Pmol／ml）被判定者をA群とする。また、MDQにより該当した愁訴数が半数程度、負の情動指数が半数程度、図3に見られるような月経周期のいずれかの時期においてサーカディアンリズムが消失している（目安としてCS起床時値8～9Pmol／ml）被判定者をB群とする。また、MDQにより該当した愁訴数が多く、負の情動指数が高く、図4に見られるようないずれの月経周期においてもサーカディアンリズムが消失している（目安としてCS起床時値2～5Pmol／ml）被判定者をC群とする。なお各群への選別は、既述のように被判定者の該当愁訴数、負の情動指数、サーカディアンリズムのすべての要素に基づいて行うことが最も好ましいが、3つの要素のすべてを用いず、要素の1つあるいは2つのみを用いて被判定者を各群に選別することも可能である。

【0017】そして各群に分類された被判定者の肌状態について、A群の被判定者は月経周期による変化なし、B群の被判定者は黄体期において変化して肌荒れを起こし、C群の被判定者は黄体期の変化（肌荒れ）が顕著である、というように判定を行う。

【0018】次に、C群に分類され、黄体期の変化（肌荒れ）が顕著である、と判定された被判定者に対する処置について説明する。当該被判定者に対しては、クラリセージ油などを用いた処理、例えば、クラリセージ油などを浴槽内の湯に数滴入れて入浴させ、又はアロマポットを用いてクラリセージ油などを内容分に含む香料を鼻腔から吸入させる等の処置を行う。ここでクラリセージ油は、クラリセージの花の部分と花の咲いた茎の先端部分を蒸留して精油されたもので、これを使用するとリラクセーション効果があることが知られているため、かかる効果から被判定者におけるサーカディアンリズムの現出、ひいては肌状態の改善という派生効果が現れることを企図して用いるものである。なお、ここでの処理はリラクセージ油などを用いることに主眼が置かれるので、クラリセージ油などを用いた処置の方法は上記入浴や鼻腔からの吸入に限られるものではない。

【0019】

【適用例】上述のA・B・Cの各群に属する被判定者に対し、その皮膚について、経皮水分損失量（TEWL）、皮脂量（LP）の測定を行った。図6は月経周期のうち黄体期と卵胞期の経皮水分損失量（TEWL）の平均値の差をグラフ化したものである。また、図7，8は同じく黄体期と卵胞期の皮脂量（LP）の平均値の差をグラフ化したものであり、図7は被判定者の頬の皮膚を、図8は顎の皮膚を測定したものである。これらのグラフによれば、黄体期とPMSがほとんど存在しない卵胞期とのTEWL及びLPの数値の差が一番大きいのがC群の被判定者であり、次いでB群、そして一番小さいのがA群の被判定者である。これより各月経周期間において肌状態に一番差があるのがC群の被判定者であり、次いでB群、そして一番差がないのがA群の被判定者であることが理解できる。なお各グラフにおいて、TEWLの数値の単位はg／m^2 h、LPの数値の単位は、皮脂の量が多いほど透過濃度が上昇するフィルムを当てた際のフィルムの透過濃度である。

【0020】次に、C群に属することとされた被判定者に対し、クラリセージ油などを用いた処置を行い、唾液中コルチゾール（CS）濃度を測定した。ここでは当該被判定者に対するクラリセージ油を用いた処置として、PMSが発現する時期である月経開始約1週間前からクラリセージ油などを浴槽内の湯に数滴入れて入浴させると共に、就寝前から就寝中においてアロマポットを用いてクラリセージ油などを内容分に含む香料を鼻腔から吸入させる処置を行った。図9は、C群に属する被判定者における上記クラリセージ油などを用いた処理前と処置後の唾液中コルチゾール（CS）濃度の数値をグラフ化したものであり、測定は、起床時、10時、11時40分、14時、16時の一日計5回測定した。このグラフによれば、処置前のグラフ(a)においては図4と同様にサーカディアンリズムが消失してるのに対し、処置後のグラフ(b)においては図2と同様にサーカディアンリズムが明確に現れており、被判定者における肌状態が改善されていることが理解できる。

【0021】

【発明の効果】この発明によれば、被判定者の該当愁訴数の強弱、負の情動指数の高低、サーカディアンリズムのパターンに基づいて、被判定者を複数の集合群に選別し、各集合群の属性要素を指標として被判定者の肌状態

を判定することができるから、従来観察者の知見に委ねられていた肌状態の判定を客観的に行うことが可能となる。

【００２２】また、かかる判定方法により黄体期の変化（肌荒れ）が顕著であると判定された被判定者に対し、肌状態を改善させることが可能となる。

【図面の簡単な説明】

【図１】サーカディアンリズムの一例を示すグラフ

【図２】サーカディアンリズムが現出した被判定者の唾液中ＣＳ数値のグラフ

【図３】サーカディアンリズムがやや消失した被判定者の唾液中ＣＳ数値のグラフ

【図４】サーカディアンリズムが消失した被判定者の唾液中ＣＳ数値のグラフ

【図５】被判定者の該当愁訴数、負の情動指数、サーカディアンリズムと各集合群の対応関係を表した図

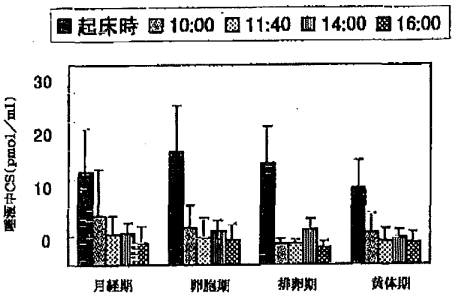
【図６】黄体期と卵胞期の経皮水分損失量（ＴＥＷＬ）の平均値の差を示したグラフ

【図７】類の皮膚における黄体期と卵胞期の皮脂量（ＬＰ）の平均値の差を示したグラフ

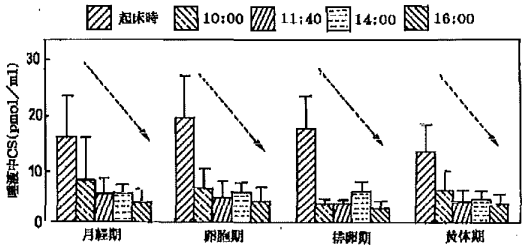
【図８】顎の皮膚における黄体期と卵胞期の皮脂量（ＬＰ）の平均値の差を示したグラフ

【図９】クラリセージ油を用いた処置前と処置後の被判定者の唾液中ＣＳ数値のグラフ

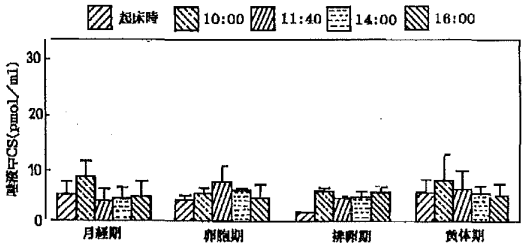
【図１】



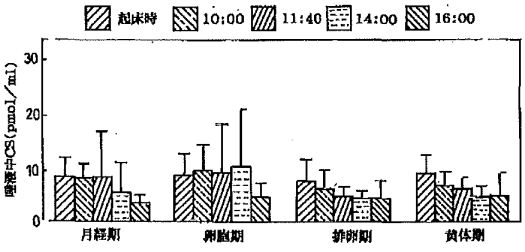
【図２】



【図４】



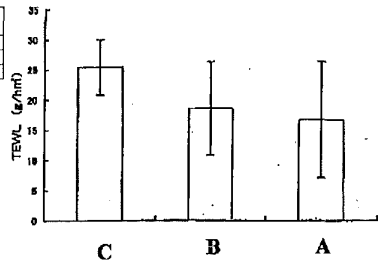
【図３】



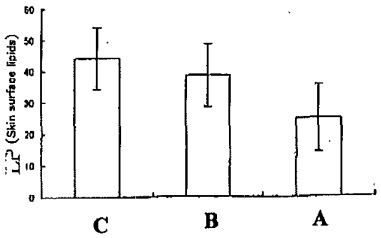
【図５】

分類	MDQによる該当愁訴数	負の情動指数	サーカディアンリズム	CS起床時値 (Pmol/ml)
A	小	低	現出	14～20
B	中	中	やや消失	8～9
C	大	高	消失	2～5

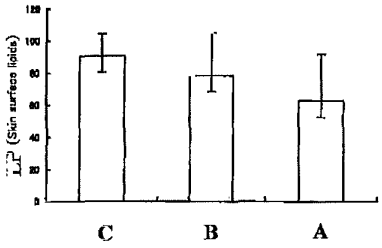
【図６】



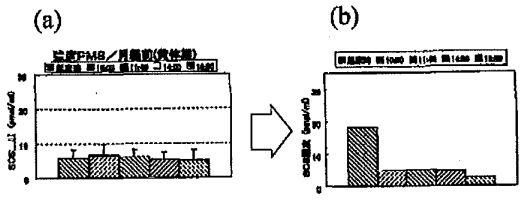
【図7】



【図8】



【図9】



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Bibliographic data: JP2004283523 (A) — 2004-10-14

INSTRUMENT FOR ANALYZING AUTONOMIC NERVOUS RHYTHM

No documents available for this priority number.

Inventor(s): USHIYAMA YOSHIHISA; OKAJIMA HIDEO; ARAI YOSHIAKI ± (USHIYAMA YOSHIHISA, ; OKAJIMA HIDEO, ; ARAI YOSHIAKI)

Applicant(s): USHIYAMA YOSHIHISA; OKAJIMA HIDEO; ARAI YOSHIAKI ± (USHIYAMA YOSHIHISA, ; OKAJIMA HIDEO, ; ARAI YOSHIAKI)

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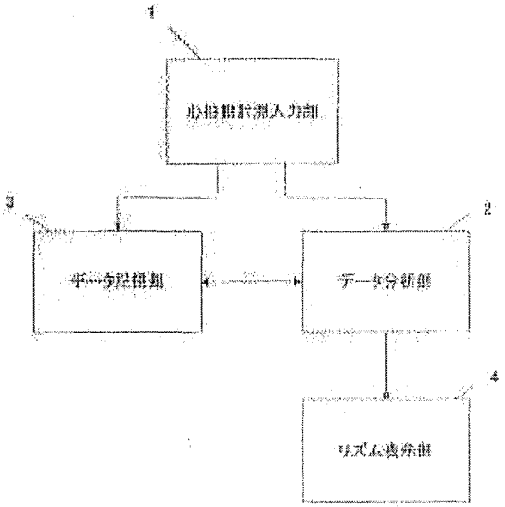
Abstract of JP2004283523 (A)

PROBLEM TO BE SOLVED: To reveal correlation between sympathetic nerve and parasympathetic nerve functions for determining the circadian rhythm of an autonomic nervous system by detecting autonomic nervous rhythm inherent in heart beat change in 24 hours. ; SOLUTION: A heart beat measurement input part 1 measures the number of heart beats for 24 hours and time sequential data at RR interval. A data analyzing part 2 performs FFT processing and reverse FFT processing. Then the autonomic nervous rhythm in a 24-hour period inherent in the heart beat change is determined and evaluated. ; COPYRIGHT: (C) 2005,JPO&NCIPI



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(71)出願人　503151409
牛山　喜久
長野県松本市笹部１丁目２番３４号
(71)出願人　503151432
岡島　英男
長野県長野市富竹８０―１２
(71)出願人　503152451
荒井　善昭
長野県長野市若槻団地３７２―１６
(72)発明者　牛山　喜久
長野県松本市笹部１丁目２番３４号
(72)発明者　岡島　英男
長野県長野市富竹８０－１２
(72)発明者　荒井　善昭
長野県長野市若槻団地３７２－１６
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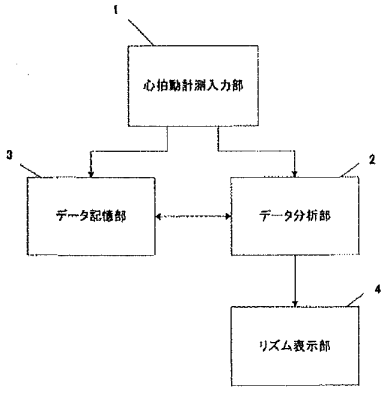
(54)【発明の名称】自律神経リズム解析装置

(57)【要約】
【課題】２４時間の心拍変動に内在する自律神経リズムを検出して、自律神経系のサーカディアンリズムを決めている交感神経及び副交感神経機能の相互関係を明らかにする。
【解決手段】２４時間の心拍数やＲＲ間隔の時系列データを心拍動計測入力部１で測定し、データ分析部２でＦＦＴ及び逆ＦＦＴ処理を行って、心拍変動に内在する２４時間周期の自律神経リズムを決定し評価する。
【選択図】　図１



【特許請求の範囲】
【請求項1】
連続記録した２４時間の心拍数変動（以下、心拍変動という）の時系列データから、自律神経系が有する２４時間を一周期とする概日リズムまたはサーカディアンリズム（以下、自律神経リズムという）を抽出・確定し、その自律神経リズムの構成要素である交感神経及び副交感神経の各々の活動状態を分離して評価できる自律神経リズム解析装置。
【請求項2】
２４時間の心拍変動記録としてアナログ及びデジタルのいずれの信号形式でも入力可能な心拍動計測入力部、入力されたそれらの２４時間心拍変動の時系列原データ並びにその解析結果である自律神経リズム等を保存するデータ記憶部、２４時間の心拍変動データをスペクトラム分析して心拍変動に内在している０．５Ｈｚ以下の超低周波変動成分を求めて自律神経リズムを決定するデータ分析部、また解析した自律神経リズムを時系列変動曲線として出力するリズム表示部とから構成されることを特徴とする請求項１記載の自律神経リズム解析装置（図１）。
【請求項3】
自律神経リズム解析装置のデータ分析部における超低周波変動成分である自律神経リズムの変動曲線の検出は、高速フーリェ変換（ＦＦＴ）法によるスペクトル分析と逆高速フーリェ変換（ＩＦＦＴ）法とから成る周波数領域と時間領域の直列処理アルゴリズムを有し、スペクトル周波数成分を最高３次～５次の高調波になるようにデジタルフィルタを最適化する手段を有した請求項１記載の自律神経リズム解析装置。
【請求項4】
自律神経リズム解析装置の心拍動計測入力部の入力データ形式としては、連続２４時間の心電図、圧脈波及び光電脈波といったアナログ信号から、２４時間の心拍数値や心電図ＲＲ間隔の変動といったデジタル信号までいずれの形式のデータも入力可能とした請求項１記載の自律神経リズム解析装置。

【発明の詳細な説明】
【０００１】
【産業上の利用分野】本発明では、ヒトの心臓の拍動現象（心拍数とも）の長時間連続記録から、その心拍変動に内在する基本的なリズム、すなわち自律神経リズムを解析・抽出して、このリズムを評価することで、そのリズム形成に大きな影響を与え心拍変動を主体的に調節している自律神経系の活動状態を正確且つ詳細に把握することができる。またこの２４時間周期の自律神経リズムから、自律神経系の２つの構成要素である交感神経と副交感神経の機能状態をそれぞれ分けて評価できる点もこの自律神経リズム解析装置の大きな特色である。よって本発明の主眼は、医学分野において今後のきわめて重要な課題となるであろう「こころの病」に注目し、それを発症源とする各種疾患の増加に対処すべき一端を担うものである。特に現代病の代表といわれる「ストレス」に起因した自律神経失調症候群をはじめ自律神経機能障害を有する各種疾患の診断・治療に有益な情報を提供し役立てることができる。
【０００２】
【従来の技術】長時間の心拍変動記録から心臓の拍動リズムの異常（＝不整脈）を検査・診断する医療機器として、すでにホルター（Ｈｏｌｔｅｒ）心電図解析装置なるものがある。このホルター心電図とは、２４時間～４８時間のヒト心電図波形を磁気テープ、磁気カード及びＩＣカードに連続記録したものである。その長時間記録の時系列心電図を解析することにより、この記録期間内に発生した心電図波形の異常（狭心症例）やリズムの異常（不整脈例）等を発生時間とともに検出し、心臓病の診断や治療効果の判定に役立っている。
【０００３】心拍変動と自律神経機能との関係を説明する指標の１つに心電図のＲＲ間隔の変動係数（ＣＶＲＲ：％）があり、安静臥床３０分後の連続１００個の心電図ＲＲ間隔の記録から容易に求めることがでる。これは特に副交感神経機能の有用な指標として利用されており、今までの研究からの参考値として若年者で５．０±１．５％、老年者で３．

１±１．３％のように、加齢とともにＣＶＲＲ値は低下することが知られている（文献：自律神経機能検査（第２版），ｐｐ４２，自律神経学会編，１９９７）。またこのＣＶＲＲを上述のホルター心電図から評価することも一般化されており、２４時間内の任意の時刻の１００個の心電図からＣＶＲＲを容易に求めることができ、それをさらに長時間観察に拡大することで２４時間にわたる副交感神経活動の評価に応用されている。

【０００４】心拍変動及び血圧の長時間同時記録（２４～４８時間記録）から、数学的なｃｏｓｉｎｅ　ｆｉｔｔｉｎｇ法や統計的な最大エントロピー法を用いて、心拍数・血圧の時系列変動に内在する概日リズム及びその周期性の有無について検討した例も多い（文献：呼と循，３８：６２１－６２８，１９９０）。その結果心拍数の時系列変動には明確な１周期２４時間の概日リズムが存在することが確認された。また海外旅行時の心拍数の概日リズムの検討の結果、東回りではリズムの周期は短縮し、西回りでは延長するといった時差の影響とも考えられる明らかな概日リズム周期の変化が注目されている。

【０００５】最近の２４時間心電図のＲＲ間隔のスペクトル分析では、２４時間の心拍変動リズムを周波数領域から明らかにしようとする試みも多くある（その１つの文献：Ｈｅａｒｔ　Ｒａｔｅ　Ｖａｒｉａｂｉｌｉｔｙ，Ｃｉｒｃｕｌａｔｉｏｎ：９３，１０４３－１０６５，１９９６）。その結果、心拍変動の概日リズムには低周波変動成分（ＬＦ：０．０４～０．１５Ｈｚ領域）と高周波変動成分（ＨＦ：０．１５～０．４０Ｈｚ領域）の２成分が存在し、各々の成分と自律神経の機能との関係が明らかにされつつある。すなわち、ＨＦは副交感神経活動を反映する指標とされ、ＬＦは交感・副交感神経の両活動を意味する指標とされ、ＬＦをＨＦで除した値（ＬＦ／ＨＦ）は交感神経活動を反映する指標として各生理的学意義が確立されつつあるが、明確な結論には至っていない。

【０００６】一方この２４時間周期の心拍変動は一日における人間の活動状態とよく相関する面を有し、医学的には交感神経と副交感神経の両神経支配のバランスを反映している。よってその概日リズム（自律神経リズム）には、両神経系の調節結果の変動が含まれていることが重要な意味を持つことになる。すなわち心拍変動は、交感神経が優位になる（緊張が高まる）と心拍数は増加し、逆に副交感神経が優位になると（緊張が高まる）と心拍数は減少するように修飾される。このように心拍変動は交感・副交感の両神経の相反的作用を受けており、両神経のうちどちらの神経支配が優位に働くかによって心拍数の概日リズムの変動が調節される。しかし、この点に関する詳細な検討は今まで皆無といってよく、心拍数からみた自律神経の概日リズム形成に直接的に関係する交感神経及び副交感神経の各々の支配様式を分離して分析する自律神経リズム解析装置の実用化がこの特許である。

【０００７】

【発明が解決しようとする課題】連続２４時間の心拍変動記録の時系列データから、超低周波変動成分（０．５Ｈｚ以下の変動成分）を取り出して自律神経リズムの変動曲線を求めるが、本特許請求項目の１つであるその抽出方法でこの明細書内に記載したようなＦＦＴ及びＩＦＦＴを用いたリアルタイムデジタルフィルター方式は技術的にもすでに確立している。自律神経リズムの変動曲線に内在する交感神経及び副交感神経の寄与度の分析は、本特許の他方の重要課題である。その解決策は、２４時間周期の自律神経リズム変動曲線の上に２つのクロスポイントを決め、両クロスポイント内及び外の時間を確定し、その２つの時間相を覚醒や睡眠といった生体リズムにおける昼夜の活動状態と対応させることである。その結果、昼間を交感神経優位期、夜間を副交感神経優位期と決め、この２つのクロスポイント時刻を両者の切替点と定義して２つの時刻の差から自律神経リズムの健常・異常を判断するものである。

【０００８】本発明では、２４時間周期の自律神経リズム変動曲線上における２つのクロスポイントの決定方法が本特許のキーポイントである。自律神経リズムの変動曲線の周期及び振幅値には個体差があって自律神経リズムは様々なパターンを呈するため個人毎のクロスポイントの確定が必要となる。それには各個人の変動曲線を検出し、その変動曲線上での平均値（直線）を算出して、その平均値と変動曲線との交点から２つのクロスポイントを求めるアルゴリズムが、本特許請求範囲に含まれる請求項目の１つである。

【０００９】
【課題を解決するための手段】本発明に係る自律神経リズム解析装置にあっては、上記の課題を解決するために、図１に示すように、２４時間の心拍変動記録としてアナログ及びデジタルのいずれの信号形式でも入力できる心拍動計測入力部１と、入力されたそれらの２４時間心拍変動の時系列データとその分析結果である自律神経リズム等を保存するデータ記憶部３と、２４時間の心拍変動時系列データをスペクトラム分析し、心拍変動に内在している０．５Ｈｚ以下の超低周波変動成分を抽出して自律神経リズムを決定するデータ分析部２と解析した自律神経リズムを経時的な変動曲線として出力するリズム表示部４とから構成されることを特徴とするものである。
【００１０】本発明の自律神経リズムの解析にあたるデータ分析部２における自律神経リズム変動曲線の抽出手段の信号処理アルゴリズムは、図２の検出手法のフローチャートに示すような処理構造を有することを特徴とするものである。
【００１１】
【作用】本発明においては、心拍動計測入力部１に入力される２４時間の心拍数、心電図ＲＲ間隔等の経時的変動は、データ記憶部３で原データとして記憶されると同時に、データ分析部２で２４時間を基本周期とするＦＦＴ処理７、高調波成分のカット１１、逆ＦＦＴ処理１２、正規化による概日リズム曲線の抽出１４、クロスポイントの決定１８等のデシタルフィルタ処理過程で自律神経リズムの抽出手段がリアルタイムに実行される。その結果、自律神経系の概日リズム変動曲線の評価及びクロスポイント時刻の検出を通して、１日における交感神経及び副交感神経機能の相互関係を医学的に明らかにできる。
【００１２】
【実施例】本発明の一実施例のブロック構成図を図１に示す。本実施例では、心拍動計測入力部１に入力される信号は、図３に示したような２４時間連続記録されたヒトの心拍数の時系列データであり、データ記憶部３に原データとして保存すると同時に、データ分析部２へ送られ自律神経リズムの抽出手段がなされる。
【００１３】データ分析部２での解析処理は図２のフローチャートに示した処理過程によって進められる。入力された２４時間の心拍動時系列データ５は、図３のような夜間睡眠期に比較して昼間活動期に鋭く大きな心拍数の変化を伴っていることを特徴とする心拍変動の原データある。その時系列原データを移動平均処理してデータ数を１０２４に変換処理６したものが、図４に示した２４時間の心拍変動データである。それを２４時間を基本周期（Ｔ）としてＦＦＴ解析７し、平均心拍レベルを検出８する。ＦＦＴ解析した後の周波数スペクトルは図５である。周波数スペクトル上の高調波成分の次数ｎとしその初期値９をｎ＝１１とする。次にｎより１つ減じた次数ｎ＝ｎ－１を求め１０、そのｎでの遮断周波数（＝ｎ／ＴＨｚ）以上の高周波数成分をカット１１する。そのスペクトラムを逆ＦＦＴ変換１２し、正規化処理１３した２４時間の心拍動時系列データ（変動曲線）上での最大値及び最小値から平均値を算出１４，１５し、この正規化した変動曲線と平均値（レベル）とからクロスポイントを計算１６する。そこでクロスポイント数を判断１７し、もしクロスポイント数が３以上の場合は高調波次数を減じる処理１０にもどって次数を１つ減じ、高調波成分のカット処理１１からクロスポイント検出処理１６までの処理をクロスポイント数が２になるまで繰り返す。クロスポイント数が２になった時点でクロスポイントの時刻を決定し、データ分析部２における自律神経リズムの変動曲線抽出手段の解析処理は終了する。逆ＦＦＴ変換処理１２、正規化処理１３、クロスポイントの検出処理１８、の実施例をそれぞれ図６、図７、図８に示す。
【００１４】データ分析部２で検出された２つのクロスポイントを有する自律神経リズムの変動曲線はデータ記憶部３及びリズム表示部４に送られ、リズムの保存と２４時間の自律神経リズムにおける交感神経及び副交感神経の両機能の相互関係が評価される。
【００１５】
【発明の効果】本発明の自律神経リズム解析装置は、２４時間というやや長時間ではあるが無侵襲で容易に測定できる心臓の拍動変化から、そこに内在する基本的な自律神経リズムを抽出・確定することにより、サーカディアンリズムにおける交感神経及び副交感神経

機能の経時的な相互関係が明らかになり自律神経失調症などの医学的評価に大いに貢献できる。しかし、自律神経機能を被験者に負担をかけずに測定・解析する装置はきわめて少なく、特にサーカディアンリズムから交感神経及び副交感神経機能のバランスを評価するアプローチは皆無に等しい。

【図面の簡単な説明】

【図１】本発明の全体構成を示すブロック図である。

【図２】本発明のリズム及びクロスポイントの検出アルゴリズムを示すフローチャートである。

【図３】２４時間心拍数の日内変動例を示す図である。

【図４】移動平均処理によりデータ数を１０２４に変換した例である。

【図５】ＦＦＴによるスペクトルの一例である。

【図６】逆ＦＦＴによる時系列データの一例である。

【図７】正規化した心拍変動例である。

【図８】クロスポイントの検出例である。

【符号の説明】

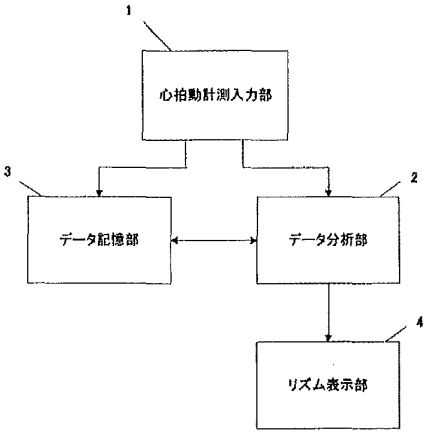
１心拍動計測入力部

２データ分析部

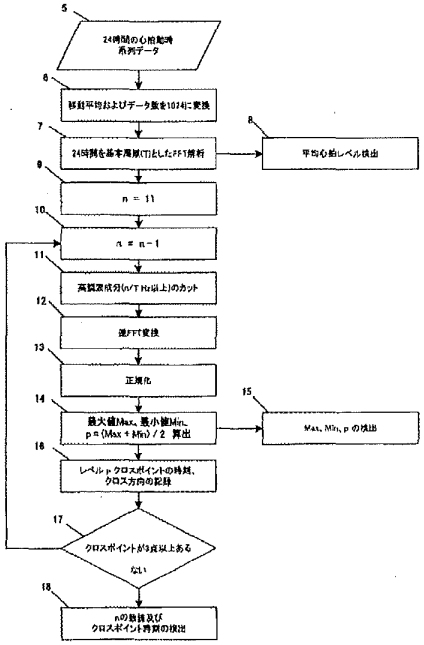
３データ記憶部

４リズム表示部

【図1】



【図2】



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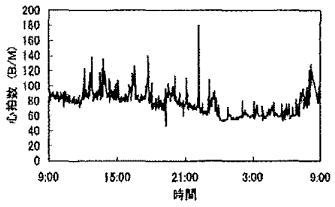
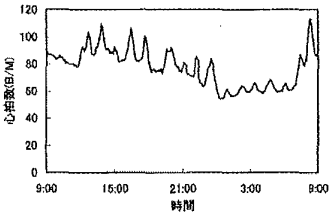
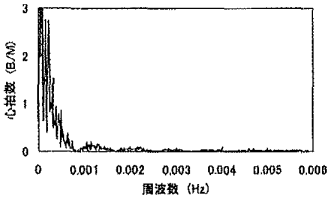


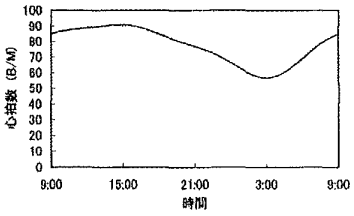
【図4】



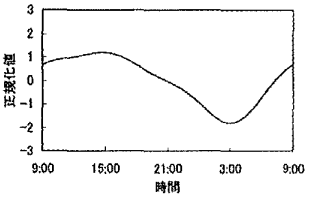
【図5】



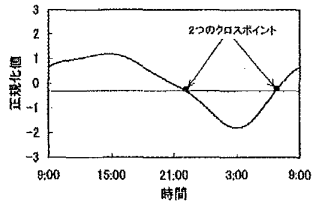
【図6】



【図7】



【図8】



Fターム(参考) 4C017 AA02 AA10 AA19 BB12 BC11 BC14 BC16 CC01
4C038 PP03 PS00

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BIOINFORMATION MEASURING INSTRUMENT AND ITS METHOD

No documents available for this priority number.

Inventor(s): KANAYAMA SHOICHI ± (KANAYAMA SHOICHI)

Applicant(s): TOSHIBA CORP; TOSHIBA MEDICAL SYS CORP ± (TOSHIBA CORP, ; TOSHIBA MEDICAL SYSTEMS CORP)

Classification: **- international:** ***A61B5/1455; A61B5/1495***
- cooperative:

Application number: JP20050231018 20050809

Priority number (s): JP20050231018 20050809

Also published as: JP4744976 (B2)

Abstract of JP2007044203 (A)

PROBLEM TO BE SOLVED: To highly precisely calculate information related to substances inside a subject without being affected by factors such as a circadian rhythm, a food taking time, a sleeping time, a body condition, a clinical condition, or dosing of the subject. ; SOLUTION: An optimization section 19 selects an optimal calibration model out of a plurality of preset calibration models based on respective measurement data by a non-invasive measurement, and sleep information F<SB>1</SB>, food information F<SB>2</SB>, movement information F<SB>3</SB>, and dosing information F<SB>4</SB>as living information of the subject H or optimizes parameters of the calibration model, so as to highly precisely calculate information related to the substances inside the subject, for example, the glucose concentration inside the subject H without being affected by fluctuation factors such as hemodynamics dependent on the circadian rhythm, the food taking times, the sleeping time, the body condition, the clinical condition, or the dosing of the subject H. ; COPYRIGHT: (C)2007,JPO&INPIT

Last updated: 09.10.2013 Worldwide Database 5.8.11.5; 92p

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A61B	5/1495	(2006.01)	A61B	5/14	360	

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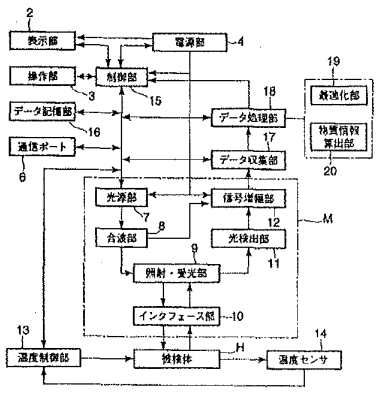
(71)出願人　000003078
株式会社東芝
東京都港区芝浦一丁目１番１号
(71)出願人　594164542
東芝メディカルシステムズ株式会社
栃木県大田原市下石上１３８５番地
(74)代理人　100058479
弁理士　鈴江　武彦
(74)代理人　100091351
弁理士　河野　哲
(74)代理人　100088683
弁理士　中村　誠
(74)代理人　100108855
弁理士　蔵田　昌俊

最終頁に続く

(54)【発明の名称】生体情報計測装置及びその方法

(57)【要約】
【課題】被検体のサーカディアンリズムや食事摂取時間、睡眠時間、体調、病態、投薬などの要因の影響を受けずに、高精度に被検体内の物質に関する情報を算出すること。
【解決手段】最適化部１９によって非侵襲計測による各計測データと、被検体Ｈの生活情報としての睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4とに基づいて予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択又はキャリブレーションモデルのパラメータを最適化するので、被検体Ｈのサーカディアンリズムや食事摂取時間、睡眠時間、体調、病態、投薬などに依存した血行動態等の変動要因の影響を受けずに、高精度に被検体内の物質に関する情報、例えば被検体Ｈの体内のグルコース濃度を算出する。
【選択図】図２

図２



【特許請求の範囲】
【請求項1】
被検体内の物質を非侵襲的に計測する計測部と、
前記被検体の生活情報を入力する情報入力部と、
前記計測部により計測された前記物質の情報と前記情報入力部から入力された前記生活情報との相関関係の最適化を行う最適化部と、
前記最適化部により最適化された相関関係により前記物質に関する情報を算出する物質情報算出部と、
を具備したことを特徴とする生体情報計測装置。
【請求項2】
前記計測部は、前記被検体内の前記物質を計測すると共に、前記物質を計測した時刻情報を取得することを特徴とする請求項１記載の生体情報計測装置。
【請求項3】
前記情報入力部は、前記生活情報として前記被検体の睡眠情報、食事情報、運動情報又は投薬情報のうち少なくとも１つの情報を入力することを特徴とする請求項１記載の生体情報計測装置。
【請求項4】
前記情報入力部は、少なくとも表示器を有し、当該表示器の表示画面に対する対話形式で前記生活情報を入力することを特徴とする請求項１記載の生体情報計測装置。
【請求項5】
前記情報入力部は、音声ガイドの発声により前記生活情報を入力することを特徴とする請求項４記載の生体情報計測装置。
【請求項6】
前記情報入力部は、複数の選択肢から選択して前記生活情報を入力することを特徴とする請求項４記載の生体情報計測装置。
【請求項7】
前記情報入力部は、前記被検体のバイタル情報を入力することを特徴とする請求項１記載の生体情報計測装置。
【請求項8】
前記情報入力部は、前記バイタル情報として前記被検体の体温、血圧、心拍数又は血液のうち少なくとも１つの検査情報、又は前記被検体の病態情報を入力することを特徴とする請求項７記載の生体情報計測装置。
【請求項9】
前記最適化部は、前記計測部により計測された前記物質情報と前記情報入力部から入力された前記生活情報とに基づいて予め設定された複数のキャリブレーションモデルの中から最適な前記キャリブレーションモデルを選択、又は前記キャリブレーションモデルのパラメータを最適化することを特徴とする請求項１記載の生体情報計測装置。
【請求項10】
前記最適化部は、前記キャリブレーションモデルを複数の計測時間帯毎に予め設定し、前記生活情報に応じて前記キャリブレーションモデルのパラメータを最適化することを特徴とする請求項９記載の生体情報計測装置。
【請求項11】
前記最適化部は、前記最適化した前記キャリブレーションモデルの適合性を定量的に評価することを特徴とする請求項９記載の生体情報計測装置。
【請求項12】
前記最適化部は、少なくとも統計的検定法又は多変量分析法を用いて前記キャリブレーションモデルの適合性を定量的に評価することを特徴とする請求項９記載の生体情報計測装置。
【請求項13】

前記物質情報算出部は、前記最適化部による前記キャリブレーションモデルの前記適合性の評価結果に基づいて前記物質に関する情報の予測される計測誤差を算出することを特徴とする請求項１記載の生体情報計測装置。
【請求項14】
前記物質情報算出部は、前記被検体の生体組織の細胞中、又は前記生体組織の前記細胞外の体液成分の濃度を算出することを特徴とする請求項１記載の生体情報計測装置。
【請求項15】
前記物質情報算出部は、前記体液成分の濃度としてグルコース濃度を算出することを特徴とする請求項１０記載の生体情報計測装置。
【請求項16】
被検体内の物質情報を計測部によって非侵襲的に計測し、
前記被検体の生活情報を操作部を介して入力し、
コンピュータの処理によって、前記計測された前記物質情報と前記操作部を介して入力された前記被検体の前記生活情報との相関関係の最適化を行い、この最適化された相関関係により前記物質に関する情報を算出する、
ことを特徴とする生体情報計測方法。
【請求項17】
前記計測部による前記被検体内の前記物質情報の計測前又は計測後に、前記被検体の前記生活情報を前記操作部を介して入力することを特徴とする請求項１６記載の生体情報計測方法。
【発明の詳細な説明】
【技術分野】
【0001】
本発明は、例えば健康管理、疾病の診断及び治療、美容のために血液や生体組織細胞中又はその細胞外の体液中の物質濃度、或いは生体組織の物性情報を非侵襲的に計測する生体情報計測装置及びその方法に関する。
【背景技術】
【0002】
現代の主要死因である心筋梗塞等の心臓病、脳梗塞等の脳血管疾患などは、生活習慣病と呼ばれている。このような生活習慣病は、その殆どが高血圧、糖尿病、脂質代謝異常、肥満、喫煙などによってもたらされる動脈硬化を原因としている。これら高血圧、糖尿病、脂質代謝異常など高リスク状態は、健康診断により診断された場合でも、その多くは病状が相当進行するまで症状が出難い。このような病状を持った患者は、日常生活を送りながら指示された頻度、時間に血圧や血糖など生体情報の計測を患者自身で行ない、処方された通りの薬品の服用、指示された運動、食事などの自己管理を行うことが多い。
【0003】
このうち糖尿病の重要な指標の一つである血糖の測定では、患者である被検体自身によって指や腕などの部位の一部に針を刺して少量の血液サンプルを採取し、この採取した血液中のグルコースを化学反応させてその濃度を測定するという所謂自己血糖計を広く利用している。この自己血糖計の最も一般的なグルコース濃度の計測法としては、酵素電極を用いた方法がある。グルコース検知に使用される酵素としては、例えばグルコースオキシダーゼ（ＧＯＤ）がある。グルコース濃度の測定は、例えばＧＯＤを高分子膜などに固定化し、患者の物質中のグルコースがＧＯＤ固定化膜に接触することによって酸素が消費されるので、この酸素の変化を捕らえることで行われる。このような採血式の自己血糖計は、携帯可能な大きさであり、糖尿病を持つ被検体の血糖値の管理に利用されている。
【0004】
しかしながら、採血式の自己血糖計を用いたグルコース濃度の測定では、採血のために指や腕などの一部に針を刺す必要があり被検者の皮膚を損傷するとともに苦痛を伴う。これに対して被検者の皮膚損傷や苦痛を軽減することを目的とする測定方法がある。例えば、微小な針やレーザを用いて痛みを伴わない程度の微小な穴を皮膚表面に開け微量の細胞間質液を採取して測定する方法、皮膚表面に電圧や超音波を印加して皮膚の浸出透過性を

良くし細胞間質液等の浸出液を抽出して測定する方法、更には採血や細胞間質液の抽出を必要としない非侵襲で測定する方法がある。

【0005】

このうち非侵襲で測定する方法としては、例えば特許文献１或いは特許文献２に開示されているような電磁波を利用した方法がある。これら特許文献１或いは特許文献２には、それぞれ被検体の皮膚表面などに異なる複数の波長の近赤外光を照射し、皮膚表面などからの光を検出してその検出信号を基準信号と測定信号とに分け、これらの値を演算処理することにより被検体内に存在する物質の成分や濃度を測定する方法が開示されている。

【0006】

このような非侵襲で測定する方法では、予め血液などの体液を採取して測定した所望の物質濃度の値と非侵襲的に得られる信号との相関関係を求めるという所謂キャリブレーションが行われる。そして、このキャリブレーションされた相関関係に基づき非侵襲的に得られる信号から所望の物質の定量化が行われる。

しかしながら、非侵襲で測定する方法は、被検体のサーカディアンリズム（日周期リズム）や食事摂取時間、睡眠時間、体調、病態、投薬などの要因によって影響を受け、測定精度の低下を生じる。

【特許文献1】特公平３－４７０９９号公報

【特許文献1】特公平５－５８７３５号公報

【発明の開示】

【発明が解決しようとする課題】

【0007】

本発明の目的は、被検体のサーカディアンリズム（日周期リズム）や食事摂取時間、睡眠時間、体調、病態、投薬などの要因の影響を受けずに、高精度に被検体内の物質に関する情報を算出できる生体情報計測装置及びその方法を提供することにある。

【課題を解決するための手段】

【0008】

本発明の主要な局面に係る生体情報計測装置は、被検体内の物質を非侵襲的に計測する計測部と、被検体の生活情報を入力する情報入力部と、計測部により計測された物質の情報と情報入力部から入力された生活情報との相関関係の最適化を行う最適化部と、最適化部により最適化された相関関係により物質に関する情報を算出する物質情報算出部とを具備する。

【0009】

本発明の別の局面に係わる生体情報計測方法は、被検体内の物質情報を計測部によって非侵襲的に計測し、被検体の生活情報を操作部を介して入力し、コンピュータの処理によって、計測された物質情報と操作部を介して入力された被検体の生活情報との相関関係の最適化を行い、この最適化された相関関係により物質に関する情報を算出する。

【発明の効果】

【0010】

本発明によれば、被検体のサーカディアンリズム（日周期リズム）や食事摂取時間、睡眠時間、体調、病態、投薬などの要因の影響を受けずに、高精度に被検体内の物質に関する情報を算出できる生体情報計測装置及びその方法を提供できる。

【発明を実施するための最良の形態】

【0011】

以下、本発明の第１の実施の形態について図面を参照して説明する。

図１は生体情報計測装置の外観図を示し、図２は同装置のブロック構成図を示す。同装置は、例えば特公平６－１０３２５７号公報、特表２００２－５１５２７７号公報、米国特許第５５５１４２２号公報及び米国特許第５７７０４５４号公報に開示されているような光の照射点と受光点との距離を変えることによって実質的に光拡散光路長が異なる複数の測定データから物質の吸光度を算出する空間分解拡散反射法と、例えば特開平１０－３２５７９４号公報、特開平１１－５０６２０７号公報及び米国特許第５７４７８０６号公報

に開示されているような複数の波長の光を利用して計測する方法とを用い、被検体の体内のグルコース濃度を測定する。

以下、同装置の具体的な構成について説明する。図１に示すように装置筐体１の表面には、表示部２の表示画面２ａと、操作部３の操作ボタン３と、電源部４の電源ボタン４と、被検体Ｈの例えば指を保持する例えばＵ字溝に形成されたセンサ窓５とが設けられている。このセンサ窓５は、被検体Ｈの例えば腕を保持するものでもよく、その形状は、保持する被検体Ｈの部位の形状に合わせて変更可能である。装置筐体１の一側面には、通信ポート６が設けられている。この通信ポート６は、通信回線を介して外部機器との間で各種データやプログラムデータ等を双方向で転送等のデータ通信を可能とする。

【0012】

装置筐体１内には、図２に示すように被検体Ｈ内の物質を非侵襲的に計測すると共に、被検体Ｈ内の物質を計測した時刻情報を取得する計測部Ｍが設けられている。この計測部Ｍには、光源部７が設けられている。この光源部７は、所望の一つの波長の単色光又はそれぞれ波長の異なる複数の単色光、或いはこれら単色光に近い波長の光を出力する。この光源部７は、例えば半導体レーザ（ＬＤ）又は発光ダイオード（ＬＥＤ）等の小型の発光素子を用いる。この光源部７は、例えば所望の波長の光を出力するＬＤ又はＬＥＤ等の発光素子を一つ又は複数用いる。合波部８は、光源部７から出力された光の各波長の単色光を同一光軸に重ね合わせる。照射・受光部９は、合波部８により各波長の単色光を同一光軸に重ね合わせられた光をインタフェース部１０を介して被検体Ｈの所望の一部位又は複数の被測定部位に照射し、かつ被検体Ｈの所望の一部位又は複数の被測定部位を拡散、透過又は反射した各光を同時に受光するための各光の光軸を制御する。インタフェース部１０は、図１に示すように例えば被検体保持部５の底部に設けられ、照射・受光部９からの光を被検体Ｈに照射し、かつ被検体Ｈからの拡散、透過又は反射した各光を光検出部１１に導く。

この光検出部１１は、照射・受光部９により各光軸が制御された被検体Ｈの所望の一部位又は複数の被測定部位を拡散、透過又は反射した各光信号を同時に受光し、これら光信号をそれぞれアナログの電気信号である各検出信号に変換する。被検体Ｈを拡散、透過又は反射した各光の強度は、被検体Ｈ内に存在する所定の物質、例えばグルコースの存在比率や濃度に依存する。従って、光検出部１１から出力される各検出信号のレベルは、被検体Ｈ内に存在する所定の物質の存在比率や濃度に依存している。信号増幅部１２は、光検出部１１から出力される各検出信号を所望の振幅に増幅する。

【0013】

装置筐体１内には、温度制御部１３と温度センサ１４とが設けられている。これら温度制御部１３と温度センサ１４とは、被検体保持部５の近傍、すなわち被検体Ｈの所望の一部位又は複数の被測定部位の近傍に設けられている。温度制御部１３は、温度センサ１４から出力される温度測定信号を入力し、被検体Ｈの所望の一部位又は複数の被測定部位の温度を所定温度にフィードバック制御する。この温度制御部１３は、例えば被検体Ｈとの熱インタフェース部として熱伝導製の良いアルミニュームなどの金属材料を用い、この熱インタフェース部の底面部に熱源となるペルチェ素子を取り付けて成る。温度センサ１４は、被検体Ｈの所望の一部位又は複数の被測定部位の温度を測定し、その温度測定信号を出力する。この温度センサ１４は、例えば熱電対又はサーミスタなどから成り、被検体Ｈとの熱インタフェース部に埋め込まれる。

【0014】

制御部１５には、表示部２と、操作部３と、通信ポート６と、データ記憶部１６と、データ収集部１７と、データ処理部１８とが接続されている。制御部１５は、コンピュータを構成するＣＰＵを有し、表示部２に対して表示指令を発し、操作部３からの操作指示を受け、通信ポート６を通して外部機器との間でデータ通信を行い、データ記憶部１６に対してデータの書き込み、読み取りを行い、データ収集部１７とデータ処理部１８とに対して各処理指令を発する。

表示部２は、例えば液晶表示装置により成り、その表示画面２ａに例えば被検体Ｈの体

内の物質、例えばグルコース濃度の計測結果Ｒと、この被検体Ｈ内の物質を計測した時刻情報Ｔとを視覚的に表示する。この表示部２は、例えば音声出力装置又はバイブレータ等の振動装置のうちいずれか一方又は両方を備えてもよい。音声出力装置は、例えば被検体Ｈの体内のグルコース濃度の計測結果を聴覚的に報知する。振動装置は、同グルコース濃度の計測結果を触覚的に伝達する。

【0015】

操作部３は、例えばマン・マシン・インタフェースによる情報入力部として機能し、例えばキーボード、マウス、ボタン、タッチキーパネル又は音声ガイドの発声による情報の入力装置のうち少なくとも1つを有し、表示部２の表示画面２ａに対する対話形式で例えば被検体Ｈの生活情報を当該表示画面２ａに表示される複数の選択肢から選択することにより入力する。この被検体Ｈの生活情報は、例えば被検体Ｈの睡眠情報、食事情報、運動情報又は投薬情報のうち少なくとも１つの情報である。又、操作部３は、被検体Ｈのバイタル情報として例えば被検体Ｈの体温、血圧、心拍数又は血液のうち少なくとも１つの検査情報、又は被検体Ｈの病態情報を入力する。

【0016】

データ収集部１７は、信号増幅部１２により所望の振幅に増幅された各検出信号をデジタル信号に変換して各計測データとして収集する。

データ処理部１８は、データ収集部１７により収集された各計測データを処理して被検体Ｈ内に存在する物質の成分や濃度、或いは被検体Ｈの組織の変性に関する情報、例えば被検体Ｈの体内のグルコース濃度を算出し、このグルコース濃度等を必要に応じてデータ記憶部１６に記憶する。このデータ処理部１８は、最適化部１９と物質情報算出部２０とを有する。

最適化部１９は、データ収集部１７により収集された各計測データと操作部３により入力された被検体Ｈの生活情報との相関関係の最適化、すなわち予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択、又はキャリブレーションモデルのパラメータを最適化する。又、最適化部１９は、キャリブレーションモデルを複数の計測時間帯毎に予め設定し、被検体Ｈの生活情報に応じてキャリブレーションモデルのパラメータを最適化する。

物質情報算出部２０は、最適化部１９により最適化されたキャリブレーションモデルにより物質に関する情報、被検体Ｈの体内のグルコース濃度を算出する。

【0017】

制御部１５は、操作部３からの操作信号等に基づいて表示部２、電源部４、光源部７、信号増幅部１２、温度制御部１３、データ記憶部１６、データ収集部１７、データ処理部１８などを動作制御する。又、制御部１５は、必要に応じて温度制御部１３、データ記憶部１６、データ処理部１８などに電力を供給する。電源部４は、表示部２、光源部７、信号増幅部１２、制御部１５などに電力を供給する。

次に、上記の如く構成された装置の動作について図３に示す計測処理フローチャートに従って説明する。

非侵襲計測を行うステップ＃１では、電源ボタン４が押操作されると、電源部４から表示部２、光源部７、信号増幅部１２、制御部１５などに電力が供給される。これにより、制御部１５が起動する。そして、被検体Ｈの例えば指がセンサ窓５に保持され、操作ボタン３が操作されると、非侵襲計測が行われる。すなわち、光源部７からは、所望の一つの波長の単色光又はそれぞれ波長の異なる複数の単色光、或いはこれら単色光に近い波長の光が出力される。この光は、合波部８に入射して各波長の単色光が同一光軸に重ね合わされる。この合波器８から出射された光は、照射・受光部９によりインタフェース部１０を介して被検体Ｈの所望の一部位又は複数の被測定部位に照射される。このとき、被検体Ｈの所望の一部位又は複数の被測定部位で拡散、透過又は反射した各光は、照射・受光部９によって光検出部１１で同時に受光するために各光の光軸が制御される。

【0018】

光検出部１１は、照射・受光部９により各光軸が制御された被検体Ｈの所望の一部位又

は複数の被測定部位を拡散、透過又は反射した各光を同時に受光し、これら光をそれぞれアナログの電気信号である各検出信号に変換する。このときの被検体Ｈを拡散、透過又は反射した各光信号の強度は、被検体Ｈ内に存在する所定の物質、例えばグルコースの存在比率や濃度に依存する。従って、光検出部１１から出力される各検出信号のレベルは、被検体Ｈ内に存在する所定の物質の存在比率や濃度に依存している。信号増幅部１２は、光検出部１１から出力される各検出信号を所望の振幅に増幅する。

【0019】

このような非侵襲計測時、温度制御部１３は、温度センサ１４から出力される温度測定信号を入力し、被検体Ｈの所望の一部位又は複数の被測定部位の温度を所定温度にフィードバック制御する。

データ収集部１７は、信号増幅部１２により所望の振幅に増幅された各検出信号をデジタル信号に変換して各計測データＤｈとして収集する。これら収集された計測データは、制御部１５によって計測時の時刻情報Ｄｔと共にデータ記憶部１６に記憶される。

【0020】

一方、非侵襲計測の計測前又は計測後に、生活情報入力がステップ＃２で行われる。すなわち、制御部１５は、表示部２の表示画面２ａに生活情報入力用の画面を表示し、この画面を見ながら操作部３が操作されると、操作部３からの操作入力を生活情報としてデータ記憶部１６に記憶する。生活情報としては、図４Ａに示す被検体Ｈの睡眠情報F_1、図４Ｂに示す食事情報F_2、図４Ｃに示す運動情報F_3又は図４Ｄに示す投薬情報F_4のうち少なくとも１つの情報が入力される。これら被検体Ｈの睡眠情報F_1、食事情報F_2、運動情報F_3及び投薬情報F_4は、それぞれ階層のデータ構造を有し、例えばデータ記憶部１５に記憶されている。例えば睡眠情報F_1は、「時間」と「睡眠情報」との各データ項目を有し、このうち「時間」の下層には、「起床時間」「就寝時間」を有し、「睡眠情報」の下層には、「熟眠できた」「よく眠れなかった」を有する。

図５は表示部２の表示画面２ａに表示される生活情報入力用としての投薬情報F_4の画面の一例を示す。この投薬情報F_4の画面には、例えば服用・投与時間と、各薬品と、これら薬品の投与量との各入力欄R_1、R_2、R_3が表示されている。投薬情報F_4は、図４Ｄに示すように「服用・投与時間」と「種類」との各データ項目を有し、このうち「種類」の下層に「糖尿病治療薬」「高血圧治療薬」等を有し、さらに「糖尿病治療薬」の下層に「インスリン」「スルホニン尿素薬」「インスリン抵抗性改善薬」等を有し、「インスリン」の下層に「ランタス」「５単位」を有する。

従って、表示部２の表示画面２ａに表示されている投薬情報F_4の画面を見ながら操作部３の例えばキーボード、マウス、ボタン又はタッチキーパネルを操作するという対話形式で各薬品を複数の選択肢から選択、すなわちプルダウンメニューにより選択して入力欄R_2に入力する。例えば入力欄R_2に「ランタス」を選択すると、入力欄R_3に「５単位」が表示される。

【0021】

投薬情報F_4の画面を見ながら操作部３を操作するという対話形式で各薬品を選択するとき、例えば音声出力装置又はバイブレータ等の振動装置のいずれか一方又は両方を用い、音声ガイド等の質問形式に従って投薬情報F_4を入力したり、振動装置により投薬情報F_4の入力を要求するような振動を発声するようにしてもよい。なお、音声出力装置を用いた場合には、音声により回答するようにしてもよい。

【0022】

以下に、表示部２の表示画面２ａへの表示又は音声ガイドに従って質問形式により生活情報を入力する一例を示す。この生活情報は、朝に計測する場合である。

１．血糖測定を開始します。
２．はじめに、睡眠情報を入力してください。
３．昨晩は何時に寝ましたか。メニューから選択してください。
　◇２０：００－２１：００，２１：００－２２：００，２２：００－２４：００，
　　２４：００以降，

４．今朝は何時に起きましたか。メニューから選択して下さい。
　◇０６：００以前，０６：００－０７：００，０７：００－０８：００，
　　０８：００－０９：００，０９：００以降，
５．昨晩はよく眠れましたか。
　　◇よく眠れた，よく眠れなかった。
６．次に食事情報を入力して下さい。
７．朝食は食べましたか。
　　◇はい，いいえ，
８．朝食は何時に食べましたか。メニューから選択して下さい。
　　◇０６：００以前，０６：００－０６：３０，０６：３０－０７：００，
　　０７：００－０７：３０，０７：３０－０８：００，０８：００－０８：３０，
９．食事内容を入力して下さい。
１０．食べたものを下記メニューから選択して下さい。
　　◇ご飯，肉，魚，野菜，乳製品，飲み物，その他，
１１．ご飯はお茶碗に何杯食べましたか。メニュｒから選択して下さい。
　　◇１杯，２杯，３杯，４杯，
１２．それでは血糖測定を開始しますので、指をセンサ窓５に載せて操作ボタン３ａを押して下さい。
１３．計測が終了しました。
１４．あなたの現在の血糖値は１１０ｍｇ／ｄＬです。
１５．この計測結果の予測誤差範囲は±１０ｍｇ／ｄＬです。
１６．キャリブレーションモデルの適合度は８０％です。
１７．あなたの現在の睡眠状態は、キャリブレーションモデルに十分反映されていません。睡眠情報を確認し、間違いがある場合は再入力してから血糖値をもう一度計算し直してください。
　なお、上記「１３」～「１７」は、計測終了後の音声による報知の一例を示す。
　このようにして操作部３を操作することにより被検体Ｈの生活情報として睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4が入力され、これら生活情報が制御部１５によって例えばデータ記憶部１６に記憶される。

【0023】
　さらに、操作部３からは、被検体Ｈのバイタル情報として体温、血圧、心拍数又は血液のうち少なくとも１つの検査情報、又は被検体Ｈの既往症を含む病態情報が入力される。例えば、被検体Ｈが糖尿病であれば、操作部３からは、バイタル情報として病院の血液検査で計測された血糖値、グリコヘモグロビン（ＨｂＡ１Ｃ）、グリコアルブミン、コレステロール、中性脂肪、ＣＲＰ（Ｃ反応性タンパク）等を入力してもよい。これらバイタル情報は、キャリブレーションモデルのパラメータを最適化するための情報として用いることが可能である。

【0024】
　次に、最適化部１９は、データ収集部１７により収集された各計測データと、操作部３により入力された被検体Ｈの生活情報として睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4との相関関係の最適化を行う。すなわち最適化部１９は、非侵襲計測による各計測データと、被検体Ｈの睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4とに基づいて予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択、又はキャリブレーションモデルのパラメータを最適化する。
　例えば、キャリブレーションモデル［Ｇ］の一例を示すと、
$$[G]=a_0+a_1\cdot S_1+a_2\cdot S_2+a_3\cdot S_3+a_4\cdot S_4$$
であり、a_0，a_1，a_2，a_3，a_4がパラメータを示し、S_1，S_2，S_3，S_4が被検体Ｈの複数の被測定部位を拡散、透過又は反射した各光を受光して検出された各計測データを示す。従って、最適化部１９は、各パラメータa_0，a_1，a_2，a_3，a_4を最適化する。なお、これらパラメータa_0，a_1，a_2，a_3，a_4は、被検体Ｈの睡眠

情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4の各組み合わせによりそれぞれ複数有する。

又、最適化部１９は、非侵襲計測による各計測データと、被検体Hの睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4と、被検体Hのバイタル情報として例えば体温、血圧、心拍数、血液、既往症を含む病態情報、さらに被検体Hが糖尿病であれば、病院の血液検査で計測された血糖値、グリコヘモグロビン（ＨｂＡ１Ｃ）、グリコアルブミン、コレステロール、中性脂肪、ＣＲＰ（Ｃ反応性タンパク）等とに基づいて予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択、又はキャリブレーションモデルのパラメータを最適化してもよい。

【0025】

又、最適化部１９は、図６に示すようにキャリブレーションモデルを複数の計測時間帯毎に予め設定し、被検体Hの生活情報に応じてキャリブレーションモデルのパラメータを最適化する。同図では各計測時間帯t_0-t_1、t_1-t_2、…、t_6-t_7毎にそれぞれ各キャリブレーションモデルM_1、M_2、…M_7が予め設定されている。Ｄｈｂは、血糖値の計測データを示す。最適化部１９は、各計測時間帯t_0-t_1、t_1-t_2、…、t_6-t_7毎にそれぞれ各キャリブレーションモデルM_1、M_2、…M_7の各パラメータを被検体Hの生活情報に応じて最適化してもよい。

【0026】

次に、物質情報算出部２０は、ステップ＃４において、最適化部１９により最適化されたキャリブレーションモデルにより物質に関する情報、例えば被検体Hの体内のグルコース濃度を算出する。

【0027】

次に、物質情報算出部２０は、ステップ＃５において、算出したグルコース濃度等を表示部２の表示画面２ａに表示し、次のステップ＃６において、算出したグルコース濃度等を必要に応じてデータ記憶部１６に記憶する。

【0028】

このように上記第１の実施の形態によれば、非侵襲計測による各計測データと、被検体Hの生活情報としての睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4とに基づいて予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択、又はキャリブレーションモデルのパラメータを最適化するので、被検体Hのサーカディアンリズム（日周期リズム）や食事摂取時間、睡眠時間、体調、病態、投薬などに依存した血行動態等の変動要因の影響を受けずに、高精度に被検体内の物質に関する情報、例えば被検体Hの体内のグルコース濃度を算出できる。

【0029】

最適なキャリブレーションモデルの選択、又はキャリブレーションモデルのパラメータを最適化するには、被検体Hのバイタル情報として例えば体温、血圧、心拍数、血液、既往症を含む病態情報、さらに被検体Hが糖尿病であれば、病院の血液検査で計測された血糖値、グリコヘモグロビン（ＨｂＡ１Ｃ）、グリコアルブミン、コレステロール、中性脂肪、ＣＲＰ（Ｃ反応性タンパク）等を用いることもできる。

【0030】

睡眠情報F_1、食事情報F_2、運動情報F_3、投薬情報F_4等の被検体Hの生活情報の入力は、表示部２の表示画面２ａへの表示又は音声ガイドに従って質問形式等の対話形式で行うので、間違いなく、被検体Ｈ自身で入力できる。

【0031】

次に、本発明の第２の実施の形態について図面を参照して説明する。

図７は生体情報計測装置の特徴部分の一部ブロック構成図を示す。なお、本実施の形態の装置は、上記図２に示す構成と略同一であり、最適化部１９と物質情報算出部２０との各機能が異なる。又、図８は計測処理フローチャートを示し、図３に示す計測処理フローチャートに各ステップ＃１０、＃１１を追加している。

最適化部１９は、非侵襲計測による各計測データと、被検体Hの睡眠情報F_1、食事情

報F_2、運動情報F_3、投薬情報F_4とに基づいて予め設定された複数のキャリブレーションモデルの中から最適なキャリブレーションモデルを選択、又はキャリブレーションモデルのパラメータを最適化すると、この最適化したキャリブレーションモデルの適合性を定量的に評価する。

具体的に最適化部１９は、少なくとも統計的検定法又はマハラノビス距離の多変量分析法を用いてキャリブレーションモデルの適合性を定量的に評価する。すなわち、制御部１５には、キャリブレーションデータベース２１が接続されている。なお、このキャリブレーションデータベース２１は、データ記憶部１６内に形成してもよい。このキャリブレーションデータベース２１には、例えばキャリブレーションモデルの選択やキャリブレーションモデルのパラメータの最適化に用いる各条件因子とキャリブレーションモデルの相関性をクラスタ分析した情報が記憶されている。このキャリブレーションデータベース２１は、各被検体H毎に形成可能である。

【0032】

しかるに、最適化部１９は、図８に示す計測処理フローチャートのステップ＃１０において、キャリブレーションデータベース２１に記憶されているキャリブレーションモデルの選択やキャリブレーションモデルのパラメータの最適化に用いる各条件因子とキャリブレーションモデルの相関性をクラスタ分析した情報を用い、統計的検定法又はマハラノビス距離の多変量分析法を用いてキャリブレーションモデルの適合性を定量的に評価する。

【0033】

なお、キャリブレーションモデルの適合性を定量的に評価する際、キャリブレーションモデルの選択に必要な生活情報が不足している場合、又はキャリブレーションモデルの適合性が所望のレベル以下の場合、最適化部１９は、生活情報が不足している旨、又はキャリブレーションモデルの適合性のレベル及び所望のレベル以下の旨を表示部２の表示画面２ａに表示する。

【0034】

物質情報算出部２０は、最適化部１９によるキャリブレーションモデルの適合性の評価結果に基づいて被検体Hの物質に関する情報の予測される計測誤差を算出する。具体的に物質情報算出部２０は、ステップ＃１１において、最適化部１９によるキャリブレーションモデルの適合性の評価結果を受け、生活情報と、計測信号又は例えば被検体Hの体内のグルコース濃度等の算出値と、キャリブレーションデータベース２１に記憶されているキャリブレーションモデルの選択やキャリブレーションモデルのパラメータの最適化に用いる各条件因子とキャリブレーションモデルの相関性をクラスタ分析した情報とに対して統計学的誤差推定法等を適用して被検体Hの物質に関する情報の予測される計測誤差を算出する。

【0035】

さらに、物質情報算出部２０は、ステップ＃６において、例えば被検体Hの体内のグルコース濃度等の算出値等の計測結果に、キャリブレーションモデルの適合性情報、予測される計測誤差の情報を付加し、これら情報をキャリブレーションデータベース２１に記憶する。

【0036】

このように上記第２の実施の形態によれば、最適化したキャリブレーションモデルの適合性を定量的に評価するので、キャリブレーションモデルの適合性の評価結果やその理由を被検体Hに示すことができる。又、予測される計測誤差を算出するので、被検体Hに対して計測状態や計測結果の信頼度を正確に示すことができる。これにより、例えば誤差の少ない計測時間帯に計測をすることができる。

【0037】

なお、本発明は、上記各実施の形態に限定されるものではなく、次のように変形してもよい。

例えば、上記各実施の形態では、被検体Hの体内のグルコース濃度を算出する場合について説明したが、これに限らず、被検体Hの生体組織の細胞中、又は生体組織の細胞外等

に存在する所望の生体内物質の成分や濃度、例えば血液中のヘモグロビン濃度等を計測するようにしてもよい。

キャリブレーションモデルは、計測時間に応じて変更するようにしてもよい。

【図面の簡単な説明】

【0038】

【図1】本発明に係る生体情報計測装置の第１の実施の形態を示す外観図。

【図2】同装置のブロック構成図。

【図3】同装置における計測処理フローチャート。

【図4A】同装置において操作入力される生活情報のうち被検体の睡眠情報を示す図。

【図4B】同装置において操作入力される生活情報のうち被検体の食事情報を示す図。

【図4C】同装置において操作入力される生活情報のうち被検体の運動情報を示す図。

【図4D】同装置において操作入力される生活情報のうち被検体の投薬情報を示す図。

【図5】同装置における表示部の表示画面に表示される生活情報入力用としての投薬情報の画面の一例を示す図。

【図6】同装置において各計測時間帯毎にキャリブレーションモデルを複数設定した場合の一例を示す図。

【図7】本発明に係る生体情報計測装置の第２の実施の形態の特徴部分を示す一部ブロック構成図。

【図8】同装置における計測処理フローチャート。

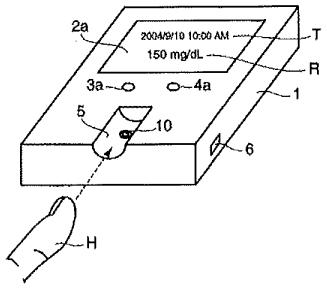
【符号の説明】

【0039】

１：装置筐体、２：表示部、２ａ：表示画面、３：操作部、３ａ：操作ボタン、４：電源部、４ａ：電源ボタン、Ｈ：被検体、５：センサ窓、６：通信ポート、Ｍ：計測部、７：光源部、８：合波部、９：照射・受光部、１０：インタフェース部、１１：光検出部、１２：信号増幅部、１３：温度制御部、１４：温度センサ、１５：制御部、１６：データ記憶部、１７：データ収集部、１８：データ処理部、１９：最適化部、２０：物質情報算出部、２１：キャリブレーションデータベース。

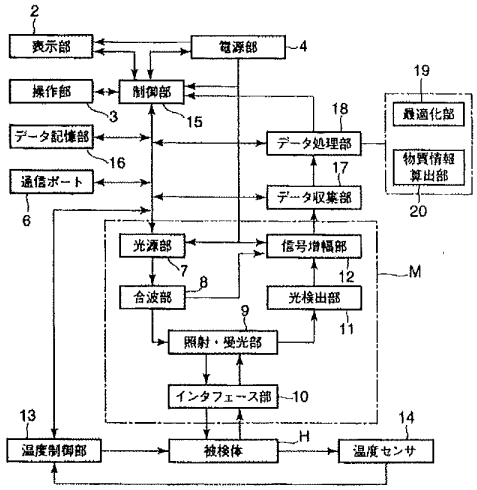
【図1】

図１



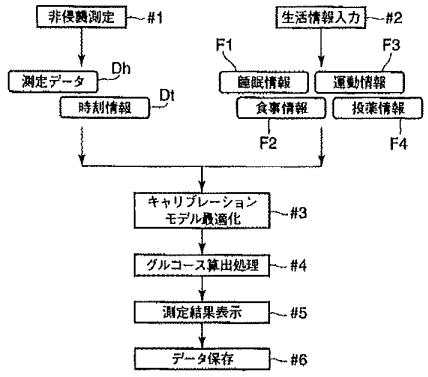
【図2】

図２



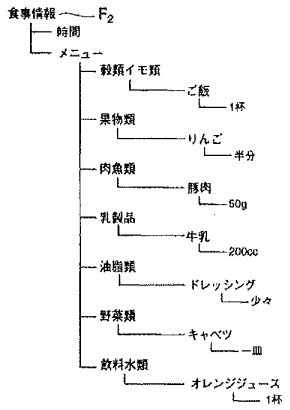
【図3】

図３



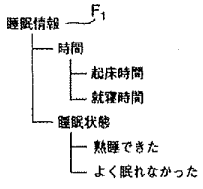
【図4B】

図４Ｂ



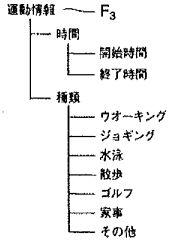
【図4A】

図４Ａ



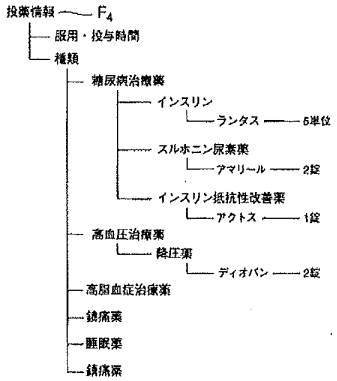
【図4C】

図４Ｃ



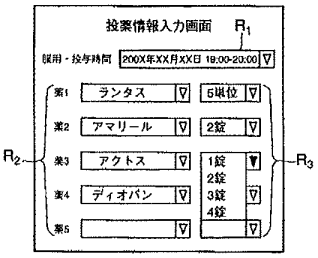
【図4D】

図 4D



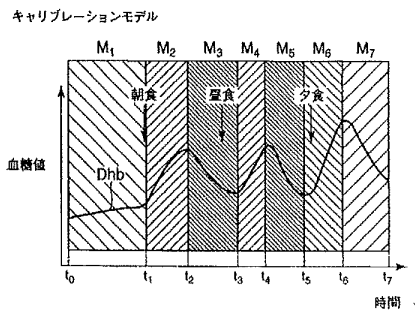
【図5】

図 5



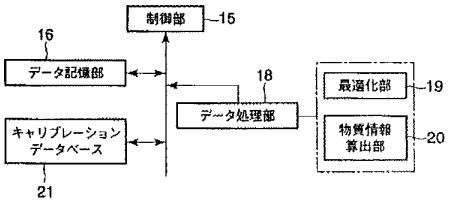
【図6】

図 6



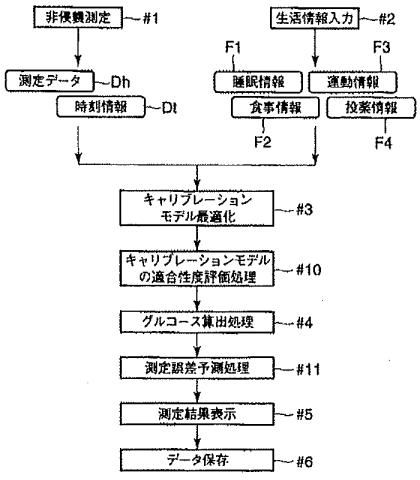
【図7】

図 7



【図8】

図 8



(74)代理人　100075672
　　弁理士　峰　隆司
(74)代理人　100109830
　　弁理士　福原　淑弘
(74)代理人　100084618
　　弁理士　村松　貞男
(74)代理人　100092196
　　弁理士　橋本　良郎
(72)発明者　金山　省一
　　栃木県大田原市下石上１３８５番地　東芝メディカルシステムズ株式会社本社内
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NON-INVASIVE CHARACTERIZATION OF A PHYSIOLOGICAL PARAMETER

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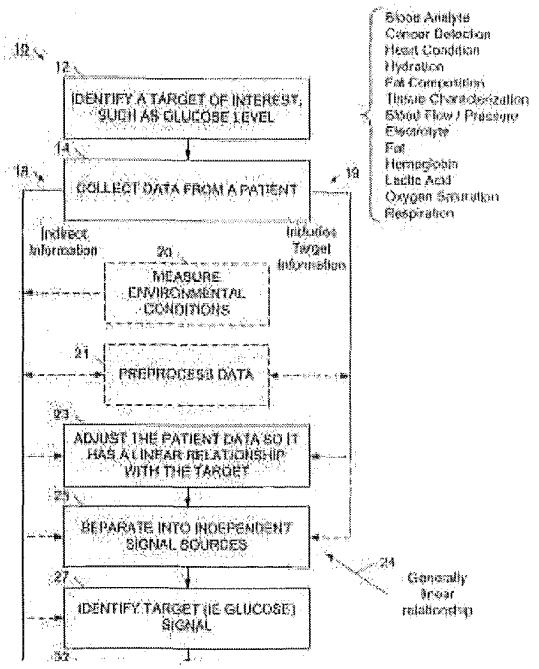

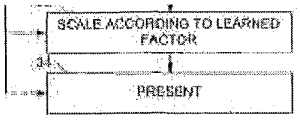

FIG. 1

The present invention provides a method and device for characterizing a physiological parameter. The method, in one application, uses one or more non-invasive sensors to collect patient data, and may also collect data on environmental conditions. At least some of the patient data has a direct relationship with the physiological parameter, that is, a change in the physiological parameter is reflected in the data set, although the magnitude of the physiological parameter may masked by noise, interference, or other environmental or patient influences. The direct patient data preferably has a generally linear relationship with the physiological parameter, and if not, the patient data is linearized according to an algorithm, table, or other adjustment process. These linearizing processes may be predefined, and may adaptively learn or adjust.; A blind signal source process is applied to the linearized data to generate separated signals, and the signal associated with the physiological parameter is identified. The identified signal is scaled or further processed, and the characterization result is presented. Although the method and device are described for use with a human, they may be advantageously used on animals.

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(71)出願人　509311942
シグメッド，インコーポレーティッド
ＳＩＧＭＥＤ，ＩＮＣ．
アメリカ合衆国，カリフォルニア州　９２１３０，サンディエゴ，バレー　センター　ドライブ　３８３０，スイート　７０５－６３２
３８３０　Ｖａｌｌｅｙ　Ｃｅｎｔｅｒ　Ｄｒ．，Ｓｕｉｔｅ　７０５－６３２，Ｓａｎ　Ｄｉｅｇｏ，ＣＡ　９２１３０
(74)代理人　110000202
新樹グローバル・アイピー特許業務法人

最終頁に続く

(54)【発明の名称】生理学的パラメータの非侵襲的特徴決定

(57)【要約】
本発明は、生理学的パラメータを特徴決定するための方法及び装置を提供する。前記方法は、非侵襲的センサーを用いて患者データを収集するが、環境条件についてのデータを収集してもよい。患者データの一部は、前記生理学的パラメータと直接的関係を有し、前記生理学的パラメータの大きさは、ノイズ、干渉又は環境や患者による他の影響によってマスキングされることもあるが、前記生理学的パラメータにおける変化はデータセットに反映される。前記直接患者データは、生理学的パラメータとほぼ線形関係を有するが、そうでない場合は、アルゴリズム等によって線形化される。前記線形化されたデータにブラインド信号源処理を適用することにより、分離信号が生成され、前記生理学的パラメータに付随する信号が同定される。前記同定された信号は、スケーリングされるか、さらに処理され、特徴決定の結果が提示される。

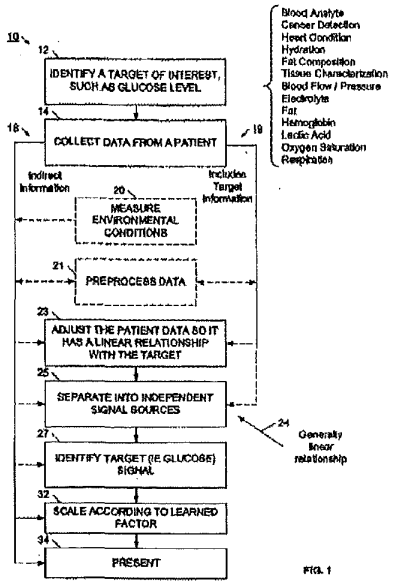


FIG. 1

【特許請求の範囲】
【請求項1】
血中分析物の濃度レベルを推定する方法であって、
患者における複数の変数を非侵襲的に測定し、入力データのセットを得ること、
前記入力データのセットの少なくとも一部を、非線形的にフィルタし、フィルタされたデータのセットを得ること、及び
前記フィルタされたデータのセットに源分離法を適用して出力データのセットを得ることを含み、
前記複数の変数のうち少なくとも１つの第１変数が、患者の血中分析物の濃度レベルに依存し、かつ
前記複数の変数のうち少なくとも１つの第２変数が、患者の血中分析物の濃度レベルに依存しない方法。
【請求項2】
前記血中分析物が、グルコースを含むことを特徴とする請求項１に記載の方法。
【請求項3】
前記源分離法が、少なくとも一部適応的であることを特徴とする請求項１に記載の方法。
【請求項4】
前記非線形的にフィルタリングすることが、少なくとも一部適応的な成分を含むことを特徴とする請求項１に記載の方法。
【請求項5】
前記少なくとも１つの第１変数が、電気インピーダンス変数、静電容量変数、及び電流変数から選択される変数を含むことを特徴とする請求項１に記載の方法。
【請求項6】
前記少なくとも１つの第１変数が、電気インピーダンス変数を含むことを特徴とする請求項１に記載の方法。
【請求項7】
前記少なくとも１つの第１変数が、インピーダンス分光学変数を含むことを特徴とする請求項１に記載の方法。
【請求項8】
前記少なくとも１つの第１変数が、皮膚の静電容量変数を含むことを特徴とする請求項１に記載の方法。
【請求項9】
前記少なくとも１つの第１変数が、前記少なくとも１つの第２変数に依存することを特徴とする請求項１に記載の方法。
【請求項10】
前記複数の変数が、皮膚温度、体温、気温、皮膚水分、血流、血圧、水和変数、ＥＣＧ変数、ＥＥＧ変数、皮膚装置間の圧力変数、装置の移動、気圧、酸素飽和変数、及び湿度から選択される変数を含むことを特徴とする請求項１に記載の方法。
【請求項11】
前記複数の変数が、時刻を含むことを特徴とする請求項１に記載の方法。
【請求項12】
前記非侵襲的に測定することが、少なくとも１対の波長を、エネルギー源から患者の第１の所定領域へ放射させ、患者の第２の所定領域から放出されるエネルギーを検出することを含むことを特徴とする請求項１に記載の方法。
【請求項13】
前記少なくとも１対の波長が、約６００～約１ミリメータの範囲内にあることを特徴とする請求項１２に記載の方法。
【請求項14】

血中分析物に依存する変数を侵襲的に測定することをさらに含むことを特徴とする請求項１に記載の方法。
【請求項15】
前記侵襲的に測定した変数を、前記複数の変数の少なくとも１つと比較することをさらに含むことを特徴とする請求項１４に記載の方法。
【請求項16】
前記侵襲的に測定した変数を、前記フィルタリングされたデータのセットの少なくとも１つの変数と比較することをさらに含むことを特徴とする請求項１４に記載の方法。
【請求項17】
前記侵襲的に測定した変数を、前記出力データのセットの少なくとも１つの変数と比較することをさらに含むことを特徴とする請求項１４に記載の方法。
【請求項18】
前記源分離法が、独立成分分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｃｏｍｐｏｎｅｎｔ　Ａｎａｌｙｓｉｓ、ＩＣＡ）及び独立ベクタ分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｖｅｃｔｏｒ　Ａｎａｌｙｓｉｓ、ＩＶＡ）法の少なくとも一方を含むことを特徴とする請求項１に記載の方法。
【請求項19】
非侵襲的血中分析物モニタ装置であって、
患者における血中分析物の濃度レベルに関連する分析物感受性変数を測定するように構成された分析物感受性測定部と、
患者における血中分析物の濃度レベルに関連する分析物非感受性変数を測定するように構成された分析物非感受性測定部と、
少なくとも１つの変数を非線形的にフィルタリングするように構成された非線形算出部を含む分析物算出部と、を含み、
前記分析物算出部が、前記分析物感受性変数及び前記分析物非感受性変数を入力として受信し、前記患者の血中分析物の推定濃度レベルを算出するように構成されている装置。
【請求項20】
前記血中分析物が、グルコースを含むことを特徴とする請求項１９に記載の装置。
【請求項21】
前記分析物算出部が、少なくとも一部適応的であることを特徴とする請求項１９に記載の装置。
【請求項22】
前記分析物感受性変数が、電気インピーダンス変数、静電容量変数及び電流変数から選択される変数を含むことを特徴とする請求項１９に記載の装置。
【請求項23】
前記分析物感受性変数が、インピーダンス変数を含むことを特徴とする請求項１９に記載の装置。
【請求項24】
前記分析物非感受性変数が、皮膚温度、体温、気温、皮膚水分、水和変数、皮膚装置間の圧力変数、気圧、装置の移動及び湿度から選択される変数を含むことを特徴とする請求項１９に記載の装置。
【請求項25】
前記分析物感受性測定部が、少なくとも１つの電極を含むことを特徴とする請求項１９に記載の装置。
【請求項26】
刺激出力部をさらに含むことを特徴とする請求項１９に記載の装置。
【請求項27】
温度測定部をさらに含むことを特徴とする請求項１９に記載の装置。
【請求項28】
圧力測定部をさらに含むことを特徴とする請求項１９に記載の装置。

【請求項29】
光学センサーをさらに含むことを特徴とする請求項１９に記載の装置。
【請求項30】
前記刺激出力部が少なくとも１つの電極を含むことを特徴とする請求項２４に記載の装置。
【請求項31】
前記非線形的にフィルタリングすることが、前記少なくとも１つの変数の対数をとることを含むことを特徴とする請求項１９に記載の装置。
【請求項32】
前記分析物算出部が、少なくとも２つの信号を分離するように構成されているブラインド源分離モジュールを含むことを特徴とする請求項１９に記載の装置。
【請求項33】
前記ブラインド源分離モジュールが、独立成分分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｃｏｍｐｏｎｅｎｔ　Ａｎａｌｙｓｉｓ、ＩＣＡ）モジュール及び独立ベクタ分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｖｅｃｔｏｒ　Ａｎａｌｙｓｉｓ、ＩＶＡ）モジュールの少なくとも１つを含むことを特徴とする請求項３２に記載の装置。
【請求項34】
ディスプレイ部をさらに含むことを特徴とする請求項１９に記載の装置。
【請求項35】
前記ディスプレイ部が、患者の血中分析物の推定濃度レベルを表示するように構成されていることを特徴とする請求項３１に記載の装置。
【請求項36】
データ保存部をさらに含むことを特徴とする請求項１９に記載の装置。
【請求項37】
前記データ保存部が、血中分析物の推定濃度レベルのデータを保存することを特徴とする請求項３６に記載の装置。
【請求項38】
患者の血中分析物の推定濃度レベルを時間の関数として表示するように構成されたディスプレイ部をさらに含むことを特徴とする請求項３７に記載の装置。
【請求項39】
前記装置が、腕時計を含むことを特徴とする請求項１９に記載の装置。
【請求項40】
患者における血中分析物の濃度レベルを推定する方法であって、
入力変数の第１セットが侵襲的に測定した変数を含まず、
入力変数の第１セットの少なくとも１つの第１変数が、患者の血中分析物の濃度レベルによって影響され、及び
入力変数の第１セットの少なくとも１つの第２変数が、患者の血中分析物の濃度レベルによって影響されない
入力変数の第１セットを受信すること、
入力変数の第１セットの少なくとも１つを前処理して、変数の第２セット生成すること、及び
線形分離法を変数の第２セットに適用して、変数の第３セットを生成すること
を含む方法。
【請求項41】
前記血中分析物が、グルコースを含むことを特徴とする請求項４０に記載の方法。
【請求項42】
前記入力変数の第１セットの少なくとも１つを前処理することが、入力変数の第１セットの少なくとも１つを非線形的に変換することを特徴とする請求項４０に記載の方法。
【請求項43】
前記入力変数の第１セットの少なくとも１つを前処理することが、少なくとも一部適応

的であることを特徴とする請求項４０に記載の方法。
【請求項44】
前記線形分離法が、ブラインド源分離法を含むことを特徴とする請求項４０に記載の方法。
【請求項45】
前記線形分離法が、少なくとも一部適応的であることを特徴とする請求項４０に記載の方法。
【請求項46】
前記ブラインド源分離法が、独立成分分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｃｏｍｐｏｎｅｎｔ　Ａｎａｌｙｓｉｓ、ＩＣＡ）法及び独立ベクタ分析（Ｉｎｄｅｐｅｎｄｅｎｔ　Ｖｅｃｔｏｒ　Ａｎａｌｙｓｉｓ、ＩＶＡ）法の少なくとも一方を含むことを特徴とする請求項４０に記載の方法。
【請求項47】
前記変数の第３セットの少なくとも１つを後処理することをさらに含むことを特徴とする請求項４０に記載の方法。
【請求項48】
非侵襲的に測定した変数と侵襲的に測定した変数の両方を含むテストデータを用いて、前記非線形変換を決定することをさらに含むことを特徴とする請求項４０に記載の方法。
【請求項49】
ニューラルネットワークを用いて、非侵襲的に測定した変数を含むテストデータを侵襲的に測定した変数を含むテストデータと関連付けして、前記非線形変換を決定することをさらに含むことを特徴とする請求項４０に記載の方法。
【請求項50】
非侵襲的に測定した変数と侵襲的に測定した変数の両方を含むテストデータを用いて、前記線形分離法のパラメータを決定することをさらに含むことを特徴とする請求項４０に記載の方法。
【請求項51】
ニューラルネットワークを用い、非侵襲的に測定した変数を含むテストデータを侵襲的に測定した変数を含むテストデータと関連付けし、線形分離のパラメータを決定することをさらに含むことを特徴とする請求項４０に記載の方法。
【請求項52】
前記方法が、コンピュータに実装された方法であることを特徴とする請求項４０に記載の方法。
【請求項53】
対象の生理学的パラメータを特徴決定する方法であって、
対象の生理学的パラメータと直接的関係を有する、患者のデータの第１のデータセットを収集すること、
第２のデータセットを収集すること、
処理済みの第１のデータセットが対象の生理学的パラメータとほぼ線形関係を有するように第１のデータセットを処理すること、
処理済みの第１のデータセットを独立信号に分離すること、
対象の生理学的パラメータをその源として有するパラメータ信号を同定すること、
第２のデータセットに応じてパラメータ信号をスケーリングすること及び
スケーリングしたパラメータを提示することを含む方法。
【請求項54】
前記第１のデータセットを収集することが、光学的、電気的、ＲＦ、赤外センサー、あるいはインピーダンス・センサーを用いることをさらに含むことを特徴とする請求項５３に記載の方法。
【請求項55】
前記第２のデータセットを収集することが、対象の生理学的パラメータと直接的関係を

有するデータのセットであることを特徴とする請求項５３に記載の方法。
【請求項56】
前記第２のデータセットを収集することが、対象の生理学的パラメータと間接的関係を有するデータのセットであることを特徴とする請求項５３に記載の方法。
【請求項57】
前記第２のデータセットを収集することが、対象の生理学的パラメータと直接的関係を有するデータのセットであることを特徴とする請求項５３に記載の方法。
【請求項58】
前記第２のデータセットの収集が、患者からのものであって、生理学的パラメータを示すことを特徴とする請求項５３に記載の方法。
【請求項59】
前記第２のデータセットの収集することが、患者からであって、生理学的パラメータを示さないことを特徴とする請求項５３に記載の方法。
【請求項60】
前記第２のデータセットを収集することが、環境条件を示すことを特徴とする請求項５３に記載の方法。
【請求項61】
処理工程によって前記第１のデータセット内のデータ値が変更されないように、前記第１のデータセットが、対象の生理学的パラメータとほぼ線形関係を有することを特徴とする請求項５３に記載の方法。
【請求項62】
処理工程が、前記第１のデータセットと前記第１のデータセットがほぼ線形関係を有すると決定することを特徴とする請求項５３に記載の方法。
【請求項63】
処理工程が、前記第１のデータセットと前記第１のデータセットがほぼ非線形関係を有すると決定することを特徴とする請求項５３に記載の方法。
【請求項64】
処理工程が、処理済みのデータセットを作成するために、前記第１のデータセットにアルゴリズムあるいはテーブルを適用することを含むことを特徴とする請求項５３に記載の方法。
【請求項65】
前記分離処理が、ブラインド信号分離処理あるいは独立成分分析処理であることを特徴とする請求項５３に記載の方法。
【請求項65】
前記分離処理が、ブラインド信号分離処理あるいは独立成分分析処理であることを特徴とする請求項５３に記載の方法。
【請求項66】
前記分離工程が、前記第２のデータセットに合わせて適応されることを特徴とする請求項５３に記載の方法。
【請求項67】
前記同定工程が、前記第２のデータセットに合わせて適応されることを特徴とする請求項５３に記載の方法。
【請求項68】
前記スケーリング工程が、前記第２のデータセットに合わせて適応されることを特徴とする請求項５３に記載の方法。
【請求項69】
前記提示工程が、視覚的に表示する、音声で伝える、警告を設定する、警告を鳴らす、メッセージを通知する、あるいは他の装置を作動させることを含むことを特徴とする請求項５３に記載の方法。
【請求項70】

対象の生理学的パラメータが、血中分析物、癌検出、心臓の状態、水和状態、脂肪組成、組織特徴決定、血流・血圧、電解液、脂肪、血色素、乳酸、酸素飽和、及び呼吸を含む群から選択されることを特徴とする請求項５３に記載の方法。

【請求項71】

グルコースモニターであって、

ハウジングと、

ＲＦインピーダンス・データを収集する非侵襲的センサーと、

他の患者データを収集する他のセンサーと、

測定したグルコース濃度を提示するハウジング内のディスプレイ、及び

前記ＲＦインピーダンス・データのセットを受信する工程、

前記ＲＦインピーダンス・データをグルコースに線形化する工程、

前記線形化したデータを、ブラインド信号源アルゴリズムを用いて分離する工程、

グルコース信号を同定する工程、

他の患者データに応じて前記グルコース信号をスケーリングする工程、及び

前記スケーリングされたグルコース信号を、測定したグルコース濃度として提示する工程、を行うハウジング内のプロセッサと、

を含むグルコースモニター。

【請求項72】

前記非侵襲的センサーが、前記ハウジング内にあることを特徴とする、請求項７１に記載のグルコースモニター。

【請求項73】

前記他のセンサーが、前記ハウジング内にあることを特徴とする請求項７１に記載のグルコースモニター。

【請求項74】

前記非侵襲的センサーが、前記ハウジング内にあることを特徴とする請求項７１に記載のグルコースモニター。

【請求項75】

前記他のデータが、皮膚温度、皮膚湿度、非侵襲的センサーと皮膚との間の圧力、あるいは周囲温度であることを特徴とする請求項７１に記載のグルコースモニター。

【請求項76】

前記プロセッサが、さらに前記他のデータ用いて前記ＲＦインピーダンス・データのノイズをフィルタリングすることを特徴とする請求項７１に記載のグルコースモニター。

【発明の詳細な説明】

【技術分野】

【0001】

本発明の実施態様は、非侵襲的な装置及びヒトなどの生体内における生理学的パラメータを特徴決定する方法に関する。本発明は、一例において、グルコース濃度などの血中分析物の濃度レベルを推定する装置及び方法を提供する。

【背景技術】

【0002】

糖尿病は、治療法がない慢性疾患である。２００５年には、アメリカ合衆国国民の約２，０８０万人（人口の７％）が糖尿病にかかっていると推定された。糖尿病は、２０００年の病気による死亡原因の第６位として、アメリカ合衆国の医療保険制度に年間推定１，３２０億ドルの負担を与えている。National Diabetes Information Clearinghouse, NIH Publication No. 04-3892, November 2003を参照。糖尿病による経済的費用よりも重大なのは、糖尿病による生活の質の低下、健康における重大な合併症・影響、及び死亡である。

【0003】

糖尿病は、インスリンの生産、インスリンの作用、あるいはその両方の欠損による高血糖値を特徴とする疾病群である。食物の炭水化物は単糖グルコースに変換され、これがベ

ータ細胞にインスリンを血中に放出させる。インスリンは、エネルギー、分子変換または貯蔵のための、他の細胞によるグルコース吸収を可能にする。インスリンは、肝内及び筋細胞内での貯蔵のためのグリコーゲンへのグルコース変換に対する制御を示す。しかしながら、生成されるインスリンの量が十分でない場合、インスリンに欠陥がある場合又は細胞がインスリンに適切に反応しない場合、グルコースが適切に調整されないこともある。これにより、高血糖値、不良なタンパク質合成及びその他の代謝性障害といった結果になることもある。

【0004】

糖尿病患者の高血糖は、心血管疾患、動脈硬化症、失明、脳卒中などの脳血管疾患、高血圧、腎不全、末梢血管疾患及び早世などの、糖尿病の長期作用に関与すると強く疑われている。重度の低血糖でも同様の重篤な結果をもたらす。正常人において、血糖値は、１デシリットル当たり６０～１３０ミリグラムで変動することがあり、分散が１００％を超えているが、糖尿病患者においては場合によって、濃度が１デシリットル当たり４０～５００ミリグラムで変動することがあり、高血糖についての分散は１１５０％である。低血糖については、１デシリットル当たり６０ミリグラムで治療が必要であることを示し、グルコースは、１デシリットル当たり２０ミリグラムという危険な濃度に到達することもある。これらのグルコース濃度の大きな変動は、疾患の病徴や合併症を防ぐためにも回避しなければならない。理想的には、糖尿病患者は、自分の血糖値を簡易的にモニターし、カロリー摂取、食生活及びインスリンを変化させてグルコース濃度を制御することによって、これらの変動を回避することであろう。効果的な制御のためには、血糖を頻繁にモニターしなければならない。

【0005】

現在グルコースをモニターする好ましい手法として、採血法がある。糖尿病患者は、通常手指の表皮を針やランセットで刺し、血液を一滴取り、その血液を化学処理された紙片上に吸収させる。その後、前記片を糖測定器（グルコースの濃度を読み取る分光光度計）に入れることによって、グルコース濃度を読み取ることができ、または前記片の色変化を目盛り付けされた色表と比較することもできる。他には、前記片の電気抵抗を、１デシリットル当たりのミリグラムで目盛り付けされたオームメーターである糖測定器で測定する方法などがある。一部の糖尿病患者は、効果的な制御のために、指頭血を一日４回以上使用しなければならない。

【0006】

しかし、糖尿病患者にとっては多くの場合、このような検査のための採血がたいへん負担になることから、グルコース濃度を定期的にモニターすることができない。手順が侵襲性であるため、並びに頻繁に指先を刺すことに伴う疼痛のため、糖尿病患者はグルコース濃度を日常的にモニターしにくい。さらに、検査に用いる化学試薬は、特に検査回数が多いことを考えると、かなり高価である。従って、糖尿病患者はグルコース濃度を適切にモニターできない場合がある。

【0007】

グルコースなどの分析物の体内濃度をモニターするために、負担がより少ない又は侵襲性がより低いアプローチが多数試行されているが、今のところ成功したものはない。例えば、これらのアプローチは十分に正確でないことが判明したり、環境条件に敏感すぎて測定値が無意味になってしまうということがあった。さらに、被験者において妥当なデータを出力する装置には通常、相当数の較正データが必要となり、数日にわたって多数の較正を行う場合が多い（例えば、血糖値の個数が２０を超える）。限界を別にすれば、グルコースの非侵襲的モニタリングなどの生理学的パラメータの非侵襲的モニタリングは、未だに、糖尿病管理、並びに循環器疾患や一つ以上の生理学的パラメータを使用してモニター又は検出できるその他の疾患の至高の目標となっている。例えば、血中分析物などの生理学的パラメータをモニターする光学技法は、真に非侵襲性である。組織を照射し、吸収された又は分散された放射線を分析し、その情報を処理することにより、皮膚組織内の血中分析物の濃度に比例した測定値が出る。これらの技法には、近赤外線から遠赤外線及びラ

マン分光法、旋光分析法、光散乱法又は光吸収法、及び光音響分光法などがある。

【0008】

多くの注目が集まった１つの非侵襲的アプローチには、組織（皮膚）電気インピーダンス測定などの誘電率測定が関与している。このアプローチでは、複素インピーダンスが幅広い（Ｈｚ～ＭＨｚ～ＧＨｚ～ＴＨｚ）周波数範囲にわたって測定される。インピーダンス分光法では、分析物の変動によって誘導される組織の誘電特性の変化を測定する。低周波数での応答は、水中でのイオン回転によるものと考えられている。この回転は、電解質（ＮａＣｌなど）の濃度及び溶媒の粘度を変化させる物質（グルコースまたは組織水和の変化など）の両方から影響を受けることがある。高周波数での応答は、主に電解質成分の双極子モーメントの変化に起因する。しかしながら、純粋なインピーダンス測定の特異性が低いため、このアプローチが成功する見込みは少ない。これらの問題を克服するために、データは通常、幅広い周波数範囲で取得され（いわゆる、インピーダンス分光法）、部分最小二乗法、主成分分析法及び神経回路網解析を含め、複雑な統計的アルゴリズムによって分析されることが多い。

【0009】

被験者の血糖値を求める皮膚インピーダンスの非侵襲的測定は、例えば、米国特許第５，８９０，４８９号及び第６，５１７，４８２号と、国際特許出願ＰＣＴ／ＵＳ　９８／０２０３７号に記載されている。インピーダンスに基づく技術は、１９２０年代の初期から医学的な目的で使用されてきたが、新しい計器や方法は、ここ数十年になってやっと様々な臨床的応用において利用可能となった。例えば、心肺断層撮影（Ｍｅｔｈｅｒａｌｌら、Ｎａｔｕｒｅ　１９９６；３８０：５０９－　５１２）、皮膚及び組織の水和（例えば、ＰＣＴ出願ＷＯ　０５／０１８４３２号及びＷＯ　０６／０２９０３４号、Ｔａｇａｍｉら、Ｉｎｖｅｓｔ　Ｄｅｒｍａｔｏｌ　１９８０；７５：５００－５０７を参照）、虫歯の検出（Ｌｏｎｇｂｏｔｔｏｍら、Ｎａｔ　Ｍｅｄ　１９９６、２：２３５－２３７）、または新形成の検出（Ｂｒｏｗｎら、Ｌａｎｃｅｔ　２０００、３５５－８９２－８９５；Ａｂｅｒｇら、ＩＥＥＥ　Ｔｒａｎｓ　Ｂｉｏｍｅｄ　Ｅｎｇ　２００４、５１：２０９７－２１０２；Ａｂｅｒｇら、Ｓｋｉｎ　Ｒｅｓ　Ｔｅｃｈｎｏｌ、２００５、１１：２８１－２８６；Ｅｍｔｅｓｔａｍら、Ｓｋｉｎ　Ｒｅｓ　Ｔｅｃｈｎｏｌ　２００７、１３：７３－７８；Ｈｏｐｅ　＆　Ｉｌｅｓ、Ｂｒｅａｓｔ　Ｃａｎｃｅｒ　Ｒｅｓ、２００４：６（２）６９－７４）及び皮膚における各種病理所見（例えば、Ｅｍｔｅｓｔａｍ　＆　Ｎｙｒｅｎ，　Ａｍ　Ｊ　Ｃｏｎｔａｃｔ　Ｄｅｒｍａｔｉｔｉｓ　１９９７、８：２０２－２０６；Ｈａｇｓｔｒｏｍｅｒら、Ｓｋｉｎ　Ｐｈａｒｍａｃｏｌ　Ａｐｐｌ　Ｓｋｉｎ　Ｐｈｙｓｉｏｌ　Ｐｈｙｓｉｏｌ　２００１、１４：２７－３３；Ｎｉｃａｎｄｅｒ、Ｂｒ　Ｊ　Ｄｅｒｍａｔｏｌ　１９９６、１３４：２２１－　２２８；Ｅｍｔｅｓｔａｍら、Ｄｅｒｍａｔｏｌｏｇｙ　１９９８、１９７：３１３－３１６、Ｎｉｃａｎｄｅｒら、Ｓｋｉｎ　Ｒｅｓ　Ｔｅｃｈｎｏｌ　１９９７、３：１２１－１２５１０を参照）が挙げられ、それぞれ参照することにより本明細書に組み込まれる。電磁波を用いる分析物の誘電特性の検討により、血中分析物の実時間検出及び制御について有用な情報が取得できる。これらの検討は、他の応用においても注目されている（ミクロメータ波、ミリメータ・テラヘルツ範囲のＲＦ信号について、例えば、米国仮特許出願第２００６／００２５６６４号、Ｓｉｅｇｅｌ、Ｐ．Ｈ．、ＩＥＥＥ　Ｔｒａｎｓ．　Ｍｉｃｒｏｗａｖｅ　Ｔｈｅｏｒｙ　ａｎｄ　Ｔｅｃｈｎｉｑｕｅｓ、２００４；５２（１０）：２４３８－　２４４７；Ｈｕｏら、ＩＥＥＥ　Ｔｒａｎｓ．　Ｂｉｏｍｅｄ．　Ｅｎｇ．　２００４；５１（７）：１０８９－　１０９４も参照）。

【0010】

したがって、哺乳類の体内の分析物（例えば、グルコース）の濃度などの、生理学的パラメータを測定する又は特徴決定する、非侵襲的でありながら信頼できる方法及び装置が必要とされている。

【発明の開示】

【0011】

本発明は、生理学的パラメータを特徴決定するための方法及び装置を提供する。一応用において、前記方法は、一つ以上の非侵襲的センサーを用いて患者データを収集するが、環境条件についてのデータを収集することもある。前記患者データの少なくとも一部は、前記生理学的パラメータと直接的関係を有し、即ち、前記生理学的パラメータの大きさは、ノイズ、干渉、又は環境や患者による他の影響によってマスキングされることもあるが、前記生理学的パラメータにおける変化は、データセットに反映される。前記直接患者データは、好ましくは生理学的パラメータとほぼ線形関係を有するが、そうでない場合は、前記患者データは、アルゴリズム、テーブル、又はその他の調整処理によって線形化される。これらの線形化処理は、あらかじめ定義されていてもよく、適応的に学習又は調整してもよい。前記線形化されたデータにブラインド信号源処理を適用することにより、分離された信号が生成され、前記生理学的パラメータに付随する信号が同定される。前記同定された信号は、スケーリングされるか、さらに処理され、特徴決定の結果が提示される。ヒトにおける使用に関して前記方法及び装置を説明したが、これらは動物において好適に使用してもよい。

【0012】

本発明は、一例において、グルコース・モニター装置及び方法を提供する。前記グルコース・モニターは、グルコース濃度と直接的関係を有するデータの第１セットを非侵襲的に収集する。データの第１セットは、例えば、ＲＦインピーダンス・データ又は赤外線データであってもよいが、その他多くの種類のデータも使用できる。前記グルコース・モニターはまた、患者又は環境からその他のデータをいくつか収集し、そのデータを使用してデータの第１セットをより効率的に処理する。前記その他のデータは、例えば、皮膚温度、皮膚湿度、非侵襲的センサーと皮膚の間の圧力、または室温であってもよい。前記データの第１セットは、例えば、帯域通過フィルターを介する処理によって、ノイズを減少してから、予め定義されたアルゴリズム又はテーブルに従って線形化されてもよい。一部の例において、線形化処理は、学習することなどによる適応的なものであってもよい。前記線形化されたデータは、グルコース信号が同定される独立成分分析処理に渡される。その後、前記グルコース信号は、例えば、他のデータに従ってスケーリングされ、現在のグルコース濃度として患者に提示される。一例において、前記グルコース装置は、携帯型及び電池式の装置である。他の例では、前記グルコース・モニターは、事務所や病院内で使用するための計器である。

【0013】

有利には、これらの新規の特徴決定方法及び装置は、変動する患者及び環境条件に対して比較的に非感受性である。このおかげで、前記方法及び過程によって、生理学的パラメータをより正確に特徴づけられ、より幅広い範囲の応用において確実な特徴決定が可能になる。一部の応用においては、前記方法及び装置により、完全に非侵襲的な測定が可能になり、患者は疼痛及び恐怖を回避できる。例えば、この方法を使用するグルコース・モニターは完全に非侵襲的であり、針を刺すことによる疼痛やその結果生じる血液による汚れを回避できる。さらに、前記グルコース・モニターは患者条件又は環境条件に対して比較的に非感受性であるため、糖尿病患者は、広範囲の環境においてグルコース・モニターを安心して使うことができる。例えば、前記グルコース・モニターは、患者が寒かろうと、暖かろうと、安静にしていようと、活動していようと、暖かい部屋にいようと、寒い部屋にいようと、高湿度の場所にいようと、乾燥した場所にいようと、朝測定しようと、遅くに測定しようと関係なく、良好な測定値を提示し得る。

【図面の簡単な説明】

【0014】

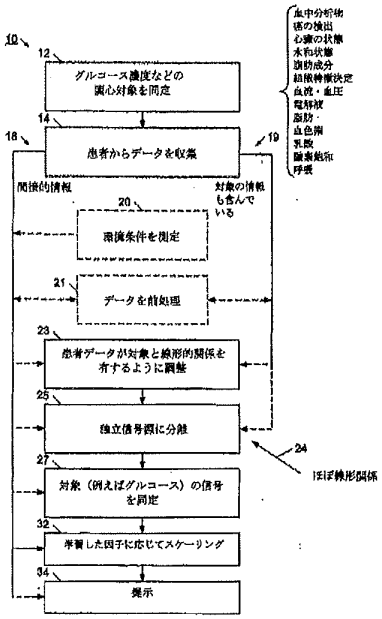
【図1】本発明による対象の生理学的パラメータを特徴決定する過程を示すフローチャートである。

【図2】本発明による対象の生理学的パラメータを特徴決定する過程を示すフローチャートである。

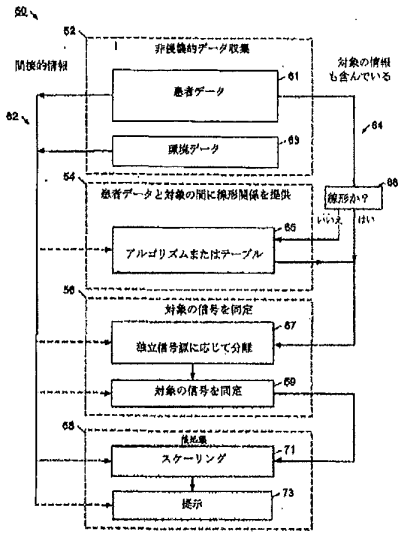
【図3】本発明による血中分析物の濃度レベルを推定する過程を示すフローチャートであ

る。
【図4】本発明による血中分析物の濃度レベルを推定する装置のコンポーネントを示すブロック図である。
【図5】図４の算出部のサブコンポーネントを示すブロック図である。
【図6】本発明によるヒトにおけるグルコース濃度を特徴決定する過程を示すフローチャートである。
【図7】本発明によるグルコースを特徴決定する過程を用いた一実施例のデータ及び結果を示すグラフである。
【図8】本発明によるグルコースを特徴決定する過程を用いた一実施例のデータ及び結果を示すグラフである。
【図9】本発明によるグルコースを特徴決定する過程を用いた一実施例のデータ及び結果を示すグラフである。
【図10】本発明による対象の生理学的パラメータを特徴決定する過程を示すフローチャートである。

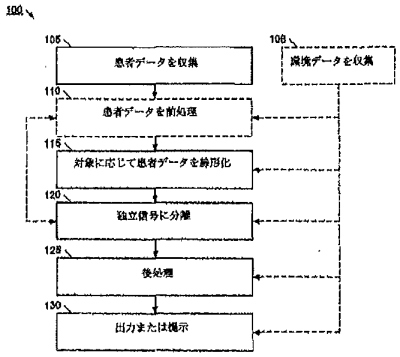
【図1】


10
12
グルコース濃度などの
関心対象を同定
14
患者からデータを収集
18
19
関連的情報
対象の情報
も含んで
いる
20
環境条件を測定
21
データを前処理
23
患者データが対象と線形的関係を
有するように調整
25
独立信号源に分離
24
ほぼ線形関係
27
対象（例えばグルコース）の信号
を同定
32
学習した因子に応じてスケーリング
34
提示
血中分析物
値の検出
心臓の状態
水和状態
脂肪成分
組織特徴決定
血流・血圧
電解質
脂肪
血色素
乳酸
酸素飽和
呼吸

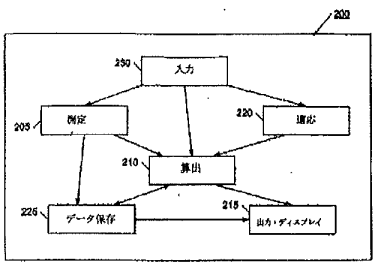
【図2】


50
52
非侵襲的データ収集
関接的情報
対象の情報も含んでいる
患者データ
61
62
環境データ
63
64
54
患者データと対象の間に線形関係を提供
線形か？
66
いいえ
はい
アルゴリズムまたはテーブル
65
56
対象の信号を同定
独立信号源に応じて分離
67
対象の信号を同定
69
68
後処理
スケーリング
71
提示
73

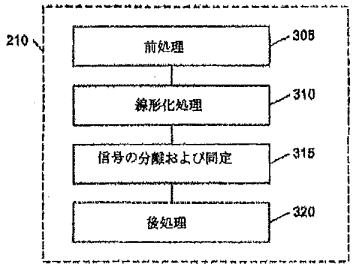
【図3】


100
105
患者データを収集
108
環境データを収集
110
患者データを前処理
115
対象に応じて患者データを終形化
120
独立信号に分離
128
後処理
130
出力または提示

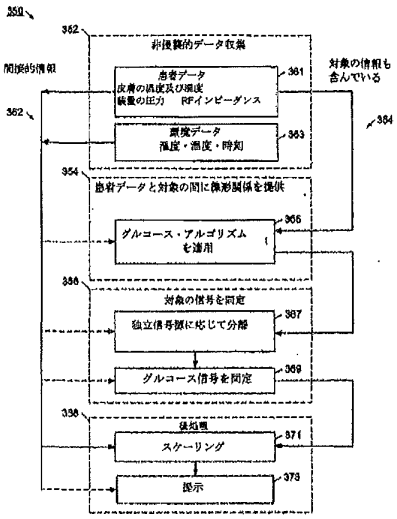
【図4】



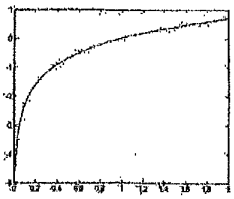
【図5】



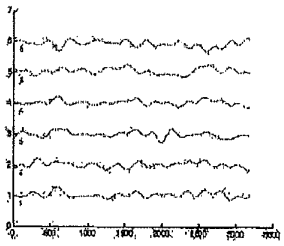
【図6】


350
352
非侵襲的データ収集
間接的情報
患者データ
皮膚の導度及び湿度
筋電の圧力　RFインピーダンス
361
対象の情報も
含んでいる
362
環境データ
湿度・温度・時刻
363
364
354
患者データと対象の間に線形関係を提供
グルコース・アルゴリズム
を適用
365
356
対象の信号を同定
独立信号源に応じて分離
367
グルコース信号を同定
369
358
後処理
スケーリング
371
提示
373

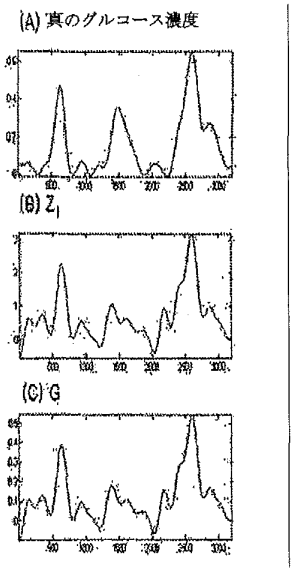
【図7】



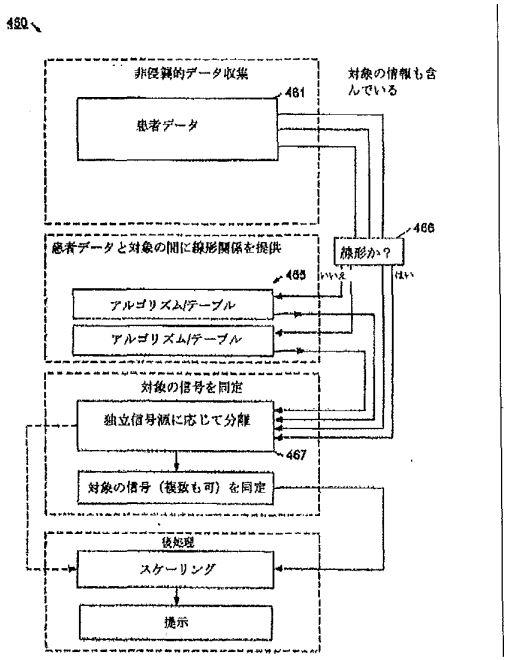
【図8】



【図9】



【図10】


450
非侵襲的データ収集
461
患者データ
対象の情報も含んでいる
466
線形か？
いいえ
はい
患者データと対象の間に線形関係を提供
465
アルゴリズム/テーブル
アルゴリズム/テーブル
対象の信号を同定
独立信号源に応じて分離
467
対象の信号（複数も可）を同定
後処理
スケーリング
提示

【国際調査報告】

【図10】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/63469

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - C12Q 1/54; A61B 5/00 (2008.04)
USPC - 435/14, 600/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - C12Q 1/54; A61B 5/00 (2008.04)
USPC - 435/14, 600/365

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - C12Q 1/54; A61B 5/00 (2008.04) - see keyword below
USPC - 435/14, 600/365; 600/309, 800/347 - see keyword below

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,EPAB,JPAB); Medline, Google
Search terms: analyte, blood, non-invasive, filter, input, data, source separation, output, plurality, adaptive, electric, capacitance, current, spectroscopy, skin, glucose, nonlinearly, Independent Component Analysis , ICA, Independent Vector Analysis, variable, wavelengths

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2002/0161289 A1 (HOPKINS et al.) 31 October 2002 (31.10.2002), entire document especially para [0002], [0008], [0013], [0014], [0021], [0025], [0032], [0033], [0034], [0035], [0036], [0037], [0039], [0042], [0046], and [0047]	1-7, 9, 14, 40-43, 45 --- 8, 10-13, 15-18, 44, 46-52
Y	US 2007/0059196 A1 (BRISTER et al.) 15 March 2007 (15.03.2007), para [0112], [[0256], [0324], [[0327], [0331], [0333], [0351], [0352], [0353], [0453], [0502], and [0535]	8, 10-11, 52
Y	US 2003/0023152 A1 (ABBINK et al.) 30 January 2003 (30.01.2003), para [0018], [0025], [0052], [0053], [0119], and [0243]	12, 13, 15-17, 48-51
Y	US 2004/0148106 A1 (HAHN et al.) 29 July 2004 (29.07.2004), Abstract, para [0006], [0012], and [0033]	18
Y	US 2003/0166996 A1 (KIM et al.) 04 September 2003 (04.09.2003), Abstract, para [0081], and [0082]	44, 46-47
Y	Bota et al. Online workbenches for neural network connections. J Comp Neurol. 2007 Feb, Vol. 500(5), p.807-14. (actual publication date is indicated on secondary prior art document enclosed herein) Abstract; and pg 801, col 1, Computer Science Strategy.	49, 51

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 December 2008 (17.12.2008)	24 DEC 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/63489

Box No. II　Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

Group I Claims 1-18 and 40-52 directed to a method for estimating a concentration level of a blood analyte.

Group II Claims 19-39 directed to a non-invasive blood-analyte-monitoring apparatus.

Group III Claims 53-70 directed to a method for characterizing a target physiological parameter.

Group IV claims 71-76 are directed to a blood glucose monitor.

**********Continued in extra sheet**********

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

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

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

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-18 and 40-52

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/63469

Continuation of:

Box No III (unity of invention is lacking)

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is non-invasively measuring a plurality of variables in a patient to obtain a set of input data which is not present in Groups II-IV. The special technical feature of group II is an analyte-sensitive measuring component configured to measure an analyte -sensitive variable related to a concentration level of the blood analyte in a patient which is not present in Groups I or III - IV. The special technical feature of Group III is collecting a first data set of data from a patient, the first data set having a direct relationship with the target physiological parameter which is not present in Groups I-II or IV. The special technical feature of group IV is a non-invasive sensor collecting RF impedance data which is not present in Groups I-III.

The shared technical feature of Groups I-IV is measuring or collecting data related to physiological parameters. However, this is not an improvement over the prior art of US 20050030764 to Porges et al. (09.02.2005) that teaches a physiological monitoring system having the capability to indicate an accuracy of an estimated physiological condition (abstract, para [0010]).

Form PCT/ISA/210 (extra sheet) (April 2007)

(81)指定国　　AP(BW,GH,GM,KE,LS,MW,MZ,NA,SD,SL,SZ,TZ,UG,ZM,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,BG,CH,CY,CZ,DE,DK,EE,ES,FI,FR,GB,GR,HR,HU,IE,IS,IT,LT,LU,LV,MC,MT,NL,NO,PL,PT,RO,SE,SI,SK,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GQ,GW,ML,MR,NE,SN,TD,TG),AE,AG,AL,AM,AO,AT,AU,AZ,BA,BB,BG,BH,BR,BW,BY,BZ,CA,CH,CN,CO,CR,CU,CZ,DE,DK,DM,DO,DZ,EC,EE,EG,ES,FI,GB,GD,GE,GH,GM,GT,HN,HR,HU,ID,IL,IN,IS,JP,KE,KG,KM,KN,KP,KR,KZ,LA,LC,LK,LR,LS,LT,LU,LY,MA,MD,ME,MG,MK,MN,MW,MX,MY,MZ,NA,NG,NI,NO,NZ,OM,PG,PH,PL,PT,RO,RS,RU,SC,SD,SE,SG,SK,SL,SM,SV,SY,TJ,TM,TN,TR,TT,TZ,UA,UG,US,UZ,VC,VN,ZA,ZM,ZW

(72)発明者　ズーーピン，ジュン
アメリカ合衆国，カリフォルニア州，ガーデン　グローブ，カミニート　デル　マール　サンズ　１２２３５
(72)発明者　ヒョンージン，パク
アメリカ合衆国，カリフォルニア州　９２１３０，サンディエゴ，バレー　センター　ドライブ　３８３０，スイート　７０５－６３２

Ｆターム(参考)　2G059 AA01　AA06　BB13　CC16　HH01　MM01　MM02　PP04
4C038 KK01　KK10　KL05　KL07　KL09　KM01　KM03　KX02

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
9653-12-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2012/046446	**12 JULY 2012 (12.07.2012)**	25 JULY 2011 (25.07.2011)

Applicant

VALENCELL, INC. et al

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of :
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figure is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/046446

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/02(2006.01)i, A61B 5/145(2006.01)i, G06Q 50/24(2012.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/02; A61B 5/107; A61B 5/0245; A61B 5/1477; A61B 5/1455; A61B 5/1495; A61B 5/16; A61B 5/00

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

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: physiological data, circadian rhythm, environmental parameter

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	JP 2007-044203 A (TOSHIBA CORP. et al.) 22 February 2007 See abstract and paragraphs [0011]-[0037].	1-7,9-20,22-26 ,38-41,43-49,51-56 8,21,27-37,42,50
Y	JP 2010-526646 A (SIGMED INC.) 05 August 2010 See abstract and paragraphs [0035]-[0119].	8,21,27-37,42,50
A	JP 2003-159221 A (SHISEIDO CO., LTD.) 03 June 2003 See abstract and paragraphs [0011]-[0017].	1-56
A	JP 2004-283523 A (USHIYAMA YOSHIIISA et al.) 14 October 2004 See abstract and paragraphs [0012]-[0014].	1-56

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 JANUARY 2013 (11.01.2013)	**14 JANUARY 2013 (14.01.2013)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
NA, Sun Hee
Telephone No. 82-42-481-5746

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2012/046446

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2007-044203 A	22.02.2007	JP 4744976 B2	10.08.2011
JP 2010-526646 A	05.08.2010	EP 2152895 A2	17.02.2010
		IL202041D0	16.06.2010
		JP 2010-526646 T	05.08.2010
		US 2010-0324398 A1	23.12.2010
		WO 2008-141306 A2	20.11.2008
		WO 2008-141306 A3	12.02.2009
		WO 2008-141306 A3	20.11.2008
JP 2003-159221 A	03.06.2003	None	
JP 2004-283523 A	14.10.2004	None	

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

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. BOX 37428
RALEIGH, NC 27627

DOCKETED
By PS
Date 10/11/12
ROUTE TO: PMH ☑ MSB ☑

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 9653-13-WO	Date of mailing *(day/month/year)* **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 12/48079	International filing date *(day/month/year)* 25 July 2012 (25.07.2012)
Applicant VALENCELL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer Lee W. Young PCT Helpdesk: 571-272-4300 Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2010)

10-11-12 10:39 RCVD

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. BOX 37428
RALEIGH, NC 27627

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 09 OCT 2012
Applicant's or agent's file reference 9653-13-WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 12/48079	International filing date *(day/month/year)* 25 July 2012 (25.07.2012)
Applicant VALENCELL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450	Authorized officer Lee W. Young PCT Helpdesk: 571-272-4300
Facsimile No. 571-273-3201	Telephone No. PCT OSP: 571-272-7774

Form PCT/ISA/220 (July 2010)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 9653-13-WO	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 12/48079	International filing date *(day/month/year)* 25 July 2012 (25.07.2012)	(Earliest) Priority Date *(day/month/year)* 02 August 2011 (02.08.2011)
Applicant VALENCELL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

DOCKETED
By PS
Date 10/11/12
ROUTE TO:
PMH ☐
MSB ☐
_____ ☐
_____ ☐

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 1

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/48079

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/301
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/301

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/301, 508, 481, 483, 485, 500, 501, 502, 504, 509, 529; 705/2

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB); Google (Patents, Scholar, Web)
Search Terms: Physiological, signal, waveform, electrocardiogram, ECG, electroencephalogram, EEG, photoplethysmograph, PPG, sensor, lung, heart, cardiovascular, pulmonary, signal, waveform, map, mapping, tomogrphay, high, pass, filter, low, variable, adaptable,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ======= Y	US 2010/0222655 A1 (STARR et al.) 02 September 2010 (02.09.2010) Abstract; Fig. 1-2, 9, 13A-14; Para [0020], [0048]-[0049], [0052]-[0053], [0056]-[0058], [0078]-[0080], [0090], [0112]-[0119], [0122]-[0144], [0152]-[0172]	1-4, 11-12, 19, 21-24, 27, 34, 36-40, 50, 52-54, 62 ========== 5-10, 13-18, 20, 25-26, 28-33, 35, 41-49, 51, 55-61, 63
X	US 2004/0133123 A1 (LEONHARDT et al.) 08 July 2004 (08.07.2004) Claim 7, Fig. 1-2; Para [0008], [0018]-[0019], [0025]	1
Y	US 2003/0083583 A1 (KOVTUN et al.) 01 May 2003 (01.05.2003) Para [0026], [0028], [0030], [0033]-[0034]	5-8, 25-26, 41-43, 55
Y	US 2010/0185105 A1 (BALDINGER) 22 July 2010 (22.07.2010) Para [0038], [0197]	9
Y	US 2008/0004536 A1 (BAXI et al.) 03 January 2008 (03.01.2008) Fig. 13A-134B; Para [0052], [0112]-[0118]	10, 17-18, 32-33, 48-49, 60-61
Y	US 2009/0093687 A1 (TELFORT et al.) 09 April 2009 (09.04.2009) Para [0314]	13, 28, 44, 56
Y	US 2007/0088221 A1 (STAHMANN) 19 April 2007 (19.04.2007) Fig. 8-9; Para [0063]-[0064], [0066]-[0068]	14-17, 29-32, 45-48, 57-60
Y	US 2003/0050563 A1 (SURIBHOTLA et al.) 13 March 2003 (13.03.2003) Para [0079]-[0080]	20, 35, 51, 63

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 2012 (20.09.2012)	09 OCT 2012

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. BOX 37428
RALEIGH, NC 27627

DOCKETED
By PS
Date 10/11/12
ROUTE TO:
PMH ☐
MSB ☐
☐
☐

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	09 OCT 2012
Applicant's or agent's file reference 9653-13-WO	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 12/48079	25 July 2012 (25.07.2012)	02 August 2011 (02.08.2011)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/301

Applicant VALENCELL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 *bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to th IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Fom PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	20 September 2012 (20.09.2012)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 12/48079

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

   ☐ on paper

   ☐ in electronic form

   b. (time)

   ☐ in the international application as filed

   ☐ together with the international application in electronic form

   ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 12/48079

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	3, 5-10, 13-18, 20, 24-26, 28-33, 35, 40-49, 51, 54-61, 63	YES
	Claims	1-2, 4, 11-12, 19, 21-23, 27, 34, 36-39, 50, 52-53, 62	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-63	NO
Industrial applicability (IA)	Claims	1-63	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2, 4, 11-12, 19, 21-23, 27, 34, 36-39, 50, 52-53, and 62 lack novelty under PCT Article 33(2) as being anticipated by US 2010/0222655 A1 to Starr et al. (hereinafter: Starr).

As per claim 1, Starr discloses a physiological signal processing system (Abstract) comprising:
a physiological sensor (32, Fig. 1) that is configured to generate a physiological waveform that includes cardiovascular and pulmonary signal components therein (Fig. 1-2; Para [0048]-[0049], [0052]-[0053]);
a variable high pass filter and a variable low pass filter that are responsive to the physiological waveform and that are configured to high pass and low pass filter, respectively, the physiological waveform in response to at least one corner frequency that is applied thereto (Fig. 9; Para [0112]-[0118] - the high pass filter and low pass filter are combined as one digital filter (162, Fig. 9));
a heart rate metric extractor that is responsive to the variable high pass filter and that is configured to extract a heart rate metric from the physiological waveform that is filtered by the variable high pass filter (Fig. 13B; Para [0113], [0116]-[0117]);
a respiration rate metric extractor that is responsive to the variable low pass filter and that is configured to extract a respiration rate metric from the physiological waveform that is filtered by the variable low pass filter (Fig. 13A; Para [0112], [0116]-[0117]); and
a corner frequency adjustor that is responsive to the metric extractor and that is configured to determine the at least one corner frequency that is applied to the variable high pass filter and the variable low pass filter from the heart rate metric (Fig. 13A-13B; Para [0113]-[0119]).

As per claim 2, Starr discloses a physiological signal processing system according to Claim 1, and Starr further discloses wherein the variable high pass filter comprises a single high pass filter and the variable low pass filter comprises a single low pass filter, each having an adjustable corner frequency, and wherein the corner frequency adjustor is configured to determine the adjustable corner frequency for the single high pass filter and the single low pass filter (Fig. 9, 13A-13B; Para [0112]-[0118] - the high pass filter and low pass filter are combined as one digital filter (162, Fig. 9)).

As per claim 4, Starr discloses a physiological signal processing system according to Claim 1, and Starr further discloses wherein the variable high pass filter is responsive to the physiological waveform and is configured to filter the physiological waveform in response to a high pass filter corner frequency that is applied thereto (Fig. 13B; Para [0113], [0116]-[0117]);
wherein the variable low pass filter is responsive to the physiological waveform and is configured to filter the physiological waveform in response to a low pass filter corner frequency that is applied thereto (Fig. 13A; Para [0112], [0116]-[0117]); and
wherein the corner frequency adjustor is configured to determine the high pass filter corner frequency and the low pass filter corner frequency that is applied to the variable high pass filter and the variable low pass filter, respectively, in response to the heart rate metric extracted by the heart rate metric extractor (Fig. 13A-13B; Para [0113]-[0119]).

As per claim 11, Starr discloses a physiological signal processing system according to Claim 1, and Starr further discloses wherein the sensor is a plethysmograph sensor (Abstract; Para [0056]-[0058]).

As per claim 12, Starr discloses a physiological signal processing system according to Claim 11, and Starr further discloses wherein the plethysmograph sensor is a photoplethysmograph sensor (Abstract; Para [0056]-[0058]).

As per claim 19, Starr discloses a physiological signal processing system according to Claim 1, and Starr further discloses wherein the corner frequency adjuster is configured to determine the at least one corner frequency that is applied to the variable high pass filter and the variable low pass filter from the heart rate metric by applying a margin (f.sub.smear, Fig. 13A) to the heart rate metric (Fig. 13A-13B; Para [0112]-[0118], [0126]).

As per claim 21, Starr discloses a physiological signal processing system for a physiological waveform that includes a cardiovascular signal component therein (Abstract), the physiological signal processing system comprising:
a variable high pass filter that is responsive to the physiological waveform and that is configured to high pass filter the physiological waveform in response to a corner frequency that is applied thereto (Fig. 13B; Para [0113], [0116]-[0117]);
a heart rate metric extractor that is responsive to the variable high pass filter and that is configured to extract a heart rate metric from the physiological waveform that is high pass filtered (Fig. 13B; Para [0113], [0116]-[0117]); and
a corner frequency adjustor that is responsive to the heart rate metric extractor and that is configured to determine the corner frequency that is applied to the variable high pass filter, based on the heart rate metric that was extracted (Fig. 13A-13B; Para [0113]-[0119]).

***** Continued on Supplemental *****

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 12/48079

Supplemental Box

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

***** Continuation of V.2. *****

As per claim 22, Starr discloses a physiological signal processing system according to Claim 21, and Starr further discloses wherein the physiological waveform comprises an electrical physiological waveform including an electroencephalogram (EEG), an electrocardiogram (ECG) and/or a radio frequency (RF) waveform, an electro-optical physiological waveform including a photoplethysmograph (PPG) waveform, an electro-photo acoustic waveform including a photo acoustic waveform, an electro-mechanical physiological waveform including an auscultation waveform, a piezo sensor waveform and/or an accelerometer waveform, and/or an electro-nuclear physiological waveform (Abstract; Para [0056]-[0058]).

As per claim 23, Starr discloses a physiological signal processing system according to Claim 21, and Starr further discloses wherein the variable high pass filter comprises a single high pass filter having an adjustable corner frequency (Fig. 9, 13A-13B; Para [0112]-[0118]).

As per claim 27, Starr discloses a physiological signal processing system according to Claim 21, and Starr further discloses further comprising a PPG sensor that is configured to generate the PPG waveform that includes the cardiovascular signal component therein (Abstract; Para [0056]-[0058]).

As per claim 34, Starr discloses a physiological signal processing system according to Claim 21, and Starr further discloses wherein the corner frequency adjuster is configured to determine the corner frequency that is applied to the variable high pass filter from the heart rate metric (f.sub.smear, Fig. 13A) by applying a margin to the heart rate metric (Fig. 13A-13B; Para [0112]-[0118], [0126]).

As per claim 36, Starr discloses a physiological signal processing system according to Claim 21, and Starr further discloses further comprising: a physiological metric assessor that is responsive to the heart rate metric extractor and that is configured to process the heart rate metric to generate at least one physiological assessment (Para [0020], [0152]-[0172]).

As per claim 37, Starr discloses a physiological signal processing system according to Claim 36, and Starr further discloses wherein the at least one physiological assessment includes ventilator threshold, lactate threshold, cardiopulmonary status, neurological status, aerobic capacity (V02 max) and/or overall health or fitness (Para [0020], [0152]-[0172]).

As per claim 38, Starr discloses a physiological signal processing method (Abstract) comprising:
obtaining a physiological waveform that includes cardiovascular and pulmonary signal components therein (Fig. 1-2; Para [0048]-[0049], [0052]-[0053]);
variable high pass and low pass filtering the physiological waveform in response to at least one corner frequency (Fig. 9; Para [0112]-[0118] - the high pass filter and low pass filter are combined as one digital filter (162, Fig. 9));
extracting a heart rate metric from the physiological waveform that is filtered by the variable high pass filtering (Fig. 13B; Para [0113], [0116]-[0117]);
extracting a respiration rate metric from the physiological waveform that is filtered by the variable low pass filtering (Fig. 13A; Para [0112], [0116]-[0117]); and
determining the at least one corner frequency that is applied to the variable high pass and low pass filtering, from the heart rate metric that was extracted (Fig. 13A-13B; Para [0113]-[0119]).

As per claim 39, Starr discloses a physiological signal processing method according to Claim 38, and Starr further discloses wherein the determining comprises adjusting the corner frequency of the variable high pass and low pass filtering (Fig. 9, 13A-13B; Para [0112]-[0118]).

As per claim 50, Starr discloses a physiological signal processing method according to Claim 38, and Starr further discloses wherein the determining the at least one corner frequency that is applied to the variable high pass and low pass filtering from the heart rate metric comprises applying a margin (f.sub.smear, Fig. 13A) to the heart rate metric (Fig. 13A-13B; Para [0112]-[0118], [0126]).

As per claim 52, Starr discloses a physiological signal processing method for a physiological waveform that includes a cardiovascular signal component therein (Abstract), the physiological signal processing method comprising:
high pass filtering the physiological waveform in response to an adjustable high pass filter corner frequency (Fig. 13B; Para [0113], [0116]-[0117]);
extracting a heart rate metric from the physiological waveform that is high pass filtered (Fig. 13B; Para [0113], [0116]-[0117]); and
determining the adjustable high pass filter corner frequency that is applied to the high pass filtering, from the heart rate metric that was extracted (Fig. 13A-13B; Para [0113]-[0119]).

As per claim 53, Starr discloses a physiological signal processing method according to Claim 52, and Starr further discloses wherein the determining comprises adjusting a high pass filter corner frequency of a single high pass filter (Fig. 9, 13A-13B; Para [0112]-[0118]).

As per claim 62, Starr discloses a physiological signal processing method according to Claim 52, and Starr further discloses wherein the determining the corner frequency that is applied to the variable high pass filtering from the heart rate metric comprises applying a margin (f.sub.smear, Fig. 13A) to the heart rate metric (Fig. 13A-13B; Para [0112]-[0118], [0126]).

***** Continued on Supplemental *****

Supplemental Box

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

***** Continuation of V.2. *****

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by US 2004/0133123 A1 to Leonhardt et al. (hereinafter: Leonhardt).

As per claim 1, Leonhardt discloses a physiological signal processing system (Abstract) comprising:
a physiological sensor (E1-En, Fig. 1) that is configured to generate a physiological waveform that includes cardiovascular and pulmonary signal components therein (Fig. 1-2; Para [0018]-[0019]);
a variable high pass filter and a variable low pass filter that are responsive to the physiological waveform and that are configured to high pass and low pass filter, respectively, the physiological waveform in response to at least one corner frequency that is applied thereto (Claim 7; Para [0008], [0025]);
a heart rate metric extractor that is responsive to the variable high pass filter and that is configured to extract a heart rate metric from the physiological waveform that is filtered by the variable high pass filter (Claim 7; Para [0008], [0025]);
a respiration rate metric extractor that is responsive to the variable low pass filter and that is configured to extract a respiration rate metric from the physiological waveform that is filtered by the variable low pass filter (Para [0025]); and
a corner frequency adjustor that is responsive to the metric extractor and that is configured to determine the at least one corner frequency that is applied to the variable high pass filter and the variable low pass filter from the heart rate metric (Para [0025]).

Claims 3, 24, 40, 54 lack inventive step under PCT Article 33(3) as being obvious in view of Starr.

As per claim 3, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not directly disclose wherein the variable high pass filter comprises a plurality of high pass filters and the variable low pass filter comprises a plurality of low pass filters, a respective one of which includes a different corner frequency, and wherein the corner frequency adjustor is configured to select one of the plurality of high pass filters and one of the plurality of low pass filters that corresponds to the at least one corner frequency that is determined by the corner frequency adjustor.
Starr discloses something similar where multiple low pass filters can be used to filter the signal of noise and wherein the system uses them to pass signals less than the chosen cutoff frequency (Para [0078]-[0080], [0090]). It would have been obvious to one of ordinary skill in the art that selective use of low pass filters to pass signals less than the chosen cutoff frequency may be applied to the high pass filter system as well.

As per claim 24, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not directly disclose wherein the variable high pass filter comprises a plurality of high pass filters, a respective one of which includes a different value of the corner frequency, and wherein the corner frequency adjustor is configured to select one of the plurality of high pass filters that corresponds to the corner frequency that is determined.
Starr discloses something similar where multiple low pass filters can be used to filter the signal of noise and wherein the system uses them to pass signals less than the chosen cutoff frequency (Para [0078]-[0080], [0090]). It would have been obvious to one of ordinary skill in the art that selective use of low pass filters to pass signals less than the chosen cutoff frequency may be applied to the high pass filter system as well.

As per claim 40, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not directly disclose wherein the determining comprises selecting one of a plurality of high pass and low pass filters that corresponds to the at least one corner frequency that is determined.
Starr discloses something similar where multiple low pass filters can be used to filter the signal of noise and wherein the system uses them to pass signals less than the chosen cutoff frequency (Para [0078]-[0080], [0090]). It would have been obvious to one of ordinary skill in the art that selective use of low pass filters to pass signals less than the chosen cutoff frequency may be applied to the high pass filter system as well.

As per claim 54, Starr discloses a physiological signal processing method according to Claim 52, but Star does not directly disclose wherein the determining comprises selecting one of a plurality of high pass filters that corresponds to the corner frequency that is determined.
Starr discloses something similar where multiple low pass filters can be used to filter the signal of noise and wherein the system uses them to pass signals less than the chosen cutoff frequency (Para [0078]-[0080], [0090]). It would have been obvious to one of ordinary skill in the art that selective use of low pass filters to pass signals less than the chosen cutoff frequency may be applied to the high pass filter system as well.

***** Continued on Supplemental *****

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
***** Continuation of V.2. *****

Claims 5-8, 25-26, 41-43, 55 lack inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2003/0083583 A1 to Kovtun et al. (hereinafter: Kovtun).

As per claim 5, Starr discloses a physiological signal processing system according to Claim 2, but Starr does not expressly disclose wherein the variable high pass filter comprises a variable digital high pass filter having a plurality of high pass delay taps and the variable low pass filter comprises a variable digital low pass filter having a plurality of low pass delay taps, and wherein the adjustable corner frequency is determined by a number of the high pass and low pass delay taps that are selected to filter the physiological waveform.
However, Kovtun teaches wherein the variable high pass filter comprises a variable digital high pass filter having a plurality of high pass delay taps and the variable low pass filter comprises a variable digital low pass filter having a plurality of low pass delay taps, and wherein the adjustable corner frequency is determined by a number of the high pass and low pass delay taps that are selected to filter the physiological waveform (Para [0026], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the digital filter of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 6, Starr and Kovtun disclose a physiological signal processing system according to Claim 5, and Starr further discloses wherein the corner frequency adjustor comprises a mapping system that is configured to map the heart rate metric that is extracted from the physiological waveform (Fig. 10-11, 13A-14; Para [0107], [0112]-[0118], [0120]). Starr does not expressly disclose that is filtered into the number of the delay taps that are selected to filter the physiological waveform.
However, Kovtun teaches that is filtered into the number of the delay taps that are selected to filter the physiological waveform (Para [0028], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr and Kovtun with the delay taps of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 7, Starr and Kovtun disclose a physiological signal processing system according to Claim 6, and Starr further discloses wherein the mapping system is configured to determine a corner frequency of the variable digital low pass filter and the variable digital high pass filter by determining a maximum of a minimum heart rate and the heart rate metric minus a margin (Para [0112]-[0118]). Starr does not expressly disclose and is further configured to determine the number of delay taps by rounding a product of the delay of the delay taps and the minimum heart rate divided by the corner frequency that was determined.
Kovtun discloses something similar wherein determining the number of taps may include consideration of the processing capability of the system and the transition between the pass region and the stop region (Para [0033]). It would have been obvious to one of ordinary skill in the art that form follows function that that although Kovtun does not disclose an exact formula, it teaches the same concept in that an appropriate number of taps is applied to the signal to reduce the noise and provide a sharper image and that different formulae may be used to derive the number of taps.

As per claim 8, Starr and Kovtun disclose a physiological signal processing system according to Claim 6, and Starr further discloses wherein the mapping system is configured to determine a corner frequency of the variable low pass filter and the variable high pass filter by applying a margin to the heart rate metric (Para [0112]-[0118]). Starr does not expressly disclose and is further configured to determine the number of delay taps from the corner frequency that was determined.
However, Kovtum teaches and is further configured to determine the number of delay taps from the corner frequency that was determined (Para [0033] - transition between pass and stop regions is a consideration for the number of taps).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr and Kovtun with the delay taps of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 25, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not expressly disclose wherein the variable high pass filter comprises a variable digital high pass filter having a plurality of delay taps and wherein the corner frequency corresponds to a number of the plurality of delay taps that are selected to filter the physiological waveform.
However, Kovtun teaches wherein the variable high pass filter comprises a variable digital high pass filter having a plurality of delay taps and wherein the corner frequency corresponds to a number of the plurality of delay taps that are selected to filter the physiological waveform (Para [0026], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the digital filter of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 26, Starr and Kovtun disclose a physiological signal processing system according to Claim 25, and Starr further discloses wherein the corner frequency adjustor comprises a mapping system that is configured to map the heart rate metric that is extracted from the physiological waveform (Fig. 10-11, 13A-14; Para [0107], [0112]-[0118], [0120]). Starr does not expressly disclose that is filtered into the number of the delay taps that are selected to filter the physiological waveform.
However, Kovtun teaches that is filtered into the number of the delay taps that are selected to filter the physiological waveform (Para [0028], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr and Kovtun with the delay taps of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 41, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not expressly disclose wherein the determining comprises determining a number of a plurality of high pass and low pass delay taps that are selected by the variable high pass and low pass filtering.
However, Kovtun teaches wherein the determining comprises determining a number of a plurality of high pass and low pass delay taps that are selected by the variable high pass and low pass filtering (Para [0026], [0030], [0033]-[0034]). It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the digital filter of Kovtun as it allows for integrated removal of noise from the signal.
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Supplemental Box

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As per claim 42, Starr and Kovtun disclose a physiological signal processing method according to Claim 41, and Starr further discloses wherein the determining comprises mapping the heart rate metric (Fig. 10-11, 13A-14; Para [0107], [0112]-[0118], [0120]). Starr does not expressly disclose into the number of the delay taps.
However, Kovtun teaches into the number of the delay taps (Para [0028], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the system of Starr and Kovtun with the delay taps of Kovtun as it allows for integrated removal of noise from the signal.

As per claim 43, Starr and Kovtun disclose a physiological signal processing method according to Claim 42, and Starr further discloses wherein the mapping comprises: determining a corner frequency of the variable low pass and the variable high pass filtering by applying a margin to the heart rate metric (Para [0112]-[0118]).
Starr does not expressly disclose and determining the number of delay taps from the corner frequency.
Kovtun discloses something similar wherein determining the number of taps may include consideration of the processing capability of the system and the transition between the pass region and the stop region (Para [0033]). It would have been obvious to one of ordinary skill in the art that form follows function that that although Kovtun does not disclose an exact formula, it teaches the same concept in that an appropriate number of taps is applied to the signal to reduce the noise and provide a sharper image and that different formulae may be used to derive the number of taps.

As per claim 55, Starr discloses a physiological signal processing method according to Claim 52, but Starr does not expressly disclose wherein the determining comprises determining a number of a plurality of delay taps that are selected in the filtering.
However, Kovtun teaches wherein the determining comprises determining a number of a plurality of delay taps that are selected in the filtering (Para [0026], [0030], [0033]-[0034]).
It would have been obvious to one of ordinary skill in the art to combine the method of Starr with the digital filter of Kovtun as it allows for integrated removal of noise from the signal.

Claim 9 lacks inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2010/0185105 A1 (Baldinger)

As per claim 9, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the corner frequency adjuster includes hysteresis.
Baldinger discloses something similar wherein the system includes a voltage comparator with hysteresis to compared filtered signals (Para [0038], [0197]). It would have been obvious to one of ordinary skill in the art that comparing the filtered signals would include comparing the corner frequency. It would have been further obvious to one of ordinary skill in the art to combine the system of Starr with the hysteresis of Baldinger as it allows for a comparison of corner frequencies between filtered signals, which may aid in error detection and noise reduction.

Claims 10, 18, 33, 49, 61 lack inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2008/0004536 A1 to Baxi et al. (hereinafter: Baxi).

As per claim 10, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the at least one corner frequency comprises a same corner frequency that is applied to the variable high pass and low pass filters.
However, Baxi teaches wherein the at least one corner frequency comprises a same corner frequency that is applied to the variable high pass and low pass filters (Para [0048]). It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the frequency management of Baxi as it allows easy of separating the signals between the that pertaining to pulmonary function and that pertaining to cardiac function, as illustrated in Starr (Fig. 13A-134B; Para [0112]-[0118]).

As per claim 18, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to set at least one predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological sensor is not responsive to a source of the physiological waveform.
However, Baxi teaches wherein the corner frequency adjuster is configured to set at least one predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological sensor is not responsive to a source of the physiological waveform (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the system of Starr with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

As per claim 33, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to set a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological sensor is not responsive to a source of the physiological waveform.
However, Baxi teaches wherein the corner frequency adjuster is configured to set a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological sensor is not responsive to a source of the physiological waveform (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the system of Starr with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

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Supplemental Box

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As per claim 49, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not expressly disclose further comprising: setting a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological waveform is no longer being obtained.
However, Baxi teaches further comprising: setting a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological waveform is no longer being obtained (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the method of Starr with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

As per claim 61, Starr discloses a physiological signal processing method according to Claim 52, but Starr does not expressly disclose further comprising: setting a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological waveform is no longer being determined.
However, Baxi teaches further comprising: setting a predetermined corner frequency corresponding to a predetermined heart rate in response to determining that the physiological waveform is no longer being determined (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the method of Starr with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

Claims 13, 28, 44, 56 lack inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2009/0093687 A1 Telfort et al. (hereinafter: Telfort).

As per claim 13, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to reduce locking on an erroneous heart rate metric. However, Telfort discloses something similar wherein the system adjusts an amplifier if the signal exceeds a predetermined threshold level, such as that caused by talking coughing or similar as they present erroneous signals to acoustic sensors (Para [0314]). It would have been obvious to one of ordinary skill in the art to incorporate method of detecting error in the signal in the system of Starr so that the system did not lock on or process the erroneous signal, just as Telfort does with the acoustic signal.

As per claim 28, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to reduce locking on an erroneous heart rate metric. However, Telfort discloses something similar wherein the system adjusts an amplifier if the signal exceeds a predetermined threshold level, such as that caused by talking coughing or similar as they present erroneous signals to acoustic sensors (Para [0314]). It would have been obvious to one of ordinary skill in the art to incorporate method of detecting error in the signal in the system of Starr so that the system did not lock on or process the erroneous signal, just as Telfort does with the acoustic signal.

As per claim 44, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not expressly disclose wherein the determining comprises reducing locking on an erroneous heart rate metric.
However, Telfort discloses something similar wherein the system adjusts an amplifier if the signal exceeds a predetermined threshold level, such as that caused by talking coughing or similar as they present erroneous signals to acoustic sensors (Para [0314]). It would have been obvious to one of ordinary skill in the art to incorporate method of detecting error in the signal in the system of Starr so that the method did not lock on or process the erroneous signal, just as Telfort does with the acoustic signal.

As per claim 56, Starr discloses a physiological signal processing method according to Claim 52, but Starr does not expressly disclose wherein the determining comprises reducing locking on an erroneous heart rate metric.
However, Telfort discloses something similar wherein the system adjusts an amplifier if the signal exceeds a predetermined threshold level, such as that caused by talking coughing or similar as they present erroneous signals to acoustic sensors (Para [0314]). It would have been obvious to one of ordinary skill in the art to incorporate method of detecting error in the signal in the method of Starr so that the system did not lock on or process the erroneous signal, just as Telfort does with the acoustic signal.

Claims 14-16, 29-31, 45-47, 57-59 lack inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2007/0088221 A1 (Stahmann).

As per claim 14, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to initially set at least one predetermined corner frequency corresponding to a predetermined heart rate prior to determining the at least one corner frequency that is applied to the variable high pass filter and the variable low pass filter from the heart rate metric.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.
It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the predetermined and heart rate based frequencies of Stahmann as it allows the system to use the patient's own base physiological signal as the base line.

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As per claim 15, Starr and Stahmann disclose a physiological signal processing system according to Claim 14, but neither directly disclose wherein the predetermined heart rate is a resting heart rate.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.

As per claim 16, Starr and Stahmann disclose a physiological signal processing system according to Claim 14, and Stahmann further discloses wherein the corner frequency adjuster is configured to initially set the at least one predetermined corner frequency corresponding to the predetermined heart rate until the heart rate metric extractor locks on a heart rate in the physiological waveform (Fig. 9; Para [0066]-[0068]).

As per claim 29, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not expressly disclose wherein the corner frequency adjuster is configured to initially set a predetermined corner frequency corresponding to a predetermined heart rate prior to determining the corner frequency that is applied to the variable high pass filter from the heart rate metric.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.
It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the predetermined and heart rate based frequencies of Stahmann as it allows the system to use the patient's own base physiological signal as the base line.

As per claim 30, Starr and Stahmann disclose a physiological signal processing system according to Claim 29, but neither directly disclose wherein the predetermined heart rate is a resting heart rate.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.

As per claim 31, Starr and Stahmann disclose a physiological signal processing system according to Claim 29, and Stahmann discloses wherein the corner frequency adjuster is configured to initially set the predetermined corner frequency corresponding to the predetermined heart rate until the heart rate metric extractor locks on a heart rate in the physiological waveform (Fig. 9; Para [0066]-[0068]).

As per claim 45, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not expressly disclose further comprising: initially setting a predetermined corner frequency corresponding to a predetermined heart rate prior to the determining the at least one corner frequency that is applied to the variable high pass and low pass filtering from the heart rate metric.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.
It would have been obvious to one of ordinary skill in the art to combine the method of Starr with the predetermined and heart rate based frequencies of Stahmann as it allows the system to use the patient's own base physiological signal as the base line.

As per claim 46, Starr and Stahmann disclose a physiological signal processing method according to Claim 45, but neither directly disclose wherein the predetermined heart rate is a resting heart rate.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.

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As per claim 47, Starr and Stahmann disclose a physiological signal processing method according to Claim 45, and Stahmann further discloses wherein the initially setting comprises initially setting the predetermined corner frequency corresponding to the predetermined heart rate until the extracting locks on a heart rate in the physiological waveform (Fig. 9; Para [0066]-[0068]).

As per claim 57, Starr discloses a physiological signal processing method according to Claim 52, but Starr does not expressly disclose further comprising: initially setting a predetermined corner frequency corresponding to a predetermined heart rate prior to the determining the at least one corner frequency that is applied to the variable high pass filtering from the heart rate metric.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.
It would have been obvious to one of ordinary skill in the art to combine the system of Starr with the predetermined and heart rate based frequencies of Stahmann as it allows the system to use the patient's own base physiological signal as the base line.

As per claim 58, Starr and Stahmann disclose a physiological signal processing method according to Claim 57, but neither directly discloses wherein the predetermined heart rate is a resting heart rate.
However, Stahmann discloses something similar wherein the filters for the cardiac and respiratory signals are each of function of the heart rate and are each adjusted in response to a substantial change in the detected heart rate (Fig. 9; Para [0066]-[0068]), and in a second embodiment predetermined pass bands are utilized to filter a physiological signal (Fig. 8; Para [0063]-[0064]). It would have been obvious to one of ordinary skill in the art that and adaptive filter would have a starting point and the heart rate, particularly the resting heart rate, provides the metric for the predetermined frequency as it is the body's natural state of lowest activity and the state a subject naturally regresses towards. Combining the embodiments of Stahmann more clearly applies a predetermined frequency from which the system adapts.

As per claim 59, Starr and Stahmann disclose a physiological signal processing method according to Claim 57, and Stahmann further discloses wherein the initially setting comprises initially setting the predetermined corner frequency corresponding to the predetermined heart rate until the extracting locks on a heart rate in the physiological waveform (Fig. 9; Para [0066]-[0068]).

Claims 20, 35, 51, 63 lack inventive step under PCT Article 33(3) as being obvious over Starr in view of US 2003/0050563 A1 to Suribhotla et al. (hereinafter: Suribhotla).

As per claim 20, Starr discloses a physiological signal processing system according to Claim 1, but Starr does not expressly disclose wherein the variable high pass filter includes a gradual filter transition band. However, Suribhotla teaches something similar wherein the adaptive filter adjust filter coefficients gradually (Para [0079]-[0080]). It would have been obvious to one of ordinary skill in the art that the gradual filter transition band of Suribhotla could be applied to a high pass filter.
It would have been further obvious to one of ordinary skill in the art to combine the system of Starr with the gradual filter transition band of Suribhotla as it allows the system to sequentially apply multiple coefficients so that it does not overshoot a desired corner/cutoff point.

As per claim 35, Starr discloses a physiological signal processing system according to Claim 21, but Starr does not expressly disclose wherein the variable high pass filter includes a gradual filter transition band.
Suribhotla teaches something similar wherein the adaptive filter adjust filter coefficients gradually (Para [0079]-[0080]). It would have been obvious to one of ordinary skill in the art that the gradual filter transition band of Suribhotla could be applied to a high pass filter.
It would have been further obvious to one of ordinary skill in the art to combine the system of Starr with the gradual filter transition band of Suribhotla as it allows the system to sequentially apply multiple coefficients so that it does not overshoot a desired corner/cutoff point.

As per claim 51, Starr discloses a physiological signal processing method according to Claim 38, but Starr does not expressly disclose wherein the variable high pass filtering comprises a gradual filter transition band.
Suribhotla teaches something similar wherein the adaptive filter adjust filter coefficients gradually (Para [0079]-[0080]). It would have been obvious to one of ordinary skill in the art that the gradual filter transition band of Suribhotla could be applied to a high pass filter.
It would have been further obvious to one of ordinary skill in the art to combine the method of Starr with the gradual filter transition band of Suribhotla as it allows the system to sequentially apply multiple coefficients so that it does not overshoot a desired corner/cutoff point.

As per claim 63, Starr discloses a physiological signal processing method according to Claim 52, but Starr does not expressly disclose wherein the variable high pass filtering comprises a gradual filter transition band.
Suribhotla teaches something similar wherein the adaptive filter adjust filter coefficients gradually (Para [0079]-[0080]). It would have been obvious to one of ordinary skill in the art that the gradual filter transition band of Suribhotla could be applied to a high pass filter.
It would have been further obvious to one of ordinary skill in the art to combine the method of Starr with the gradual filter transition band of Suribhotla as it allows the system to sequentially apply multiple coefficients so that it does not overshoot a desired corner/cutoff point.

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Claims 17, 32, 48, 60 lack inventive step under PCT Article 33(3) as being obvious over Starr and Stahmann in view of Baxi.

As per claim 17, Starr and Stahmann disclose a physiological signal processing system according to Claim 14, but neither expressly disclose wherein the corner frequency adjuster is configured to reset the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological sensor is no longer responsive to a source of the physiological waveform.
However, Baxi teaches wherein the corner frequency adjuster is configured to reset the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological sensor is no longer responsive to a source of the physiological waveform (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the system of Starr and Stahmann with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

As per claim 32, Starr and Stahmann disclose a physiological signal processing system according to Claim 29, but neither expressly disclose wherein the corner frequency adjuster is configured to reset the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological sensor is no longer responsive to a source of the physiological waveform.
However, Baxi teaches wherein the corner frequency adjuster is configured to reset the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological sensor is no longer responsive to a source of the physiological waveform (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the system of Starr and Stahmann with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

As per claim 48, Starr and Stahmann disclose a physiological signal processing method according to Claim 45, but neither expressly disclose further comprising: resetting the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological waveform is no longer being obtained.
However, Baxi teaches further comprising: resetting the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological waveform is no longer being obtained (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the method of Starr and Stahmann with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

As per claim 60, Starr and Stahmann disclose a physiological signal processing method according to Claim 57, but neither expressly disclose further comprising: resetting the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological waveform is no longer being obtained.
However, Baxi teaches further comprising: resetting the predetermined corner frequency corresponding to the predetermined heart rate in response to determining that the physiological waveform is no longer being obtained (Para [0052]). It would have been obvious to one of ordinary skill in the art combine the method of Starr and Stahmann with the reinitialization system of Baxi as it allows the filter(s) to return to their baseline parameters and restart data acquisition after they cease providing accurate data.

Claims 1-63 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

SEARCH HISTORY

Application Number	PCT/US 12/48079
Search Conducted By	WIA
Search Approved By	CJE

US/IPC Classifications Searched	IPC(8) - A61B 5/00 (2012.01) USPC - 600/301
Date Conducted	19 September 2012 (19.09.20120)

Documentation Searched	IPC(8) - A61B 5/00 (2012.01) USPC - 600/301, 508, 481, 483, 485, 500, 501, 502, 504, 509, 529; 705/2
Search Terms Used	Physiological, signal, waveform, electrocardiogram, ECG, electroencephalogram, EEG, photoplethysmograph, PPG, sensor, lung, heart, cardiovascular, pulmonary, signal, waveform, map, mapping, tomogrphay, high, pass, filter, low, variable, adaptable, plural, multiple, many, gradual, transition, band, corner, cutoff, cut off, break, frequency, response, react, input, trigger, hysteresis, lock, prevent, reduce, initial, predetermined, rest, digital, delay, tap, rate, respiration, breathing, ventilator, lactate, threashold, cardiopulmonary, neurological, status, aerobic, capacity, fitness,
Date Conducted	19 September 2012 (19.09.20120); 20 September 2012 (20.09.20120)

Electronic Database Searched	PubWEST
Files Searched	PGPB, USPT, EPAB, JPAB
Date Conducted	19 September 2012 (19.09.20120); 20 September 2012 (20.09.20120)
Search Logic:	

SEARCH HISTORY

DB=PGPB,USPT,EPAB,JPAB; PLUR=YES; OP=ADJ

L128	L127 AND L90	36	L128	L128
L127	L126 AND L89	36	L127	L127
L126	L125 AND L121	46	L126	L126
L125	L105 AND (((ventilator OR lactate) ADJ threshold) OR ((cadiopulmonary OR neurological) ADJ status) OR (aerobic ADJ capacity) OR fitness)	48	L125	L125
L124	L123 AND ((respiration OR breath$) NEAR2 rate)	16	L124	L124
L123	L121 AND ((map OR mapping OR tomograph$) WITH (heart OR cardiovascular))	55	L123	L123
L122	L121 AND (margin WITH (heart OR rate))	0	L122	L122
L121	L102 AND (heart NEAR2 rate)	833	L121	L121
L120	L119 AND ((filter NEAR2 digital) WITH (delay OR tap))	3	L120	L120
L119	L118 AND (filter NEAR2 digital)	31	L119	L119
L118	L102 AND (filter WITH (adjust$ OR react$ OR respon$ OR variable OR adapt$) WITH (waveform))	137	L118	L118
L117	L105 AND (margin WITH (heart OR rate))	0	L117	L117
L116	L88 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH heart WITH rest$)	2	L116	L116
L115	L112 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH heart WITH rest$)	0	L115	L115
L114	L88 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L114	L114
L113	L112 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L113	L113
L112	L105 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$))	40	L112	L112
L111	L108 AND (lock$ WITH (signal OR waveform))	4	L111	L111
L110	L108 AND (lock$ WITH (prevent$ OR reduc$))	2	L110	L110
L109	L108 AND hysteresis	2	L109	L109
L108	L106 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (adjust$ OR alter$ OR chang$ OR variable OR adapt$))	48	L108	L108
L107	L106 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (respon$ OR react$ OR input$ OR trigger$) WITH ((physiological OR lung OR heart OR cardiovascular OR pulmonary) WITH (signal OR waveform) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG))	19	L107	L107
L106	L105 AND (((corner OR cutoff OR "cut off" OR break) ADJ	135	L106	L106

SEARCH HISTORY

	frequency) WITH (respon$ OR react$ OR input$ OR trigger$ OR adapt$))			
L105	L102 AND ((corner OR cutoff OR "cut off" OR break) ADJ frequency)	639	L105	L105
L104	L103 AND ((low ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	9	L104	L104
L103	L102 AND ((variable OR adapt$) NEAR3 (low ADJ pass ADJ filter))	38	L103	L103
L102	L96 AND (low ADJ pass ADJ filter)	1544	L102	L102
L101	L96 AND (gradual WITH filter)	11	L101	L101
L100	L88 AND (gradual ADJ filter ADJ transition ADJ band)	0	L100	L100
L99	L96 AND (gradual ADJ filter ADJ transition ADJ band)	0	L99	L99
L98	L97 AND ((high ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	6	L98	L98
L97	L96 AND ((variable OR adapt$) NEAR3 (high ADJ pass ADJ filter))	60	L97	L97
L96	L88 AND (high ADJ pass ADJ filter)	2273	L96	L96
L95	L91 AND (sensor WITH (photoplethysmograph OR PPG))	38	L95	L95
L94	L93 AND (sensor WITH (photoplethysmograph OR PPG))	7	L94	L94
L93	L92 AND waveform	45	L93	L93
L92	L91 AND ((signal OR waveform) WITH (lung OR pulmonary))	63	L92	L92
L91	L90 AND ((map OR mapping OR tomograph$) WITH (heart OR cardiovascular))	744	L91	L91
L90	L89 AND ((signal OR waveform) WITH (heart OR cardiovascular))	7723	L90	L90
L89	L88 AND (sensor WITH (lung OR heart OR cardiovascular OR pulmonary))	10673	L89	L89
L88	((physiological WITH (signal OR waveform)) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG)	101448	L88	L88
L87	L52 AND L63	1	L87	L87
L86	L85 AND L52	15	L86	L86
L85	L62 AND (((ventilator OR lactate) ADJ threshold) OR ((cadiopulmonary OR neurological) ADJ status) OR (aerobic ADJ capacity) OR fitness)	17	L85	L85
L84	L82 AND L83	1	L84	L84
L83	L81 AND ((respiration OR breath$) NEAR2 rate)	92	L83	L83
L82	L81 AND ((map OR mapping OR tomograph$) WITH (heart OR cardiovascular))	4	L82	L82
L81	L62 AND (heart NEAR2 rate)	173	L81	L81
L80	L62 AND ((filter NEAR2 digital) WITH (delay OR tap))	0	L80	L80

SEARCH HISTORY

L79	L78 AND ((filter NEAR2 digital) WITH (delay OR tap))	0	L79	L79
L78	L62 AND (filter NEAR2 digital)	67	L78	L78
L77	L62 AND (filter WITH (adjust$ OR react$ OR respon$ OR variable OR adapt$) WITH (waveform))	13	L77	L77
L76	L67 AND (margin WITH (heart OR rate))	0	L76	L76
L75	L51 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH heart WITH rest$)	0	L75	L75
L74	L67 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$))	11	L74	L74
L73	L67 AND (lock$ WITH (signal OR waveform))	4	L73	L73
L72	L67 AND (lock$ WITH (prevent$ OR reduc$))	1	L72	L72
L71	L67 AND hysteresis	5	L71	L71
L70	L68 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (adjust$ OR alter$ OR chang$ OR variable OR adapt$))	7	L70	L70
L69	L68 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (respon$ OR react$ OR input$ OR trigger$) WITH ((physiological OR lung OR heart OR cardiovascular OR pulmonary) WITH (signal OR waveform) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG))	2	L69	L69
L68	L67 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (respon$ OR react$ OR input$ OR trigger$ OR adapt$))	16	L68	L68
L67	L62 AND ((corner OR cutoff OR "cut off" OR break) ADJ frequency)	141	L67	L67
L66	L62 AND ((low ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	7	L66	L66
L65	L51 AND (gradual WITH filter)	7	L65	L65
L64	L60 AND L63	0	L64	L64
L63	L62 AND ((variable OR adapt$) NEAR3 (low ADJ pass ADJ filter))	1	L63	L63
L62	L59 AND (low ADJ pass ADJ filter)	326	L62	L62
L61	L59 AND ((high ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	16	L61	L61
L60	L59 AND ((variable OR adapt$) NEAR3 (high ADJ pass ADJ filter))	5	L60	L60
L59	L51 AND (high ADJ pass ADJ filter)	452	L59	L59
L58	L55 AND (sensor WITH (photoplethysmograph OR PPG))	12	L58	L58
L57	L56 AND waveform	6	L57	L57
L56	L55 AND ((signal OR waveform) WITH (lung OR pulmonary))	7	L56	L56
L55	L54 AND ((map OR mapping OR tomograph$) WITH (heart	73	L55	L55

SEARCH HISTORY

	OR cardiovascular))			
L54	L53 AND ((signal OR waveform) WITH (heart OR cardiovascular))	1268	L54	L54
L53	L51 AND (sensor WITH (lung OR heart OR cardiovascular OR pulmonary))	2409	L53	L53
L52	L51 AND ((physiological WITH (signal OR waveform)) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG)	5038	L52	L52
L51	((A61B005/00)[ipc] OR (600/301)[ccls])	31625	L51	L51
L50	L2 AND L20	6	L50	L50
L49	L48 AND L22	30	L49	L49
L48	L47 AND L2	42	L48	L48
L47	L46 AND L42	44	L47	L47
L46	L16 AND (((ventilator OR lactate) ADJ threshold) OR ((cadiopulmonary OR neurological) ADJ status) OR (aerobic ADJ capacity) OR fitness)	52	L46	L46
L45	L44 AND L43	4	L45	L45
L44	L42 AND ((respiration OR breath$) NEAR2 rate)	153	L44	L44
L43	L42 AND ((map OR mapping OR tomograph$) WITH (heart OR cardiovascular))	18	L43	L43
L42	L16 AND (heart NEAR2 rate)	388	L42	L42
L41	L40 AND ((filter NEAR2 digital) WITH (delay OR tap))	12	L41	L41
L40	L16 AND (filter NEAR2 digital)	170	L40	L40
L39	L16 AND (filter WITH (adjust$ OR react$ OR respon$ OR variable OR adapt$) WITH (waveform))	31	L39	L39
L38	L22 AND (margin WITH (heart OR rate))	2	L38	L38
L37	L1 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH heart WITH rest$)	1	L37	L37
L36	L31 AND ((frequency) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L36	L36
L35	L31 AND ((corner OR cutoff OR "cut off" OR break) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L35	L35
L34	L1 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L34	L34
L33	L31 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH heart WITH rest$)	0	L33	L33
L32	L31 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$) WITH heart WITH rest$)	0	L32	L32
L31	L22 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (initial OR predetermin$))	25	L31	L31

SEARCH HISTORY

L30	L22 AND (lock$ WITH (signal OR waveform))	7	L30	L30
L29	L22 AND (lock$ WITH (prevent$ OR reduc$))	1	L29	L29
L28	L25 AND (lock$ WITH (prevent$ OR reduc$))	1	L28	L28
L27	L22 AND hysteresis	9	L27	L27
L26	L25 AND hysteresis	0	L26	L26
L25	L23 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (adjust$ OR alter$ OR chang$ OR variable OR adapt$))	27	L25	L25
L24	L23 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (respon$ OR react$ OR input$ OR trigger$) WITH ((physiological OR lung OR heart OR cardiovascular OR pulmonary) WITH (signal OR waveform) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG))	14	L24	L24
L23	L22 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH (respon$ OR react$ OR input$ OR trigger$ OR adapt$))	54	L23	L23
L22	L16 AND ((corner OR cutoff OR "cut off" OR break) ADJ frequency)	323	L22	L22
L21	L16 AND ((low ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	19	L21	L21
L20	L19 AND ((variable OR adapt$) NEAR3 (low ADJ pass ADJ filter))	8	L20	L20
L19	L9 AND ((variable OR adapt$) NEAR3 (high ADJ pass ADJ filter))	24	L19	L19
L18	L16 AND ((variable OR adapt$) WITH (low ADJ pass ADJ filter))	41	L18	L18
L17	L16 AND ((variable OR adapt$) ADJ low ADJ pass ADJ filter)	1	L17	L17
L16	L9 AND (low ADJ pass ADJ filter)	719	L16	L16
L15	L1 AND (gradual WITH filter)	16	L15	L15
L14	L1 AND (gradual ADJ filter)	0	L14	L14
L13	L1 AND (gradual ADJ filter ADJ transition ADJ band)	0	L13	L13
L12	L9 AND (gradual ADJ filter ADJ transition ADJ band)	0	L12	L12
L11	L9 AND ((high ADJ pass ADJ filter) WITH (plural$ OR multiple OR many))	35	L11	L11
L10	L9 AND ((variable OR adapt$) ADJ high ADJ pass ADJ filter)	4	L10	L10
L9	L1 AND (high ADJ pass ADJ filter)	1056	L9	L9
L8	L5 AND (sensor WITH (photoplethysmograph OR PPG))	27	L8	L8
L7	L6 AND waveform	13	L7	L7
L6	L5 AND ((signal OR waveform) WITH (lung OR pulmonary))	16	L6	L6
L5	L4 AND ((map OR mapping OR tomograph$) WITH (heart OR cardiovascular))	229	L5	L5

SEARCH HISTORY

L4	L3 AND ((signal OR waveform) WITH (heart OR cardiovascular))	2902	L4	L4
L3	L1 AND (sensor WITH (lung OR heart OR cardiovascular OR pulmonary))	4579	L3	L3
L2	L1 AND ((physiological WITH (signal OR waveform)) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG)	9862	L2	L2
L1	((A61B005/00)[ipc] OR (600/301 | 600/508 | 600/481 | 600/483 | 600/485 | 600/500 | 600/501 | 600/502 | 600/504 | 600/509 | 600/529 | 705/2)[ccls])	45762	L1	L1

DB=PGPB,USPT,EPAB,JPAB; PLUR=YES; OP=ADJ

L13	L6 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH ("same" OR identical) WITH high WITH low WITH pass WITH filter)	5	L13	L13
L12	L9 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH ("same" OR identical) WITH high WITH low)	2	L12	L12
L11	L10 NOT L5	4	L11	L11
L10	L9 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) NEAR3 ("same" OR identical))	11	L10	L10
L9	L8 AND ((corner OR cutoff OR "cut off" OR break) ADJ frequency)	641	L9	L9
L8	L7 AND (low ADJ pass ADJ filter)	1548	L8	L8
L7	L6 AND (high ADJ pass ADJ filter)	2278	L7	L7
L6	((physiological WITH (signal OR waveform)) OR electrocardiogram OR ECG OR electroencephalogram OR EEG OR photoplethysmograph OR PPG)	101573	L6	L6
L5	L4 AND (((corner OR cutoff OR "cut off" OR break) ADJ frequency) WITH ("same" OR identical))	10	L5	L5
L4	L3 AND ((corner OR cutoff OR "cut off" OR break) ADJ frequency)	324	L4	L4
L3	L2 AND (low ADJ pass ADJ filter)	720	L3	L3
L2	L1 AND (high ADJ pass ADJ filter)	1057	L2	L2
L1	((A61B005/00)[ipc] OR (600/301 | 600/508 | 600/481 | 600/483 | 600/485 | 600/500 | 600/501 | 600/502 | 600/504 | 600/509 | 600/529 | 705/2)[ccls])	45796	L1	L1

Electronic Database Searched	Google

SEARCH HISTORY

Files Searched	Google Patents
Date Conducted	18 September 2012 (18.09.20120); 20 September 2012 (20.09.20120)

Search Logic:

- "high pass filter" "low pass filter" (cardiac | heart) signal waveform
- About 594 results (0.31 seconds)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency
- About 134 results (0.32 seconds)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency variable
- About 25 results (0.38 seconds)
- (physiological | heart | pulmonary) (signal | waveform) filter predetermined
- About 17,200 results (0.32 seconds)
- (physiological | heart | pulmonary) (signal | waveform) filter predetermined "heart rate"
- About 5,880 results (0.49 seconds)
- (physiological | heart | pulmonary) (signal | waveform) filter predetermined "heart rate" (cutoff | corner)
- About 538 results (0.34 seconds)
- (physiological | heart | pulmonary) (signal | waveform) filter (cutoff | corner) (same | identical)
- About 1,260 results (0.40 seconds)

Electronic Database Searched	Google
Files Searched	Google Scholar
Date Conducted	18 September 2012 (18.09.20120)

Search Logic:

- "high pass filter" "low pass filter" (cardiac | heart) signal waveform
- About 3,120 results (0.09 sec)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency
- About 1,510 results (0.08 sec)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency variable
- About 923 results (0.09 sec)

SEARCH HISTORY

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	18 September 2012 (18.09.20120)
Search Logic:	

- "high pass filter" "low pass filter" (cardiac | heart) signal waveform
- About 135,000 results (0.36 seconds)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency
- About 81,000 results (0.51 seconds)
- "high pass filter" "low pass filter" (cardiac | heart) signal waveform (corner | cutoff | break) frequency variable
- About 65,000 results (0.44 seconds)

********** SUPPLEMENTAL SEARCH **********

Electronic Database Searched	Thomson Innovation
Files Searched	US Grant, WO App, FR App, US App, GB App, DE Util, EP Grant, CA Grant, DE Grant, EP App, CA App, DE App, JP App, KR Grant, KR App, Other, JP Grant, CN App, CN Util, JP Util, KR Util , DWPI
Date Conducted	26 September 2012 (26.09.2012)
Search Logic:	

Patent

No.	Results	Collections	Search Query
12	40	JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI	(UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR

AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (high ADJ pass OR low ADJ pass OR band ADJ pass) SAME (heart ADJ rate* OR respirat* OR pulmonar* OR cardiovascular* OR cardiopulmonar*)) AND ALL=(photoplethysmograph OR plethysmograph);

11 271 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (high ADJ pass OR low ADJ pass OR band ADJ pass) SAME (heart ADJ rate* OR respirat* OR pulmonar* OR cardiovascular* OR cardiopulmonar*));

10 1641 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (high ADJ pass OR low ADJ pass OR band ADJ pass));

9 59 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (high ADJ pass OR low ADJ pass OR band ADJ pass)) AND ALL=((variab* OR adjust*) NEAR5 (cut ADJ off OR cutoff OR corner) ADJ frequenc*);

8 30 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Ot

SEARCH HISTORY

her,DWPI (UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (high ADJ pass AND low ADJ pass)) AND ALL=((variab* OR adjust*) NEAR5 (cut ADJ off OR cutoff OR corner) ADJ frequenc*);

7 19 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301 ADJ 600508 or 600481 or 600483 or 600485 or 600500 or 600501 or 600502 or 600504 or 600509 or 600529 or 705002) OR AIOE=(A61B000500)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (cardio* OR pulmonar* OR heart ADJ rate* OR respirat*)) AND ALL=((variab* OR adjust*) NEAR5 (cut ADJ off OR cutoff OR corner) ADJ frequenc*);

6 6 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (cardio* OR pulmonar* OR heart ADJ rate* OR respirat*)) AND ALL=((variab* OR adjust*) NEAR5 (cut ADJ off OR cutoff OR corner) ADJ frequenc*);

5 108 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301)) AND ALL=((variab* OR adjust*) SAME (filter*) SAME (cardio* OR pulmonar* OR heart ADJ rate* OR respirat*));

4 357 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301)) AND ALL=((variab* OR adjust*) SAME (filter*));

SEARCH HISTORY

3 3215 JP Util,JP App,KR App,KR Grant,JP Grant,CN App,CN Util,KR Util ,US Grant,US App,CA App,CA Grant,WO App,EP Grant,EP App,DE Grant,DE App,DE App,DE Util,GB App,FR App,Other,DWPI (UC=(600301));

2 135 All pns=(US2010/0222655 US2004/0133123 US2003/0083583 US2010/0185105 US2008/0004536 US2009/0093687 US2007/0088221 US2003/0050563);

1 135 All pns=(US2010/0222655 US2004/0133123 US2003/0083583 US2010/0185105 US2008/0004536 US2009/0093687 US2007/0088221 US2003/0050563);

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. Box 37428
Raleigh, North Carolina 27627

05-15-08 A09:11 IN

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 9653.3.WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US07/25114	International filing date *(day/month/year)* 07 December 2007
Applicant VALENCELL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

M

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. Box 37428
Raleigh, North Carolina 27627

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing *(day/month/year)*	13 MAY 2008
Applicant's or agent's file reference 9653.3.WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US07/25114	International filing date *(day/month/year)* 07 December 2007
Applicant VALENCELL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 9653.3.WO	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US07/25114	International filing date *(day/month/year)* 07 December 2007	(Earliest) Priority Date *(day/month/year)* 19 December 2006
Applicant VALENCELL, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows:

DOCKETED
By SD
Date 5/15

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant

☐ as selected by this Authority, because the applicant failed to suggest a figure

☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US07/25114

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 05/00 (2008.04)
USPC - 600/301
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 05/00 (2008.04)
USPC - 600/301

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 2004/0242976 A1 (ABREU) 02 December 2004 (02.12.2004) see whole document	1-8, 13, 18-24, 26-44, 47-51, 54-59, 61-77, 79-89 and 91-92 --- 9-12, 14-17, 25, 45-46, 52-53, 60, 78 and 90
Y	US 2005/0148883 A1 (BOESEN) 07 July 2005 (07.07.2005) see whole document	9-12, 14-17, 60 and 78
Y	US 2006/0084878 A1 (BANET et al) 20 April 2006 (20.04.2006) see whole document	45-46, 52 and 90
Y	US 2004/0186390 A1 (ROSS et al) 23 September 2004 (23.09.2004) see whole document	25 and 53

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 April 2008	13 MAY 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.
P.O. Box 37428
Raleigh, North Carolina 27627

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	13 MAY 2008
Applicant's or agent's file reference 9653.3.WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US07/25114	07 December 2007	19 December 2006

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 05/00 (2008.04)
USPC - 600/301

Applicant VALENCELL, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

NSB DOCKETED
By SD
Date 5/15

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	19 April 2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/25114

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US07/25114

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	9-12, 14-17, 25, 45-46, 52-53, 60, 78 and 90	YES
	Claims	1-8, 13, 18-24, 26-44, 47-51, 54-59, 61-77, 79-89 and 91-92	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-92	NO
Industrial applicability (IA)	Claims	1-92	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-8, 13, 18-24, 26-44, 47-51, 54-59, 61-77, 79-89 and 91-92 lack novelty under PCT Article 33(2) as being anticipated by Abreu (US 2004/0242976 A1).

Regarding claim 1, Abreu discloses a personal monitoring apparatus (Abstract), comprising: a housing configured to be attached to the body of a person (Abstract and Paragraph [0039]); at least one physiological sensor supported by the housing (Paragraphs [0039-0040]), wherein each physiological sensor is configured to detect and/or measure physiological information from a person (Paragraphs [0039-0040], [0088] and [0113]); at least one environmental sensor supported by the housing (Paragraph [0076]), wherein each environmental sensor is configured to detect and/or measure environmental conditions in a vicinity of a person (Abstract and Paragraph [0076], [0096] and [0100]); a signal processor supported by the housing and configured to receive and process signals produced by the physiological and environmental sensors (Fig. 13 and Paragraphs [0316-0318]); and a transmitter responsive to the signal processor that is configured to transmit physiological and environmental sensor signals as processed by the signal processor from the signal processor to a remote terminal (Abstract, Fig. 13 and Paragraph [0059]).

Regarding claim 2, Abreu discloses the apparatus of Claim 1, wherein the transmitter is configured to transmit signals from the signal processor to the remote terminal in real time (Abstract, Fig. 13 and Paragraph [0059] and [0095]).

Regarding claim 3, Abreu discloses the apparatus of Claim 1, wherein the signal processor is configured to process signals produced by the physiological and environmental sensors into signals that can be heard and/or viewed by the person (Abstract and Paragraph [0071]).

Regarding claim 4, Abreu discloses the apparatus of Claim 1, wherein the signal processor is configured to selectively extract environmental effects from signals produced by a physiological sensor (Paragraph [0446] and [0500]).

Regarding claim 5, Abreu discloses the apparatus of Claim 1, wherein the signal processor is configured to selectively extract physiological effects from signals produced by an environmental sensor (Paragraph [0446] and [0500]).

Regarding claim 6, Abreu discloses the apparatus of Claim 1, wherein a physiological sensor is oriented in a direction towards the person, wherein an environmental sensor is oriented in a direction away from the person, and wherein a buffer material is positioned between the physiological sensor and environmental sensors (Figs. 22A-C and Paragraphs [0355-0357]; the physiological sensor is attached to the skin of the user while the environmental sensor is connected to the rim of the glasses near the temple).

Regarding claim 7, Abreu discloses the apparatus of Claim 6, wherein the buffer material is configured to selectively reflect and/or absorb energy emanating from the environment and/or the person (Paragraph [0132]).

Regarding claim 8, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person (Paragraph [0039]), wherein a physiological sensor is an acoustical sensor oriented in a direction towards a tympanic membrane of the ear and is configured to detect acoustical (Paragraph [0525]) energy emanating from the tympanic membrane (Paragraph [0039-0040]; headphones and ear wrap sensors would sense tympanic (ear drum) activity), wherein an environmental sensor is an acoustical sensor and is oriented in a direction away from the person (Figs. 22A-C and Paragraphs [0355-0357]; the physiological sensor is attached to the skin of the user while the environmental sensor is connected to the rim of the glasses near the temple), and wherein the processor is configured to utilize signals produced by the environmental sensor to extract environmental acoustical (Paragraph [0525]) energy not emanating from the tympanic membrane from signals produced by the physiological sensor (Paragraph [0446] and [0500]).

Regarding claim 13, Abreu discloses the apparatus of Claim 8, further comprising an optical detector supported by the housing that is configured to detect acoustically (Paragraph [0525]) modulated blackbody IR radiation emanating from the tympanic membrane (Paragraph [0119]).

Regarding claim 18, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person, and wherein a physiological sensor comprises an optical detector that is configured to detect acoustically (Paragraph [0525]) modulated blackbody IR radiation emanating from the tympanic membrane (Paragraph [0119]).

(Continued in Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V
2. Citations and Explanations:

Regarding claim 19, Abreu discloses the apparatus of Claim 1, wherein the signal processor utilizes one or more filters to process signals produced by the physiological and environmental sensors (Paragraph [0393] and [0422]).

Regarding claim 20, Abreu discloses the apparatus of Claim 1, further comprising a receiver configured to receive audio and/or video information from a remote terminal (Abstract, Fig. 13 and Paragraph [0071]), and further comprising a communication module supported by the housing and that is configured to store and/or process and/or play audio and/or video information received from the remote terminal (Abstract, Paragraphs [0071], [0076] and [0485]).

Regarding claim 21, Abreu discloses the apparatus of Claim 1, further comprising a communication module supported by the housing and that is configured to alert the person when a physiological sensor detects certain physiological information from the person (Paragraph [0080]) and/or when an environmental sensor detects certain environmental information from the vicinity of the person (Paragraph [0091]).

Regarding claim 22, Abreu discloses the apparatus of Claim 21, wherein the communication module is configured to provide audible and/or visible alerts and/or physical alerts (Abstract, Paragraphs [0071], [0076] and [0485]).

Regarding claim 23, Abreu discloses the apparatus of Claim 21, wherein the communication module is configured to audibly present vital sign information to the person (Abstract, Paragraphs [0071], [0076] and [0485]).

Regarding claim 24, Abreu discloses the apparatus of Claim 21, wherein the communication module is configured to store content generated by the person and/or by the at least one physiological and environmental sensors (Abstract, Paragraphs [0071], [0076] and [0485]).

Regarding claim 26, Abreu discloses the apparatus of Claim 1, further comprising an ear hook that extends from the housing and that is configured to attach the housing to an ear of a person (Paragraph [0039]).

Regarding claim 27, Abreu discloses the apparatus of Claim 26, wherein the housing is configured to be positioned in adjacent contacting relationship with the temple of the person (Paragraph [0039]).

Regarding claim 28, Abreu discloses the apparatus of Claim 26, further comprising a physiological sensor and/or an environmental sensor supported by the ear hook (Paragraph [0039]).

Regarding claim 29, Abreu discloses the apparatus of Claim 26, wherein the hook comprises a pinna cover that is configured to contact a portion of the pinna of an ear, and wherein a physiological sensor (Abstract and Paragraphs [0039-0040]) and/or an environmental sensor (Paragraph [0076]) is supported by the pinna cover (Paragraph [0039]; contacts an ear wrap or headphones, both of which would act as a pinna cover).

Regarding claim 30, Abreu discloses the apparatus of Claim 1, wherein the housing is an earring (Paragraph [0039]).

Regarding claim 31, Abreu discloses the apparatus of Claim 1, further comprising an earring that is configured to be attached to an ear of a person (Paragraph [0039]), wherein the earring comprises an environmental sensor that is configured to detect and/or measure environmental conditions in a vicinity of the person (Paragraph [0076]), and wherein the signal processor is configured to receive and process signals produced by the earring environmental sensor (Abstract, Fig. 13 and Paragraph [0059]).

Regarding claim 32, Abreu discloses the apparatus of Claim 1, further comprising an earring that is configured to be attached to an ear of a person (Paragraph [0039]), wherein the earring comprises a physiological sensor (Abstract and Paragraphs [0039-0040]) that is configured to detect and/or measure physiological information from the person, and wherein the signal processor is configured to receive and process signals produced by the earring physiological sensor (Abstract, Fig. 13 and Paragraph [0059]).

Regarding claim 33, Abreu discloses the apparatus of Claim 1, further comprising an arm that extends from the housing and that supports one or more physiological sensors and/or environmental sensors (Figs. 22A-C and Paragraphs [0355-0357]; the physiological sensor is attached to the inner portion of the glasses while the environmental sensor is connected to the rim of the glasses near the temple).

Regarding claim 34, Abreu discloses the apparatus of Claim 33, wherein the arm supports physiological sensors configured to detect and/or measure jaw motion and/or arterial blood flow near the neck of the person (Paragraphs [0039] and [0070]).

Regarding claim 35, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person (Paragraph [0039]), and further comprising an earpiece fitting configured to be inserted within the ear canal and having one or more physiological sensors supported thereby (Abstract and Paragraph [0039]).

Regarding claim 36, Abreu discloses the apparatus of Claim 1, further comprising a transmittance pulse oximeter and/or reflectance pulse oximeter supported by the housing (Paragraph [0395]).

Regarding claim 37, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person (Paragraph [0039]), and further comprising an earlobe clip extending from the housing (Paragraph [0039]; a wrap around earpiece has an earlobe clip), and wherein a transmittance pulse oximeter is supported by the earlobe clip (Paragraph [0395]).

(Continued in next Supplemental Box)

Supplemental Box

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

Regarding claim 38, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person (Paragraph [0039]), and further comprising an earlobe clip extending from the housing (Paragraph [0039]; a wrap around earpiece has an earlobe clip), and wherein a reflectance pulse oximeter is supported by the earlobe clip (Paragraph [0395]).

Regarding claim 39, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises one or more sonic and pressure transducers supported by the housing that are configured to measure blood pressure of the person (Paragraph [0074]).

Regarding claim 40, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises electrodes configured to monitor neurological functions of the person (Paragraph [0113]).

Regarding claim 41, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises a motion sensor configured to detect body motion of the person (Paragraph [0077]).

Regarding claim 42, Abreu discloses the apparatus of Claim 41, wherein the motion sensor comprises an accelerometer (Paragraph [0077]) and/or gyroscope.

Regarding claim 43, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises a body temperature sensor (Paragraph [0096]).

Regarding claim 44, Abreu discloses the apparatus of Claim 1, wherein the at least one environmental sensor comprises a colorimetric sensor that changes color in response to detecting one or more chemicals in the environment (Paragraph [0516]).

Regarding claim 47, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises an acoustical sensor that detects breathing (Paragraph [0520]).

Regarding claim 48, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor is configured to measure caloric metabolism of the person (Paragraph [0512]).

Regarding claim 49, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises a body fat analyzer (Paragraphs [0110] and [0148-0149]).

Regarding claim 50, Abreu discloses the apparatus of Claim 1, wherein the at least one environmental sensor comprises an electromagnetic field (EMF) sensor that is configured to detect electromagnetic radiation spikes (Paragraphs [0384] and [0388]).

Regarding claim 51, Abreu discloses the apparatus of Claim 1, further comprising an air sampling system supported by the housing that samples air in a vicinity of the person (Paragraph [0520]).

Regarding claim 54, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor comprises an ultraviolet (UV) light sensor (Paragraph [0376]).

Regarding claim 55, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor is configured to detect drowsiness of the person, and further comprising an alarm configured to alert the person in response to the at least one physiological sensor detecting drowsiness (Paragraph [0097]; detects drowsiness and clumsiness by measuring for symptoms of hypothermia).

Regarding claim 56, Abreu discloses the apparatus of Claim 1, further comprising a recording device supported by the housing that is configured to record signals produced by the physiological and environmental sensors and/or signals processed by the signal processor (Paragraph [0485]; data can store data).

Regarding claim 57, Abreu discloses the apparatus of Claim 1, further comprising a user interface on the housing that provides user control over one or more of the physiological and/or environmental sensors (Paragraphs [0324] and [0496]; the user can have access to the thermal life and biological monitoring of the animal through a video stream).

Regarding claim 58, Abreu discloses the apparatus of Claim 1, further comprising a remote device in wireless communication with the apparatus (Abstract and [0059]), wherein the remote device comprises a user interface that provides user control over one or more of the physiological and/or environmental sensors (Paragraphs [0324] and [0496]; the user can have access to the thermal life and biological monitoring of the animal through a video stream).

Regarding claim 59, Abreu discloses the apparatus of Claim 1, further comprising a user interface that is configured to allow the person to store a time mark indicating a particular point in time (Paragraph [0496]; the user can store into the animal's ID time information such as the time and date of the birth of the animal).

Regarding claim 61, Abreu discloses the apparatus of Claim 1, wherein the transmitter is configured to send a signal to the remote terminal (Paragraph [0076]) when potentially erroneous data has been collected by one or more of the physiological and/or environmental sensors (Paragraphs [0076] and [0308]; all data can be sent to both the local and remote terminals).

Regarding claim 62, Abreu discloses the apparatus of Claim 1, wherein a physiological sensor is configured to detect damage to a portion of the body of the person (Paragraph [0093]).

(Continued in next Supplemental Box)

Supplemental Box

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

Regarding claim 63, Abreu discloses the apparatus of Claim 62, further comprising a communication module supported by the housing and that is configured to alert the person when a physiological sensor detects damage to a portion of the body of the person (Fig. 13 and Paragraph [0093] and [0095]).

Regarding claim 64, Abreu discloses the apparatus of Claim 1, wherein the housing comprises two portions, each configured to be attached to an ear of the person (Paragraph [0039]; the apparatus can include an earpiece and glasses; both of which would rest on or in the ear).

Regarding claim 65, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor is configured to detect and/or measure one or more of the following types of physiological information: heart rate (Paragraph [0075]), pulse rate (Paragraph [0075]), breathing rate (Paragraph [0520]), blood flow(Paragraph [0132]), heartbeat signatures (Paragraph [0075]), cardio-pulmonary health (Paragraph [0075]), organ health (Paragraph [0075]), metabolism (Abstract), electrolyte type and/or concentration (Abstract), physical activity (Paragraph [0088]), caloric intake (Paragraph [0512]), caloric metabolism (Paragraph [0512]), physical and/or psychological stress levels and/or stress level indicators, drug dosage and/or dosimetry (Paragraph [0071]), physiological drug reactions, drug chemistry, biochemistry (Abstract), position (Paragraph [0077]) and/or balance, body strain (Paragraph [0088]), neurological functioning (Paragraph [0113]), brain activity (Paragraph [0113]), brain waves (Paragraph [0113]), blood pressure (Paragraph [0074]), cranial pressure, hydration level (Abstract), auscultatory information, auscultatory signals associated with pregnancy, physiological response to infection, skin and/or core body temperature (Abstact), eye muscle movement, blood volume, inhaled and/or exhaled breath volume (Paragraph [0520]), physical exertion (Paragraph [0088]), exhaled breath physical and/or chemical composition (Paragraph [0520]), the presence and/or identity and/or concentration of viruses and/or bacteria, foreign matter in the body, internal toxins, heavy metals in the body, anxiety, fertility, ovulation, sex hormones, psychological mood, sleep patterns, hunger and/or thirst, hormone type and/or concentration, cholesterol, lipids, blood panel, bone density, organ and/or body weight, reflex response, sexual arousal, mental and/or physical alertness, sleepiness, auscultatory information, response to external stimuli, swallowing volume, swallowing rate, sickness, voice characteristics, voice tone, voice pitch, voice volume, vital signs, head tilt, allergic reactions, inflammation response, auto-immune response, mutagenic response, DNA, proteins, protein levels in the blood, water content of the blood, pheromones, internal body sounds, digestive system functioning, cellular regeneration response, healing response, stem cell regeneration response

Regarding claim 66, Abreu discloses the apparatus of Claim 1, wherein the at least one environmental sensor is configured to detect and/or measure one or more of the following types of environmental information: climate (Paragraph [0100]), humidity (Paragraph [0091]), temperature (Paragraph [0096]), pressure (Paragraph [0075]), barometric pressure, soot density, airborne particle density, airborne particle size, airborne particle shape, airborne particle identity, volatile organic chemicals (VOCs), hydrocarbons, polycyclic aromatic hydrocarbons (PAHs), carcinogens, toxins, optical radiation, X-rays, gamma rays, microwave radiation, terahertz radiation, ultraviolet radiation, infrared radiation, radio waves, atomic energy alpha particles, atomic energy beta-particles, gravity, light intensity, light frequency, light flicker, light phase, ozone, carbon monoxide, carbon dioxide, nitrous oxide, sulfides, airborne pollution, foreign material in the air, viruses, bacteria, signatures from chemical weapons, wind, air turbulence, sound and/or acoustical energy, ultrasonic energy, noise pollution, human voices, animal sounds, diseases expelled from others, exhaled breath and/or breath constituents of others (Paragraph [0520]), toxins from others, pheromones from others, industrial and/or transportation sounds, allergens, animal hair, pollen, exhaust from engines, vapors and/or fumes, fuel, signatures for mineral deposits and/or oil deposits, snow, rain, thermal energy, hot surfaces, hot gases, solar energy, hail, ice, vibrations, traffic, the number of people in a vicinity of the person, coughing and/or sneezing sounds from people in the vicinity of the person, loudness and/or pitch from those speaking in the vicinity of the person.

Regarding claim 67, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of a person (Paragraph [0039]), and further comprising a speaker (Paragraph [0318]), microphone (Paragraph [0075]), and transceiver supported by the housing (Fig. 13) , wherein the transceiver is electronically connected to the speaker and microphone and permits bidirectional wireless communications between the apparatus and a remote terminal (Abstract, Fig. 13 and Paragraphs [0327-0328]), and wherein the transceiver is electronically connected to the signal processor and is configured to transmit physiological and environmental sensor signals from the signal processor to the remote terminal (Abstract, Fig. 13 and Paragraphs [0327-0328]).

Regarding claim 68, Abreu discloses the apparatus of Claim 67, wherein the transceiver is a Bluetooth (Paragraph [0515]), Wi-Fi, or ZigBee transceiver or is interoperable with multiple wireless communication protocols.

Regarding claim 69, Abreu discloses the apparatus of Claim 67, further comprising an arm movably attached to the housing (Figs. 22A-C and Paragraphs [0355-0357]; the physiological sensor is attached to the inner portion of the glasses while the environmental sensor is connected to the rim of the glasses near the temple), wherein the microphone is supported by the arm (Paragraph [0075]), and wherein the arm is movable between a stored position and an extended, operative position Figs. 22A-C and Paragraphs [0355-0357]; when the glasses are extended they can be worn and when the glasses are folded they are in an inoperable position).

Regarding claim 70, Abreu discloses the apparatus of Claim 69, further comprising a physiological sensor and/or an environmental sensor supported by the arm (Figs. 22A-C and Paragraphs [0355-0357]; the physiological sensor is attached to the inner portion of the glasses while the environmental sensor is connected to the rim of the glasses near the temple).

Regarding claim 71, Abreu discloses the apparatus of Claim 1, wherein the transmitter is configured to transmit signals from the signal processor to the remote terminal (Abstract, Fig. 13 and Paragraph [0059]) following a predetermined time interval (Paragraph [0096] and [0101]; after being in the sun for a predetermined period of time the apparatus sends signals to the remote terminal alerting the user to vacate the sun exposed area).

(Continued in next Supplemental Box)

Supplemental Box

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

Regarding claim 72, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor and/or the at least one environmental sensor is configured to identify a person to whom the personal monitoring apparatus housing is attached (Paragraph [0490]; the ID of the user is transmitter in conjunction with the biological data).

Regarding claim 73, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor and/or the at least one environmental sensor is configured to monitor physical aging rate (Paragraphs [0049], [0088] and [0101]).

Regarding claim 74, Abreu discloses the apparatus of Claim 1, wherein the signal processor is configured to processes information from the at least one physiological sensor and/or the at least one environmental sensor to assess aging rate (Paragraphs [0049], [0088] and [0101]).

Regarding claim 75, Abreu discloses the apparatus of Claim 1, wherein the at least one environmental sensor is configured to assess aging rate (Paragraphs [0049], [0088] and [0101]), and wherein the at least one environmental sensor comprises a UV sensor (Paragraph [0376]) or a pollution sensor.

Regarding claim 76, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor is configured to assess aging rate (Paragraphs [0049], [0088] and [0101]), and wherein the at least one physiological sensor comprises a pulse rate sensor (Paragraph [0505]), a blood pressure sensor (Paragraph [0074]), an activity sensor (Paragraph [0088]), or a psychosocial stress sensor.

Regarding claim 77, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological and environmental sensors are configured to monitor physical aging rate (Paragraphs [0049], [0088] and [0101]), wherein the at least one environmental sensor comprises a UV sensor (Paragraph [0376]) or a pollution sensor, and wherein the at least one physiological sensor comprises a pulse rate sensor (Paragraph [0505]), a blood pressure sensor (Paragraph [0074]), an activity sensor (Paragraph [0088]), or a psychosocial stress sensor.

Regarding claim 79, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor is configured to measure caloric consumption and/or calories burned by the person (Paragraph [0512]).

Regarding claim 80, Abreu discloses the apparatus of Claim 1, further comprising memory supported by the housing (Fig. 74 and Paragraph [0482]), wherein the memory includes at least one algorithm (Paragraph [0511]), and wherein the signal processor is configured to process the at least one algorithm (Figs. 13 and Paragraph [0482]).

Regarding claim 81, Abreu discloses the apparatus of Claim 80, wherein the at least one algorithm can be modified wirelessly via the transmitter (Paragraph [0515]).

Regarding claim 82, Abreu discloses the apparatus of Claim 80, wherein the transmitter is configured to wirelessly upload an algorithm to the memory (Paragraph [0515]).

Regarding claim 83, Abreu discloses the apparatus of Claim 80, wherein the at least one algorithm is configured to focus processing resources on at least one extraction of physiological or environmental information (Paragraph [0511]).

Regarding claim 84, Abreu discloses the apparatus of Claim 1, further comprising a rechargeable power source that powers the at least one physiological sensor, the at least one environmental sensor, the signal processor, and the transmitter (Paragraphs [0312] and [0514]).

Regarding claim 85, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor and/or the at least one environmental sensor is configured to be regenerated through a physical and/or chemical change (Paragraphs [0312] and [0514]).

Regarding claim 86, Abreu discloses the apparatus of Claim 21, wherein the communication module communicates a treatment, therapy, or plan of action to the person upon detection of physiological or environmental concerns (Paragraph [0110]).

Regarding claim 87, Abreu discloses the apparatus of Claim 1, further comprising an audible communicator supported by the housing that is configured to communicate therapeutic sounds to the person in response to physiological or psychosocial stress (Abstract, Paragraph [0411]).

Regarding claim 88, Abreu discloses the apparatus of Claim 1, further comprising a light source supported by the housing that is configured to provide light therapy to the person in response to physiological or psychosocial stress (Paragraphs [0324], [0381] and [0391]).

Regarding claim 89, Abreu discloses the apparatus of Claim 1, wherein the at least one physiological sensor includes multiple temperature sensors configured to measure core body temperature (Paragraph [0322]) and skin temperature of the person (Paragraph [0518]).

Regarding claim 91, Abreu discloses a personal monitoring apparatus (Abstract), comprising: a wireless personal communicator (Paragraph [0515]) configured to be attached to the ear of a person (Paragraph [0039]); and at least one physiological sensor associated with the wireless personal communicator that is configured to detect and/or measure physiological information from a person (Paragraphs [0039-0040], [0088] and [0113]), wherein the wireless personal communicator is configured to transmit physiological sensor signals to a remote terminal (Abstract, Fig. 13 and Paragraphs [0515] and [0059]).

(Continued in next Supplemental Sheet)

Supplemental Box

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

Regarding claim 92, Abreu discloses a personal monitoring apparatus (Abstract), comprising: a wireless personal communicator (Paragraph [0515]) configured to be attached to the ear of a person (Paragraph [0039]); and at least one environmental sensor associated with the wireless personal communicator that is configured to detect and/or measure environmental conditions in a vicinity of a person (Abstract and Paragraph [0076], [0096] and [0100]), wherein the wireless personal communicator is configured to transmit environmental sensor signals to a remote terminal (Abstract, Fig. 13 and Paragraph [0059]).

Claims 9-12, 14-17, 60 and 78 lack$ an inventive step under PCT Article 33(3) as being obvious over Abreu (US 2004/0242976 A1) in view of Boesen (US 2005/0148883 A1).

Regarding claim 9, Abreu discloses the apparatus of Claim 8, further comprising an optical emitter supported by the housing that directs optical energy (Paragraph [0055] and [0525]), and an optical detector supported by the housing that is configured to detect secondary optical energy (Paragraphs [0055], [0418] and [0525]). Abreu does not disclose wherein the apparatus directs energy towards the tympanic membrane and emanating from the tympanic membrane. However in disclosing an apparatus that detects physiological parameters (Abstract), Boesen teaches wherein a housing directs energy towards the tympanic membrane and emanating from the tympanic membrane (Fig, 8 and Paragraph [0053]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to including directing energy towards the tympanic membrane and emanating from the tympanic membrane in the apparatus of Abreu as taught by Boesen. The motivation for including the above mentioned features is so that the user can wear the device in a manner that doesn't make the device as visually apparent (Boesen, Fig. 8, Paragraph [0049] and [0053]).

Regarding claim 14, Abreu discloses the apparatus of Claim 1, wherein the housing is configured to be attached to an ear of the person (Paragraph [0039]), and further comprising an optical emitter supported by the housing that directs optical energy (Paragraph [0055] and [0525]), and wherein a physiological sensor comprises an optical detector configured to detect secondary optical energy (Paragraphs [0055], [0418] and [0525]). Boesen teaches wherein a housing directs energy towards the tympanic membrane and emanating from the tympanic membrane (Fig, 8 and Paragraph [0053]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to including directing energy towards the tympanic membrane and emanating from the tympanic membrane in the apparatus of Abreu as taught by Boesen. The motivation for including the above mentioned features is so that the user can wear the device in a manner that doesn't make the device as visually apparent (Boesen, Fig. 8, Paragraph [0049] and [0053]).

Regarding claims 10 and 15, Abreu as modified discloses the apparatus of Claims 9 and 14, wherein the signal processor is configured to extract selected optical energy from the secondary optical energy emanating from the tympanic membrane (Paragraphs [0055] and [0525]).

Regarding claims 11 and 16, Abreu as modified discloses the apparatus of Claims 9 and 14, wherein the signal processor is configured to extract optical noise (Paragraph [0053]) from the secondary optical energy emanating from the tympanic membrane (Paragraphs [0055] and [0525]).

Regarding claims 12 and 17, Abreu as modified discloses the apparatus of Claims 9 and 14, wherein the optical detector comprises a filter (Paragraph [0393] and [0418]) configured to pass secondary optical energy at selective wavelengths (Paragraphs [0390] and [0423]).

Regarding claim 60, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the transmitter is configured to send a signal to the remote terminal when one or more of the physiological and/or environmental sensors are turned off. Boesen teaches wherein the transmitter is configured to send a signal to the remote terminal when one or more of the physiological and/or environmental sensors are turned off (Paragraph [0041]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein a transmitter is configured to send a signal to a remote terminal when one or more of the physiological and/or environmental sensors are turned off in the apparatus of Abreu as taught by Boesen. The motivation for including the above mentioned features is so that the apparatus can send and/or receive remote signals (Boesen, Paragraph [0041]).

Regarding claim 78, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the apparatus is a hearing aid. Boesen teaches wherein the apparatus is a hearing aid (Paragraph [0055]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a hearing aid in the apparatus of Abreu as taught by Boesen. The motivation for including the above mentioned feature is so that the physiological sensor can also work as a hearing improvement device (Boesen, Abstract and Paragraphs [0055]).

Claims 45-46, 52 and 90 lack an inventive step under PCT Article 33(3) as being obvious over Abreu (US 2004/0242976 A1) in view of Banet et al. (US 2006/0084878 A1;hereinafter Banet).

Regarding claim 45, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the at least one environmental sensor comprises a pedometer. However in disclosing an apparatus that detects physiological parameters (Abstract), Banet teaches wherein an at least one environmental sensor comprises a pedometer (Paragraph [0050]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein an at least one environmental sensor comprises a pedometer in the apparatus of Abreu as taught by Banet. The motivation for including the above mentioned features is so that the apparatus can measure a patient's daily exercise (Banet Paragraph [0050]).

(Continued in next Supplemental Box)

Supplemental Box

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

Regarding claim 46, Abreu as modified discloses the apparatus of Claim 45. Abreu does not disclose wherein the pedometer is an acoustic pedometer that detects sound generated by footsteps. Banet teaches wherein the pedometer is an acoustic pedometer that detects sound generated by footsteps (Paragraphs [0036] and [0050]; the device measures Korotokoff sounds such as those made by footsteps when using a pedometer). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the pedometer is an acoustic pedometer that detects sound generated by footsteps in the apparatus of Abreu as taught by Banet. The motivation for including the above mentioned features is so that the apparatus can measure a patient's daily exercise (Banet Paragraph [0050]).

Regarding claim 52, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the at least one physiological sensor comprises an impedance plethysmograph. Banet teaches wherein the at least one physiological sensor comprises an impedance plethysmograph (Paragraph [0006]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the at least one physiological sensor comprises an impedance plethysmograph in the apparatus of Abreu as taught by Banet. The motivation for including the above mentioned features is so the device can better determine a patient's heart rate (Banet, Paragraph [0006]).

Regarding claim 90, Abreu discloses the apparatus of Claim 88, wherein the temperature sensors are configured to measure core body temperature (Paragraph [0322]). Abreu does not disclose wherein the temperature is measured from the tympanic membrane or ear canal and skin temperature from the skin of the ear canal or the skin of the outer ear. Banet teaches wherein temperature is measured from the tympanic membrane or ear canal and skin temperature from the skin of the ear canal or the skin of the outer ear (Paragraph [0049]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the temperature is measured from the tympanic membrane or ear canal and skin temperature from the skin of the ear canal or the skin of the outer ear as taught by Banet in the apparatus of Abreu. The motivation for including the above mentioned features is so that a patients vitals can be easily and accurately taken (Banet, Paragraph [0049]).

Claims 25 and 53 lack an inventive step under PCT Article 33(3) as being obvious over Abreu (US 2004/0242976 A1) in view of Ross et al. (US 2004/0186390 A1; hereinafter Ross).

Regarding claim 25, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the transmitter is configured to transmit signals produced by the physiological and environmental sensors to a gaming device. However in disclosing a device that analyzes body signals (Abstract), Ross teaches wherein the transmitter is configured to transmit signals produced by the physiological and environmental sensors to a gaming device (Abstract and Paragraph [0141]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a transmitter configured to transmit signals produced by the physiological and environmental sensors to a gaming device in the apparatus of Abreu as taught by Ross. The motivation for including the above mentioned features is so that the apparatus can include the functionality of a portable computing device (Ross, Abstract and Paragraph [0141]).

Regarding claim 53, Abreu discloses the apparatus of Claim 1. Abreu does not disclose wherein the at least one environmental sensor comprises an ozone sensor or a carbon monoxide sensor. Ross teaches wherein the at least one environmental sensor comprises an ozone sensor or a carbon monoxide sensor (Paragraph [0129]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein the at least one environmental sensor comprises an ozone sensor or a carbon monoxide sensor in the apparatus of Abreu as taught by Ross. The motivation for including the above mentioned feature is so that the system can detect a hazardous gas flow (Ross, Abstract and Paragraph [0129]).

Claims 1-92 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 22 AUGUST 2012 (22.08.2012)
Applicant's or agent's file reference 9653-11-WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/US2012/022634**	International filing date *(day/month/year)* **26 JANUARY 2012 (26.01.2012)**
Applicant **VALENCELL, INC. et al**	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:

   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 . 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the PCT Applicant's Guide, National Chapters.

Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer COMMISSIONER Telephone No. 82-42-481-8754

Form PCT/ISA/220 (July 2010)

* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for three months from the date of mailing of the international search report.

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

ID : PCT international application number
PW : **8KCGNQMK**

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

Homepage: http://www.ipkcenter.com
Email: ipkc@ipkcenter.com
Phone: +1 703 388 1066
Fax: +1 703 388 1084

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

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
9653-11-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2012/022634	**26 JANUARY 2012 (26.01.2012)**	27 JANUARY 2011 (27.01.2011)
Applicant		
VALENCELL, INC. et al		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figure is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/022634

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/02(2006.01)i, A61B 5/026(2006.01)i, A61B 5/083(2006.01)i, A61B 5/1455(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/02; A61B 7/04; A61B 5/08; A61B 7/00; A61B 5/1455; H04B 17/02

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords:physiological, sensor, filter, environmental, ambient

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007-0165872 A1 (KEITH BRIDGER et al.) 19 July 2007 See abstract, paragraphs [0072]-[0073],[0077]-[0078], claims 43-52, and figures 10-12.	1-52
A	US 2007-0213020 A1 (PINCHAS NOVAC) 13 September 2007 See abstract, paragraphs [0027]-[0028],[0051]-[0052], claim 1, and figures 1, 5.	1-52
A	US 05143078 A (MATHER; BRUCE C. et al.) 01 September 1992 See abstract, column 2, line 59 - column 3, line 15, claim 1, and figure 1.	1-52
A	US 2008-0154105 A1 (LEMAY CHARLES) 26 June 2008 See abstract, paragraphs [0004]-[0006],[0033]-[0039], claims 1,9, and figures 4,5.	1-52

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 JULY 2012 (31.07.2012)	**22 AUGUST 2012 (22.08.2012)**
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer KIM Tae Hoon Telephone No. 82-42-481-5728

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2012/022634

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0165872 A1	19.07.2007	None	
US 2007-0213020 A1	13.09.2007	EP 1832227 A1 US 7988638 B2	12.09.2007 02.08.2011
US 05143078 A	01.09.1992	JP 01-037933 A JP 02-628690 B2 JP 2628690 B2	08.02.1989 18.04.1997 09.07.1997
US 2008-0154105 A1	26.06.2008	WO 2008-080043 A1	03.07.2008

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

	Date of mailing *(day/month/year)* **22 AUGUST 2012 (22.08.2012)**
Applicant's or agent's file reference 9653-11-WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2012/022634	**26 JANUARY 2012 (26.01.2012)**	27 JANUARY 2011 (27.01.2011)

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

A61B 5/02(2006.01)i, A61B 5/026(2006.01)i, A61B 5/083(2006.01)i, A61B 5/1455(2006.01)i

Applicant

VALENCELL, INC. et al

DOCKETED
By PS
Date 8/30/12

ROUTE TO:
PMH ☐
☐
☐
☐

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea Facsimile No. 82-42-472-7140	31 JULY 2012 (31.07.2012)	KIM Tae Hoon Telephone No.82-42-481-5728

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/022634

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. a sequence listing filed or furnished
      ☐ on paper
      ☐ in electronic form

   b. time of filing or furnishing
      ☐ contained in the international application as filed.
      ☐ filed together with the international application in electronic form.
      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/022634

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-52	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-52	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-52	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2007-0165872 A1 (KEITH BRIDGER et al.) 19 July 2007
D2: US 2007-0213020 A1 (PINCHAS NOVAC) 13 September 2007
D3: US 05143078 A (MATHER; BRUCE C. et al.) 01 September 1992
D4: US 2008-0154105 A1 (LEMAY CHARLES) 26 June 2008

2.1 Novelty and Inventive Step

2.1.1 Claim 1

The subject matter of claim 1 differs from these prior art documents in that claim 1 comprises a filter that attenuates time-varying environmental interference from the energy response signal, wherein the time-varying environmental interference is caused by one or more of the following sunlight, ambient light, airflow, and temperature. And it is not obvious to a person skilled in the art by the documents, taken alone or in combination. Therefore, claim 1 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

2.1.2 Claim 26

The subject matter of claim 26 differs from these prior art documents in that claim 26 comprises processing the first and second energy response signals via a filter to produce a processed energy response signal that is associated with a physiological condition of the subject, wherein the filter attenuates time-varying environmental interference caused by one or more of the following: sunlight, ambient light, airflow, and temperature. And it is not obvious to a person skilled in the art by the documents, taken alone or in combination. Therefore, claim 26 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

2.1.3 Claim 34

The subject matter of claim 34 differs from these prior art documents in that claim 34 comprises a filter that attenuates time-varying environmental interference from the energy response signal, wherein the time-varying environmental interference is caused by one or more of the following sunlight, ambient light, airflow, and temperature. And it is not obvious to a person skilled in the art by the documents, taken alone or in combination. Therefore, claim 34 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

2.1.4 Claim 42

The subject matter of claim 42 differs from these prior art documents in that claim 42 comprises an optical filter overlying at least a portion of the optical detector, wherein the optical filter is configured to attenuate light at one or more selected wavelengths, and a filter to attenuates time-varying environmental interference from the energy response signal. And it is not obvious to a person skilled in the art by the documents, taken alone or in combination. Therefore, claim 42 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

Continued on Supplemental Box

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2012/022634

Supplemental Box

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

Box V

2.1.5 Claims 2-25,27-33,35-41,43-52
Claims 2-25,27-33,35-41,43-52 are dependent on claims 1,26,34, and 42, respectively, and therefore meet the requirements of PCT Article 33(2) and (3).

2.2 Industrial Applicability
Claims 1-52 are industrially applicable under PCT Article 33(4).

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing *(day/month/year)* 30 JULY 2010 (30.07.2010)	
Applicant's or agent's file reference 9653-8-WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/US2010/021936**	International filing date *(day/month/year)* **25 JANUARY 2010 (25.01.2010)**

Applicant

VALENCELL, INC. et al

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:

   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 . 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the PCT Applicant's Guide, National Chapters.

Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea	Authorized officer COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8752

Form PCT/ISA/220 (Draft for Consultation . July 2010)

* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for three months from the date of mailing of the international search report.

http://www.kipo.go.kr/en/ => Patent Search => PCT-Service

ID : PCT international application number
PW : **064B189G**

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

Homepage: http://www.ipkcenter.com
Email: ipkc@ipkcenter.com
Phone: +1 703 388 1066
Fax: +1 703 388 1084

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
9653-8-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2010/021936	**25 JANUARY 2010 (25.01.2010)**	25 FEBRUARY 2009 (25.02.2009)
Applicant		
VALENCELL, INC. et al		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract**,
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. **4A**
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figure is to be published with the abstract.

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/021936

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/00(2006.01)i, A61B 5/02(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: ear, sensor, monitor, means, detach, removable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2008-0146890 A1 (LEBOEUF STEVEN FRANCIS et al.) 19 June 2008 See abstract; Page 5 paragraph 0065 - 0066; claim 1 and figure 1	1-17,22-33 18-21
A	US 2004-0054291 A1 (CHRISTIAN SCHULZ et al.) 18 March 2004 See abstract; Page 2 paragraph 0034; claim 1 and figure 2	1-33
A	US 2005-0148883 A1 (PETER V. BOESEN) 07 July 2005 See abstract; claims 30-40	1-33

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"B" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 JULY 2010 (30.07.2010)	**30 JULY 2010 (30.07.2010)**

Name and mailing address of the ISA/KR	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	RYU, SI UNG Telephone No. 82-42-481-5980

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2010/021936

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008-0146890 A1	19.06.2008	EP 2094152 A1 WO 2008-088511 A1	02.09.2009 24.07.2008
US 2004-0054291 A1	18.03.2004	US 7341559 B2	11.03.2008
US 2005-0148883 A1	07.07.2005	AU 3851401 A US 6852084 B1	12.11.2001 08.02.2005

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

	Date of mailing *(day/month/year)* **30 JULY 2010 (30.07.2010)**
Applicant's or agent's file reference 9653-8-WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/021936	**25 JANUARY 2010 (25.01.2010)**	25 FEBRUARY 2009 (25.02.2009)

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

A61B 5/00(2006.01)i, A61B 5/02(2006.01)i

Applicant

VALENCELL, INC. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	30 JULY 2010 (30.07.2010)	RYU, SI UNG Telephone No.82-42-481-5980

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/021936

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. a sequence listing filed or furnished
      ☐ on paper
      ☐ in electronic form

   b. time of filing or furnishing
      ☐ contained in the international application as filed.
      ☐ filed together with the international application in electronic form.
      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/021936

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	18-21	YES
	Claims	1-17,22-33	NO
Inventive step (IS)	Claims	18-21	YES
	Claims	1-17,22-33	NO
Industrial applicability (IA)	Claims	1-33	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2008-0146890 A1
D2: US 2004-0054291 A1
D3: US 2005-0148883 A1

(1) Novelty and Inventive Step

D1, which is considered to represent the most relevant state of art, discloses a apparatus and its system, the apparatus comprising: a housing configured to be attached to the body of a person, at least one physiological sensor, at least one environmental sensor, a signal processor and a transmitter.

1) Claims 1-17, 22-33

The subject matter of claims 1, 22, 33 compose a housing configured to be attached to a body, a physiological sensor. If the citation document D1 which is most similar to the subject invention is compared, all of these technical features are disclosed. And moreover the effects of these technical features are also the same as those of the citation document D1. Therefore, claims 1, 22, 33 of this application do not meet PCT Article 33(2) which is the requirement of novelty. Therefore, claims 1, 22, 33 are considered to lack novelty.

The additional features of claims 2-17, 23-32 are disclosed in D1(see Page 7 paragraph [0074], claim 1 and Fig. 1). Therefore, the subject matters of claims 2-17, 23-32 are neither novel nor inventive in view of D1, and do not satisfy the criteria set forth in PCT Article 33(2) and 33(3).

2) Claims 18-21

The subject matter of claim 18 differs from these prior art documents in that it includes updating fraction. And it is not obvious to a person skilled in the art by the documents, taken alone or in combination. Therefore, claim 18 meets the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

Claims 19-21 are dependent on claim 18 and therefore meet the requirements of PCT Article 33(2) and (3).

(2) Industrial Applicability
Claims 1-33 are industrially applicable under PCT Article 33(4).

COPY

PATENT COOPERATION TREATY

PCT/US2010/024922
09-23-10A10:43 RCVD

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

DOCKETED
By SD
Date 9/23
ROUTE TO:
NJB

Date of mailing *(day/month/year)* 16 SEPTEMBER 2010 (16.09.2010)	
Applicant's or agent's file reference 9653-9-WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/US2010/024922**	International filing date *(day/month/year)* **22 FEBRUARY 2010 (22.02.2010)**
Applicant **VALENCELL, INC. et al**	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 . 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

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For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the PCT Applicant's Guide, National Chapters.

Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea	Authorized officer COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8752

Form PCT/ISA/220 (July 2010)

* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for three months from the date of mailing of the international search report.

http://www.kipo.go.kr/en/ => Patent Search => PCT-Service

ID : PCT international application number
PW : **0QO1XZVB**

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

Homepage: http://www.ipkcenter.com
Email: ipkc@ipkcenter.com
Phone: +1 703 388 1066
Fax: +1 703 388 1084

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

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
9653-9-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2010/024922	**22 FEBRUARY 2010 (22.02.2010)**	25 FEBRUARY 2009 (25.02.2009)
Applicant		
VALENCELL, INC. et al		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figure is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/024922

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/02(2006.01)i, A61B 5/01(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/02; A61B 5/05; A61B 5/00

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & Keywords: physiological, matabolic, ear, headset

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004-0034289 A1 (ERIC TELLER et al.) 19 February 2004 See paragraph [0031] - paragraph [0034]; claims 1-71 and figures 1-3.	1-38
A	US 2008-0146892 A1 (LEBOEUF STEVEN FRANCIS et al.) 19 June 2008 See paragraph [0006] - paragraph [0163]; claims 1-19 and figures 1-7.	1-38
A	US 2007-0083095 A1 (ANTHONY RIPPO et al.) 12 April 2007 See abstract and claims 1-4.	1-38

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 SEPTEMBER 2010 (15.09.2010)	**16 SEPTEMBER 2010 (16.09.2010)**

Name and mailing address of the ISA/KR	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea	PARK, TAE WOOK
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8226

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2010/024922

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2004-0034289 A1	19.02.2004	AU 2002-330965 A1	24.02.2003
		BR 0211760 A	13.10.2004
		CA 2454655-A1	20.02.2003
		EP 1414340 A2	06.05.2004
		IL16007900	20.06.2004
		JP 2004-538066 T	24.12.2004
		JP 4283672 B2	24.06.2009
		MX PA04001055A	20.05.2004
		US 2002-019586 A1	14.02.2002
		US 2006-122474 A1	08.06.2006
		US 2007-173705 A1	26.07.2007
		US 7261690 B2	28.08.2007
		WO 0301-5005A2	20.02.2003
		WO 0301-5005A3	18.12.2003
US 2008-0146892 A1	19.06.2008	None	
US 2007-0083095 A1	12.04.2007	US 2007-0083092 A1	12.04.2007

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**16 SEPTEMBER 2010 (16.09.2010)**
Applicant's or agent's file reference 9653-9-WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/024922	**22 FEBRUARY 2010 (22.02.2010)**	25 FEBRUARY 2009 (25.02.2009)

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

A61B 5/02(2006.01)i, A61B 5/01(2006.01)i

Applicant

VALENCELL, INC. et al

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302 -701, Republic of Korea Facsimile No. 82-42-472-7140	15 SEPTEMBER 2010 (15.09.2010)	PARK, TAE WOOK Telephone No.82-42-481-8226

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/024922

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. a sequence listing filed or furnished
      ☐ on paper
      ☐ in electronic form

   b. time of filing or furnishing
      ☐ contained in the international application as filed.
      ☐ filed together with the international application in electronic form.
      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/024922

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-38	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-38	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-38	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2004-0034289 A1 (ERIC TELLER et al.) 19 February 2004
D2: US 2008-0146892 A1 (LEBOEUF STEVEN FRANCIS et al.) 19 June 2008
D3: US 2007-0083095 A1 (ANTHONY RIPPO et al.) 12 April 2007

1. Novelty and Inventive Step
The subject matter of claim 1 differs from these prior art documents in that it includes making an assessment of a physiological condition of the subject using the at least two types of physiological information, wherein each type of physiological information is individually insufficient to make the physiological condition assessment.

The subject matter of claim 12 differs from these prior art documents in that it includes making an assessment of a physiological condition of the subject using the at least two types of physiological information and the environmental information, wherein the environmental information and the at least two types of physiological information are individually insufficient to make the physiological condition assessment, providing information to the subject about the physiological condition assessment via a portable device in communication with the monitoring device.

The subject matter of claim 20 differs from these prior art documents in that it includes making an assessment of a physiological condition of the subject using the at least two types of physiological information and the environmental information, wherein the environmental information and the at least two types of physiological information are individually insufficient to make the physiological condition assessment, wherein the subject physiological condition is selected from the group consisting of: VO2, VO2max, metabolic zone, metabolic equivalent, active calories burned, total calories burned, hydration status, heart rate variability, cardiac response, stress level, warm up time, recovery time, activity performance level.

And the subject matter of claims 1, 12 and 20 are not obvious to a person skilled in the art by the documents, taken alone or in combination.

Therefore, claims 1, 12 and 20 meet the requirements of PCT Article 33(2) and (3) with respect to novelty and inventive step.

Claims 2-11, 13-19 and 21 are dependent on claim 1, 12 or 20. Therefore they meet the requirements of PCT Article 33(2) and (3).

Claims 22, 33 and 37 relate to a monitoring apparatus, a hydration status monitoring apparatus according to claim 1, 12 or 20. Claims 22, 33 and 37 are considered to be

Continued on Supplemental Box

Supplemental Box

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

Box V

novel and to involve an inventive step under PCT Article 33(2)-(3), because the subject matter of claim 1, 12 or 20 is considered to be novel and to involve an inventive step.

Claims 23-32, 34-36 and 38 are dependent on claims 22, 33 and 37. Therefore they meet the requirements of PCT Article 33(2) and (3).

2. Industrial Applicability
Claims 1-38 are industrially applicable under PCT Article 33(4).

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

10-04-10A10:46 RCVD

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 27 SEPTEMBER 2010 (27.09.2010)
Applicant's or agent's file reference 9653-10-WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. **PCT/US2010/025216**	International filing date *(day/month/year)* **24 FEBRUARY 2010 (24.02.2010)**
Applicant **VALENCELL, INC. et al**	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 . 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the PCT Applicant's Guide, National Chapters.

Name and mailing address of the ISA/KR Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea	Authorized officer COMMISSIONER
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8752

Form PCT/ISA/220 (July 2010)

NJB

DOCKETED

By VLH

Date 10/4/10

ROUTE TO:

* Attention

Copies of the documents cited in the international search report can be searched in the following Korean Intellectual Property Office English website for three months from the date of mailing of the international search report.

http://www.kipo.go.kr/en/ => Patent Search => PCT-Service

ID : PCT international application number
PW : **DA6ETQW8**

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

Homepage: http://www.ipkcenter.com
Email: ipkc@ipkcenter.com
Phone: +1 703 388 1066
Fax: +1 703 388 1084

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

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
9653-10-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2010/025216	**24 FEBRUARY 2010 (24.02.2010)**	25 FEBRUARY 2009 (25.02.2009)
Applicant		
VALENCELL, INC. et al		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☐ **Certain claims were found unsearchable** (See Box No. II)
3. ☐ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:
5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. With regard to the drawings,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1
      ☒ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☐ none of the figure is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025216

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0402(2006.01)i, A61B 5/0476(2006.01)i, A61B 5/0496(2006.01)i, A61B 5/0408(2006.01)i, A61B 5/0478(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 5/0402; A61B 5/02; A61B 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: ear, electrode, neurological, cardiopulmonary function

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008-0146890 A1 (STEVEN FRANCIS LEBOEUF et al.) 19 June 2008 See abstract, paragraphs 51-84, and figures 1-5,9-16	1-44
A	US 2005-0148883 A1 (PETER V. BOESEN) 07 July 2005 See abstract, paragraphs 30-50, and figures 1,8	1-44
A	US 2006-0084878 A1 (MATTHEW JOHN BANET et al.) 20 April 2006 See abstract, paragraphs 43-45, and figure 5	1-44
A	US 2004-0242976 A1 (MARCIO MARC ABREU) 02 December 2004 See abstract, paragraphs 328-396, and figures 13,26,38	1-44

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 SEPTEMBER 2010 (17.09.2010)	**27 SEPTEMBER 2010 (27.09.2010)**

Name and mailing address of the ISA/KR	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea	Kim, Sae Byul
Facsimile No. 82-42-472-7140	Telephone No. 82-42-481-8543

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2010/025216

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008-0146890 A1	19.06.2008	EP 2094152 A1	02.09.2009
		WO 2008-088511 A1	24.07.2008
US 2005-0148883 A1	07.07.2005	AU 3851401 A	12.11.2001
		US 6852084 B1	08.02.2005
		WO 01-82798A1	08.11.2001
US 2006-0084878 A1	20.04.2006	US 2005-0228244 A1	13.10.2005
		US 2005-0228296 A1	13.10.2005
		US 2005-0228298 A1	13.10.2005
		US 2005-0228299 A1	13.10.2005
		US 2005-0228300 A1	13.10.2005
		US 2005-0228301 A1	13.10.2005
		US 2005-0245831 A1	03.11.2005
		US 2005-0261598 A1	24.11.2005
		US 2006-0009697 A1	12.01.2006
		US 2006-0009698 A1	12.01.2006
		US 2008-0051670 A1	28.02.2008
		US 2008-0058614 A1	06.03.2008
		US 7004907 B2	28.02.2006
		US 7179228 B2	20.02.2007
		US 7238159 B2	03.07.2007
		WO 2006-105341 A2	05.10.2006
		WO 2007-011423 A1	25.01.2007
US 2004-0242976 A1	02.12.2004	US 2004-0059212 A1	25.03.2004
		US 2007-0219434 A1	20.09.2007
		US 7187960 B2	06.03.2007

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
MYERS BIGEL SIBLEY & SAJOVEC, P.A.

P.O. BOX 37428 RALEIGH NC 27627 USA

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	**27 SEPTEMBER 2010 (27.09.2010)**
Applicant's or agent's file reference 9653-10-WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/025216	**24 FEBRUARY 2010 (24.02.2010)**	25 FEBRUARY 2009 (25.02.2009)

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

A61B 5/0402(2006.01)i, A61B 5/0476(2006.01)i, A61B 5/0496(2006.01)i, A61B 5/0408(2006.01)i, A61B 5/0478(2006.01)i

Applicant

VALENCELL, INC. et al

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [x] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR	Date of completion of this opinion	Authorized officer
Korean Intellectual Property Office Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	17 SEPTEMBER 2010 (17.09.2010)	Kim, Sae Byul Telephone No.82-42-481-8543

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025216

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of :

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. a sequence listing filed or furnished
      ☐ on paper
      ☐ in electronic form

   b. time of filing or furnishing
      ☐ contained in the international application as filed.
      ☐ filed together with the international application in electronic form.
      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additioanl copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025216

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-44	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-44	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-44	YES
	Claims	NONE	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 2008-0146890 A1 (STEVEN FRANCIS LEBOEUF et al.) 19 June 2008
D2: US 2005-0148883 A1 (PETER V. BOESEN) 07 July 2005
D3: US 2006-0084878 A1 (MATTHEW JOHN BANET et al.) 20 April 2006
D4: US 2004-0242976 A1 (MARCIO MARC ABREU) 02 December 2004

D1 discloses that wearable apparatus for monitoring various physiological and environmental factors are provided. Real-time, noninvasive health and environmental monitors include a plurality of compact sensors integrated within small, low-profile devices, such as earpiece modules. Physiological and environmental data is collected and wirelessly transmitted into a wireless network, where the data is stored and/or processed.

D2 discloses that sensing and transmitting physiological pressures and body temperatures. The device includes a transducer and a transmitter. The transmitter is adapted to broadcast a signal which is modulated by the output of a transducer. The transmitter is also adapted to limit the power of theoutput signal. The method includes transducing a physiological parameter and broadcasting a signal which is modulated by the transduced parameter. The power of the output signal is limited so that the signal will attenuate within a predetermined distance.

(continued on the Supplemental Box)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025216

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 17 relates to the monitoring apparatus, but claims 28-29 dependant on claim 17 relate to the headset. As claims 28-29 do not meet the requirement of PCT Article 6 in that the matter for which protection is sought is not clearly defined.

Supplemental Box

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

(continued on the Supplemental Box)

(Box No. V)

D3 discloses that a system for measuring blood pressure from a patient that includes: 1) an optical module featuring systems for measuring signals from the patient, serial communication, and power management; 2) an external computing device configured to attach to the optical module,supply power to the optical module, and receive information from the optical module through the system for serial communication; and 3) an algorithm, operating on the external computing device, that processes information received through the system for serial communication to determine the patient's blood pressure.

D4 discloses that support structures for positioning sensors on a physiologic tunnel for measuring physical, chemical and biological parameters of the body and to produce an action according to the measured valueof the parameters. The support structure includes a sensor fitted on the support structures using a special geometry for acquiring continuous and undisturbed data on the physiology of the body. Signals are transmitted to a remote station by wireless transmission such as by electromagnetic waves, radio waves, infrared, sound and the like or by being reported locally by audio or visual transmission. The physical and chemical parameters include brain function, metabolic function, hydrodynamic function, hydration status, levels of chemical compounds in the blood, and the like. The support structure includes patches, clips, eyeglasses, head mounted gear and the like, containing passive or active sensors positioned at the end of the tunnel with sensing systems positioned on and accessing a physiologic tunnel.

(continued on the next page)

Supplemental Box

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

(the previous page)

I. Novelty and Inventive Step

Claim 1:
D1-D4 disclose wearable apparatus for monitoring various physiological and environmental factors are provided, the difference of claim 1 from D1-D4 is that D1-D4 do not disclose or teach: measure at least one neurological and/or cardiopulmonary function of the subject. Moreover, the difference is not obvious for a person skilled in the art even with any combination of D1-D4. Therefore, claim 1 is considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3).

Claims 2-16:
Claims 2-16 are also considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3) as they are dependent claims depending on claim 1.

Claim 17:
D1-D4 disclose wearable apparatus for monitoring various physiological and environmental factors are provided, the difference of claim 17 from D1-D4 is that D1-D4 do not disclose or teach: measure at least one neurological and/or cardiopulmonary function of the subject. Moreover, the difference is not obvious for a person skilled in the art even with any combination of D1-D4. Therefore, claim 17 is considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3).

Claims 18-29:
Claims 18-29 are also considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3) as they are dependent claims depending on claim 17.

(continued on the next page)

Supplemental Box

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

(the previous page)

Claim 30:
D1-D4 disclose wearable apparatus for monitoring various physiological and environmental factors are provided, the difference of claim 30 from D1-D4 is that D1-D4 do not disclose or teach: measure at least one neurological and/or cardiopulmonary function of the subject. Moreover, the difference is not obvious for a person skilled in the art even with any combination of D1-D4. Therefore, claim 30 is considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3).

Claims 31-37:
Claims 31-37 are also considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3) as they are dependent claims depending on claim 30.

Claim 38:
D1-D4 disclose wearable apparatus for monitoring various physiological and environmental factors are provided, the difference of claim 38 from D1-D4 is that D1-D4 do not disclose or teach: measure at least one neurological and/or cardiopulmonary function of the subject. Moreover, the difference is not obvious for a person skilled in the art even with any combination of D1-D4. Therefore, claim 38 is considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3).

Claims 39-41:
Claims 39-41 are also considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3) as they are dependent claims depending on claim 38.

(continued on the next page)

Supplemental Box

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

(the previous page)

Claim 42:
D1-D4 disclose wearable apparatus for monitoring various physiological and environmental factors are provided, the difference of claim 42 from D1-D4 is that D1-D4 do not disclose or teach: detecting neurological and/or cardiopulmonary function information from the subject via electrodes attached to a headset worn by the subject. Moreover, the difference is not obvious for a person skilled in the art even with any combination of D1-D4. Therefore, claim 42 is considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3).

Claims 43-44:
Claims 43-44 are also considered to be novel under PCT Article 33(2) and to involve an inventive step under PCT Article 33(3) as they are dependent claims depending on claim 42.

II. Industrial applicability

The industrial applicability of claims 1-44 is self-evident in the sense of PCT Article 33(4) because the subject matter claimed can be made or used in industry.

Electronic Patent Application Fee Transmittal

Application Number:	14484585
Filing Date:	12-Sep-2014
Title of Invention:	Wearable Light-Guiding Devices For Physiological Monitoring
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Filer:	Needham J. Boddie/Cathy Leonard
Attorney Docket Number:	9653-7TSCT5

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	21246047
Application Number:	14484585
International Application Number:	
Confirmation Number:	8375
Title of Invention:	Wearable Light-Guiding Devices For Physiological Monitoring
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Cathy Leonard
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT5
Receipt Date:	20-JAN-2015
Filing Date:	12-SEP-2014
Time Stamp:	10:26:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$180
RAM confirmation Number	12942
Deposit Account	500220
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		9653-7TSCT5_IDS.pdf	1360512 3dedc02000caef2f22ef5759b6693c505cd8f4b4	yes	10
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	10	
Warnings:					
Information:					
2	Foreign Reference	WO2008141306.pdf	3462966 01f14938fafbd8894854d4bcf4b8b57dafd935ca	no	68
Warnings:					
Information:					
3	Foreign Reference	WO2005020121A1.pdf	1451336 e7bec75b7b8f8993cb6223b6d18d34be9b0c4375	no	44
Warnings:					
Information:					
4	Foreign Reference	WO0047108.pdf	2189095 4123639efa588728302752d43720fe46afa32b90	no	44
Warnings:					
Information:					
5	Foreign Reference	GB2411719.pdf	1906593 b4c81ddc999e8511533586b12a6158e338da0258	no	20
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Information:					
6	Foreign Reference	JP2003159221.pdf	527963 0b5a9a566cf01c15dcf93a049a9e613a20d89e2c	no	7
Warnings:					
Information:					

7	Foreign Reference	JP2004283523.pdf	450916 1d9de86f8e3b403b42cd7071cefedb0a705794ea	no	9
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Information:					
8	Foreign Reference	JP2007044203.pdf	961349 1c0ba963bcae9ea2a7009bf8f548939f5a2b9780	no	16
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Information:					
9	Foreign Reference	JP2010526646.pdf	1077473 4bda09ef576c6d827fba925ac9ce7ae2d816abb2	no	28
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Information:					
10	Non Patent Literature	USArmy_Handbook.pdf	88519 0b22e42dcbb9a4da97f269001938bc158507910c	no	1
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Information:					
11	Non Patent Literature	Warfighter.pdf	8699699 09503fcd8ac1b1663ab254399f16f7b20a89f5b0	no	141
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Information:					
12	Non Patent Literature	Anpo.pdf	635880 36cbab4b7d87829170e72d631bb81c054dcb8012	no	5
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Information:					
13	Non Patent Literature	Barsan.pdf	1536770 4e2be9ab25659b7c245b4f9b5b0b5bda31623e1a	no	27
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Information:					
14	Non Patent Literature	Bott.pdf	415393 e1c2704c1388d431912e41f40e37e8a639ffac51	no	5
Warnings:					
Information:					
15	Non Patent Literature	Colligan.pdf	647524 07ef784220d3918780fe2b185a8e206ff4f15b6e	no	13
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Information:					

16	Non Patent Literature	dePaula.pdf	1053169 624fdc940115ddb3ff9415bc6d35ad1e81e7787d	no	8
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Information:					
17	Non Patent Literature	Ebert.pdf	787325 802a6065ffdd47d57f1ec9f848febfb3a5ad2ce7	no	7
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18	Non Patent Literature	ESR_07862660_3.pdf	237273 9754d58b68381954de8091ea7dbe27ec9a840d10	no	7
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Information:					
19	Non Patent Literature	Falkner.pdf	787954 465f184e9b3c0f557ecfb56d1d5d0d923c1d2df1	no	9
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20	Non Patent Literature	Fleming_A_comparison_of_Signal_Processing.pdf	491727 10836da0e99824d0344a03bd5aaf74933864b18d	no	6
Warnings:					
Information:					
21	Non Patent Literature	Geladas_Effect_of_cold_air_inhalation.pdf	758261 e3c6a8cf422e5a3a70a6449b01ffda57d59ca571	no	7
Warnings:					
Information:					
22	Non Patent Literature	Gold.pdf	605616 1dc81f8ffd4cda35a04ac403f497846d6ca10b7b	no	8
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23	Non Patent Literature	ISR_2012046446.pdf	156235 4d45c660ed1859f4de6a96ad1c7ceebcf325c68f	no	3
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24	Non Patent Literature	ISR_PCT2012048079.pdf	2623739 486e10a386d7baf24bfd3fc4bffb3f9ceba22577	no	27
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Information:					

25	Non Patent Literature	ISR_PCT2007025114.pdf	1247883 fdf6a0f2b2cba26a42b81e8fdebfd8fde54d157a	no	14
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26	Non Patent Literature	ISR_2012022634.pdf	461890 48aede9ae7eadf2790975772dca86014e7f17140	no	9
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Information:					
27	Non Patent Literature	Maomao.pdf	702497 296b7dc32c97bcba5bcf610c49383c97f1fe625b	no	7
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Information:					
28	Non Patent Literature	Martins.pdf	1059865 158749900efcf189353c55a663b55d30041e0fdb	no	11
Warnings:					
Information:					
29	Non Patent Literature	Maughan_Impact_of_mild_hydration.pdf	451188 168e13e0613e8623314650f923030704c58358e4	no	5
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Information:					
30	Non Patent Literature	Maughan_Exercise_Heat_Hydration.pdf	753062 ed52b58a7ef3407eb4c9a1762ad5939c25742ecf	no	9
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Information:					
31	Non Patent Literature	Mostardi.pdf	425730 16162a6ca635aeb80d6bc11dc7c8c41495b5fcee	no	9
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Information:					
32	Non Patent Literature	Nakajima.pdf	581448 a67f10e250fe1f5d704972355cb67fa99675f352	no	8
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Information:					
33	Non Patent Literature	ISR_2010021936.pdf	736122 6cdd0e277eb38cd42e02c44f89aa08893fa93682	no	8
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Information:					

34	Non Patent Literature	ISR_2010024922.pdf	439703 b4dc76ee7b513af83ed087d456ccf4194365a897	no	9
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Information:					
35	Non Patent Literature	ISR_2010025216.pdf	585342 5483d05d4723baac47ba696f6c2184c27a0987f1	no	13
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36	Non Patent Literature	Saladin.pdf	151733 65884fdd117a57325fa8e3fc82c00950bba182d2	no	2
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37	Non Patent Literature	Shorten.pdf	698894 d6f964a69cfeb6197e9f94f2478af2020aa18988	no	7
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Information:					
38	Non Patent Literature	Skubal.pdf	474064 ea461cdcb646cf25ad32dca2515601a36cba0e90	no	6
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39	Non Patent Literature	Skubal_Monitoring.pdf	633572 b5eaf0a39855e5e2f5be8bd4263b0617860f5ed3	no	10
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40	Non Patent Literature	Thompson_Cardiovascular_drift.pdf	1013551 49b371439f645dcb5709278205ba5543de44418b	no	10
Warnings:					
Information:					
41	Non Patent Literature	Zhang.pdf	631483 7cf506a32db1464fc5a49d60c379a325e556caa9	no	6
Warnings:					
Information:					
42	Fee Worksheet (SB06)	fee-info.pdf	30629 5f88e72e46da59e93901b3ad61ed08a6b17cf2aa	no	2
Warnings:					
Information:					

Total Files Size (in bytes):	43991943

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

Attorney Docket No. 9653-7TSCT5 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: LeBoeuf et al. Confirmation No. 8375
Application No.: 14/484,585 Examiner: Fuller, Rodney Evan
Filing Date: September 12, 2014 Group Art Unit: 2852
For: Wearable Light-Guiding Devices For Physiological Monitoring

Date: January 20, 2015

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Sir:

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

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

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

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

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

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

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

☒ (2) The fee set forth in §1.17(p);

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

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

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

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

☐ (2) The fee set forth in §1.17(p);

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

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

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

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

Respectfully submitted,

/N J Boddie II/

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

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

CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4) to the U.S. Patent and Trademark Office on January 20, 2015.

/Cathy J. Leonard/

Name: Cathy J. Leonard

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/484,585	09/12/2014	Steven Francis LeBoeuf	9653-7TSCT5

CONFIRMATION NO. 8375

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

PUBLICATION NOTICE

OC000000073102506

Title: Wearable Light-Guiding Devices For Physiological Monitoring

Publication No.US-2015-0032009-A1
Publication Date:01/29/2015

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

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

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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NOTICE OF ALLOWANCE AND FEE(S) DUE

20792 7590 02/02/2015

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

EXAMINER	
FULLER, RODNEY EVAN	
ART UNIT	PAPER NUMBER
2852	

DATE MAILED: 02/02/2015

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/484,585	09/12/2014	Steven Francis LeBoeuf	9653-7TSCT5	8375

TITLE OF INVENTION: Wearable Light-Guiding Devices For Physiological Monitoring

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	05/04/2015

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20792 7590 02/02/2015
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/484,585	09/12/2014	Steven Francis LeBoeuf	9653-7TSCT5	8375

TITLE OF INVENTION: Wearable Light-Guiding Devices For Physiological Monitoring

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	05/04/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
FULLER, RODNEY EVAN	2852	600-310000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
- ❑ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ❑ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/484,585	09/12/2014	Steven Francis LeBoeuf	9653-7TSCT5	8375

20792 7590 02/02/2015

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

EXAMINER	
FULLER, RODNEY EVAN	
ART UNIT	**PAPER NUMBER**
2852	

DATE MAILED: 02/02/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 14/484,585	Applicant(s) LEBOEUF ET AL.	
	Examiner RODNEY FULLER	Art Unit 2852	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *applicant's Response and Terminal Disclaimer, dated 11/18/2014*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-20*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 1/20/2015
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☒ Other *Detailed Action*.

/RODNEY FULLER/
Primary Examiner, Art Unit 2852

DETAILED ACTION

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

Terminal Disclaimer

2. The terminal disclaimer filed on 11/18/2014 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 8,886,269, U.S. Patent 8,700,111, and any patents granted on Application Numbers 14/298,402 and 14194891 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

3. Claims 1-20 are allowed.

Conclusion

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

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

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RODNEY FULLER/
Primary Examiner, Art Unit 2852

January 21, 2015

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	158	leboeuf-steven-francis.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:01
L2	99	tucker-jesse-berkley.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:01
L3	77	aumer-michael-edward.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:02
L4	174	1 or 2 or 3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:02
L5	28	4 and cladding	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:02
L6	15	5 and window	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:02
L7	15	6 and parallel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:02
L8	4780	((600/310) or (600/322) or (600/323) or	US-PGPUB;	OR	OFF	2015/01/21

		(600/324)).CCLS.	USPAT; USOCR			14:03
L9	0	(a16b5/0082 or a16b5/418 or a16b5/6838 or a16b5/6803 or a16b5/1455).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:04
L10	0	(a16b5/0082 or a16b5/418 or a16b5/6838 or a16b5/6803 or a16b5/1455).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:06
L11	0	(a16b5/0082).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:06
L12	17797	(a61b5/0082 or a61b5/418 or a61b5/6838 or a61b5/6803 or a61b5/1455).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:07
L13	20994	8 or 12	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:07
L14	50	13 and (layer with cladding)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:07
L15	32	14 and parallel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:08
L16	27	15 and (inner with layer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:08
L17	27	16 and (outer with layer)	US-PGPUB; USPAT; USOCR;	OR	ON	2015/01/21 14:08

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
L18	15	17 and (layer with transmissive)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:08
L19	103	("20050228299" | "20090287067" | "20100298653" | "6078829" | "20120197093" | "5086229" | "6080110" | "6371925" | "6859658" | "20080177162" | "20090105556" | "20100168531" | "20080076972" | "20090030350" | "5596987" | "6783501" | "20090054752" | "6358216" | "7107088" | "20060009685" | "20090270698" | "20110105869" | "20130131519" | "7209775" | "8512242" | "8055319" | "20050043600" | "20050177034" | "20050209516" | "20080096726" | "20080165017" | "20090054752" | "6808473" | "8251903" | "20040034293" | "20120179011" | "20040054291" | "20100217103" | "8055319" | "20030109030" | "20040225207").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:10
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L22	26	("20050177034" | "20050209516" | "20050228299" | "20060009685" | "20080076972" | "20080096726" | "20080165017" | "20080177162" | "20090030350" | "20090054752" | "20090105556" | "20090270698" | "20090287067" | "20110105869" | "20120197093" | "20130131519" | "6078829" | "6080110" | "6371925" | "6783501" | "6808473" | "6859658" | "7209775" | "8055319" | "8251903" | "8512242").PN. OR ("8700111").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:11

L23	1	("8886269").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2015/01/21 14:11
L24	38	("20030109030" | "20040034293" | "20040054291" | "20050043600" | "20050177034" | "20050209516" | "20050228299" | "20060009685" | "20080076972" | "20080096726" | "20080165017" | "20080177162" | "20090030350" | "20090054752" | "20090105556" | "20090270698" | "20090287067" | "20100168531" | "20100217103" | "20100298653" | "20110105869" | "20120179011" | "20120197093" | "20130131519" | "5086229" | "5596987" | "6078829" | "6080110" | "6358216" | "6371925" | "6783501" | "6808473" | "6859658" | "7107088" | "7209775" | "8055319" | "8251903" | "8512242").PN. OR ("8886269").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:11
L25	41	19 or 20 or 21 or 22 or 23 or 24	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:12
L26	5	25 and (cladding and layer and parallel)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:12
L27	244	12 and (outer adj layer)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:12
L28	181	13 and (inner adj layer)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:13
L29	15	28 and (layer with cladding)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:13
L30	15	29 and (sensor or detector)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:13
L31	15	30 and (parallel)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:13
L32	15	31 and (window)	US-PGPUB; USPAT; USOCR	OR	ON	2015/01/21 14:13
L33	2940	(monitor$4 and layer and cladding and window and parallel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:14
L34	2940	(monitor$4 and layer and cladding and window and parallel)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:14
L35	363	34 AND ((A61B5/0084 OR A61B8/12 OR	US-PGPUB;	OR	ON	2015/01/21

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L36	91	35 and (layer with cladding)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:16
L37	19	36 and (outer adj layer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:16
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L40	18	38 and (window with layer)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/01/21 14:16
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			USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L43	0	(outer and inner and layer and cladding and window and light and parallel and transmissive).clm.	USPAT; UPAD	OR	ON	2015/01/21 14:18

1/ 21/ 2015 2:18:28 PM
C:\ Users\ rfuller\ Documents\ EAST\ Workspaces\ rodney9.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14484585	LEBOEUF ET AL.
	Examiner	Art Unit
	RODNEY FULLER	2852

CPC- SEARCHED		
Symbol	Date	Examiner
A61B5/0082	1/21/2015	/RF/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	310	1/21/2015	/RF/

SEARCH NOTES		
Search Notes	Date	Examiner
600/310, 322, 323, 324 (w/ text search)	1/21/2015	/RF/
East text search history printout	1/21/2015	/RF/
A61B5/0082, A61B5/418, A61B6/6838, A61B5/6803, A61B5/1455 (w/ text search)	1/21/2015	/.RF/

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	Interference search history printout	1/21/2015	/RF/

	/RODNEY FULLER/ Primary Examiner.Art Unit 2852

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
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	171.	US-	2003/0050563 A1	03-13-2003	Suribhotla et al.	
	172.	US-	6,527,711	03-04-2003	Stivoric et al.	
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Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RF/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	14/484,585
				Filing Date	September 12, 2014
				First Named Inventor	Steven Francis LeBoeuf
				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B6	of	B8	Attorney Docket Number	9653-7TSCT5

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Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

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				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B7	of	B8	Attorney Docket Number	9653-7TSCT5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
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Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

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				Filing Date	September 12, 2014
				First Named Inventor	Steven Francis LeBoeuf
				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B8	of	B8	Attorney Docket Number	9653-7TSCT5

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /RF/

Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14484585	LEBOEUF ET AL.
	Examiner	**Art Unit**
	RODNEY FULLER	2852

CPC						
Symbol					**Type**	**Version**
A61B		5	/	0082	F	2013-01-01
A61B		5	/	6838	I	2013-01-01
A61B		5	/	418	I	2013-01-01
A61B		5	/	1455	I	2013-01-01
A61B		5	/	6803	I	2013-01-01
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CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
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			/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/RODNEY FULLER/ Primary Examiner.Art Unit 2852	01/21/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14484585	LEBOEUF ET AL.
	Examiner	**Art Unit**
	RODNEY FULLER	2852

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
600	310	A	6	1	B	5 / 00 (2006.01.01)					

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/RODNEY FULLER/ Primary Examiner.Art Unit 2852	01/21/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	14484585	LEBOEUF ET AL.
	Examiner	**Art Unit**
	RODNEY FULLER	2852

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17												
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10	10														
11	11														
12	12														
13	13														
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15	15														
16	16														

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	20	
/RODNEY FULLER/ Primary Examiner.Art Unit 2852	01/21/2015	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20792 7590 02/02/2015
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/484,585	09/12/2014	Steven Francis LeBoeuf	9653-7TSCT5	8375

TITLE OF INVENTION: Wearable Light-Guiding Devices For Physiological Monitoring

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	05/04/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
FULLER, RODNEY EVAN	2852	600-310000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 Myers Bigel Sibley & Sajovec
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Valencell, Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Raleigh, NC

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
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☒ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number 50-0220 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29 — NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27 — NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status. — NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date February 6, 2015
Typed or printed name Needham J. Boddie, II Registration No. 40,519

PTOL-85 Part B (10-13) Approved for use through 10/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Electronic Patent Application Fee Transmittal

Application Number:	14484585
Filing Date:	12-Sep-2014
Title of Invention:	Wearable Light-Guiding Devices For Physiological Monitoring
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Filer:	Needham J. Boddie/Candi Riggs
Attorney Docket Number:	9653-7TSCT5

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**960**

Electronic Acknowledgement Receipt	
EFS ID:	21424050
Application Number:	14484585
International Application Number:	
Confirmation Number:	8375
Title of Invention:	Wearable Light-Guiding Devices For Physiological Monitoring
First Named Inventor/Applicant Name:	Steven Francis LeBoeuf
Customer Number:	20792
Filer:	Needham J. Boddie/Candi Riggs
Filer Authorized By:	Needham J. Boddie
Attorney Docket Number:	9653-7TSCT5
Receipt Date:	06-FEB-2015
Filing Date:	12-SEP-2014
Time Stamp:	14:18:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$960
RAM confirmation Number	540
Deposit Account	500220
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	9653-7TSCT5_FeesTransmittal.pdf	133342 deac7ff5f07c3edcd78432e4bc2e14018cbfe998	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30945 228ab1eafcc7f451dd841e97f8c14576342ada2b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	164287		

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	14/484,585
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				First Named Inventor	Steven Francis LeBoeuf
				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B5	of	B8	Attorney Docket Number	9653-7TSCT5

	165.	US-	6,571,117	05-27-2003	Marbach	
	166.	US-	6,569,094 B2	05-27-2003	Suzuki et al.	
	167.	US-	2003/0083583 A1	05-01-2003	Kovtun et al.	
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Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	14/484,585
				Filing Date	September 12, 2014
				First Named Inventor	Steven Francis LeBoeuf
				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B4	of	B8	Attorney Docket Number	9653-7TSCT5

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Examiner Signature	/Rodney Fuller/	Date Considered	01/21/2015

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
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				Filing Date	September 12, 2014
				First Named Inventor	Steven Francis LeBoeuf
				Art Unit	2852
				Examiner Name	Fuller, Rodney Evan
Sheet	B2	of	B8	Attorney Docket Number	9653-7TSCT5

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/484,585	03/24/2015	8989830	9653-7TSCT5	8375

20792 7590 03/04/2015

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

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Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Steven Francis LeBoeuf, Raleigh, NC;
Valencell, Inc., Raleigh, NC, Assignee (with 37 CFR 1.172 Interest);
Jesse Berkley Tucker, Knightdale, NC;
Michael Edward Aumer, Raleigh, NC;

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/484,585	09/12/2014	2878	1600	9653-7TSCT5	20	2

CONFIRMATION NO. 8375

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FILING RECEIPT

OC000000071485462

Date Mailed: 10/22/2014

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Steven Francis LeBoeuf, Raleigh, NC;
Jesse Berkley Tucker, Knightdale, NC;
Michael Edward Aumer, Raleigh, NC;

Applicant(s)

Valencell, Inc., Raleigh, NC

Power of Attorney: The patent practitioners associated with Customer Number 20792

Domestic Priority data as claimed by applicant

This application is a CON of 14/184,364 02/19/2014 PAT 8886269
which is a CON of 12/691,388 01/21/2010 PAT 8700111
which claims benefit of 61/208,567 02/25/2009
and claims benefit of 61/208,574 02/25/2009
and claims benefit of 61/212,444 04/13/2009
and claims benefit of 61/274,191 08/14/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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If Required, Foreign Filing License Granted: 10/22/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/484,585**

Projected Publication Date: 01/29/2015

Non-Publication Request: No

Early Publication Request: No

Title

Wearable Light-Guiding Devices For Physiological Monitoring

Preliminary Class

250

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

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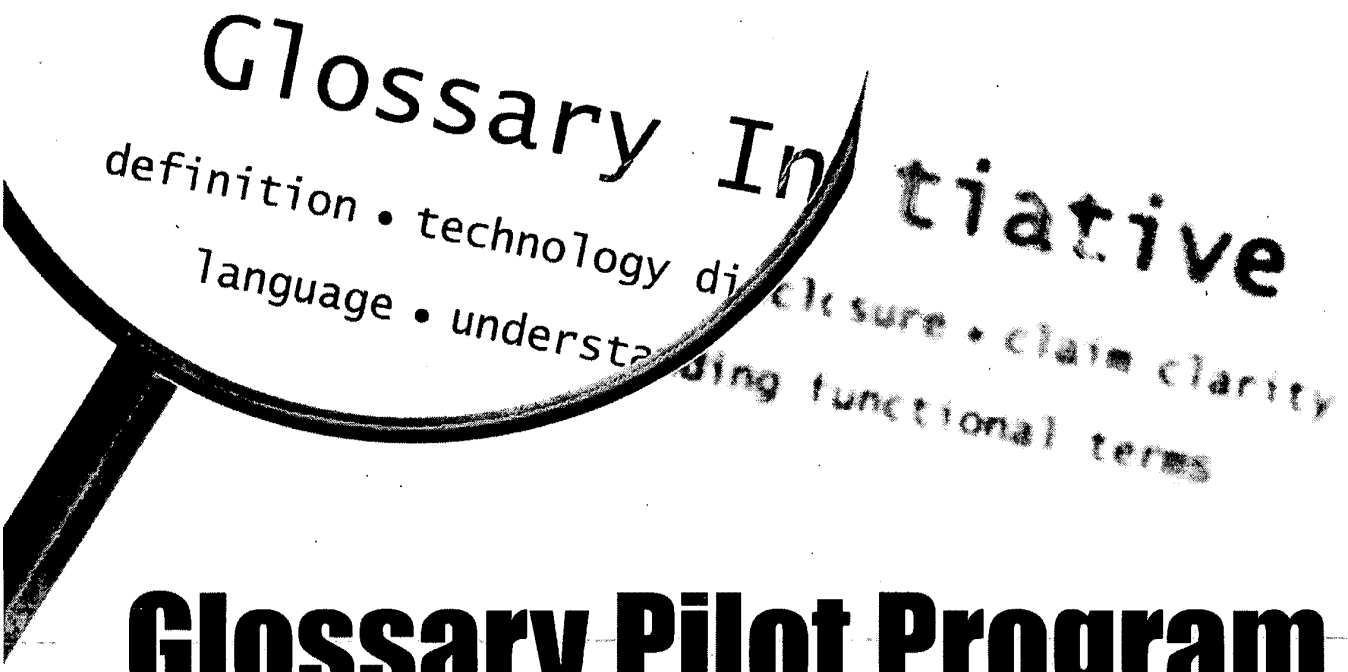

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