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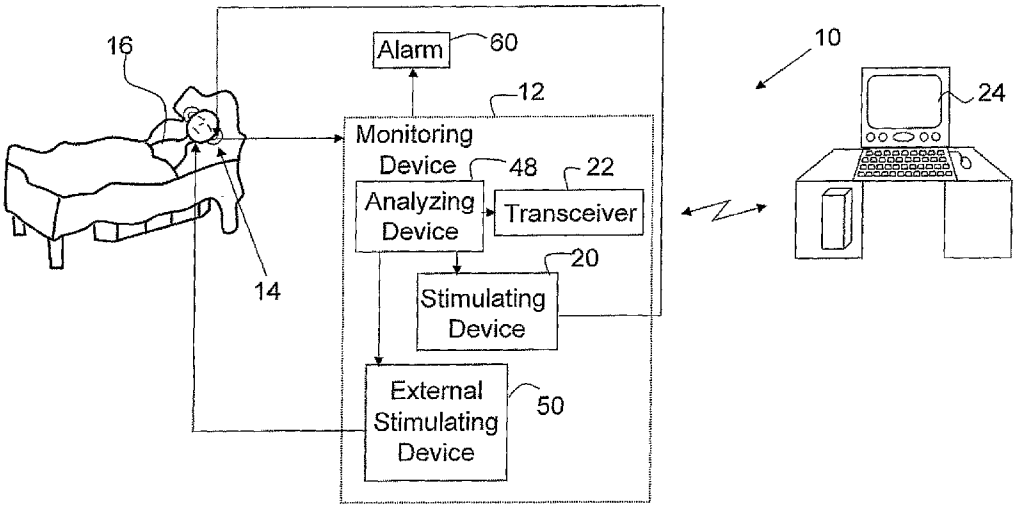

(57) Abstract: A physiological parameter measuring device (14) is disposed within or near an ear canal of a subject (16) to non-invasively sense at least one physiological parameter of the subject which one physiological parameter is associated with at least one physiological condition of the subject. An analyzing device (48) is operatively coupled to the physiological parameter measuring device (14) to analyze the sensed physiological parameter and detect the physiological condition of the subject (16). Based on the detection and analysis of the physiological condition of the subject (16), a stimulating device (20) stimulates the subject (16) with the physiological parameter measuring device (14) within or near the ear canal of the subject (16) to mitigate the physiological condition of the subject (16).

WO 2007/100958 A1

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EXTERNAL DEVICE THAT CONTINUOUSLY MONITORS FOR OSDB AND DELIVERS AUDIO STIMULATION THERAPY

DESCRIPTION

The following relates to monitoring arts. It finds particular application in conjunction with monitoring and treating of Obstructive Sleep Disordered Breathing (OSDB). It finds more particular application in monitoring and treating sleep apnea and will be described with a particular reference thereto. However, it is to be appreciated that the following is also applicable to monitoring and treatment of other physiological conditions.

Snoring typically manifests OSDB. OSDB includes upper airway resistance syndrome, non-obstructive and obstructive sleep apneas and nocturnal Cheyne-Stokes breathing. While snoring is characterized by partial occlusion of the upper airway passage during sleep, the sleep apnea and Cheyne-Stokes breathing is normally characterized by intermittently complete occlusions.

Sleep apnea is the most common piece of OSDB and is characterized by the absence of breathing for a certain period of time such as 30 to 45 seconds. Doctors estimate that about 18 million Americans suffer from sleep apnea. One cause for sleep apnea is an obstruction of the airway when the muscles of the tongue or uvula relax. Obesity and an abnormal amount of fat in the throat area are conducive to this condition. Another cause is a temporary cessation of the message from the brain that tells the diaphragm to breathe. In sleep apnea, with each period of breathlessness, which can be as many as twenty in an hour, the carbon dioxide level in the blood rises. There is a corresponding decrease in the blood oxygen levels. This, along with the stress and the struggle to draw breath, puts a strain on the heart. Untreated, sleep apnea can cause high blood pressure and other cardiovascular disease, memory problems, weight gain, impotency, and headaches. If the sleep apnea is diagnosed and treated sooner, such problems might be avoided in some cases, or at least the damage might be reduced.

Polysomnography is a standard diagnostic approach to detect the sleep apnea. It requires the person to stay overnight in the hospital for observation. A polysomnographic procedure involves tethered connections and monitoring of many parameters which makes it intensive, site dependent, and costly. Such approach is not

practical for screening a large number of patients and thus the majority of patients suffering from OSDB remain undiagnosed.

One approach to treat sleep apnea is to use a face mask and a small air compressor or fan that forces just enough air through the nasal passages to keep the nasal passages open during the night. But, although such a mask allows a good night's sleep, it causes physical discomfort to the person as well as makes the person prone to nasal congestion and infections.

Another approach is to pace the heart at a faster rate, which stimulates the sleeper's breathing. Unfortunately, this requires an implantable pacemaker type device to the heart.

Another approach is to pace or stimulate the muscles of the tongue or uvula from relaxation thus opening the constricted airway allowing the sleeper to resume breathing. Unfortunately, this approach requires an implantable nerve or muscle stimulator.

Another approach is to surgically remove a portion of the posterior tongue or uvula muscles so that when the muscles relax the airway remains sufficiently open to not totally occlude airflow. Unfortunately, this approach requires a surgical procedure and has not been proven to be a long-term solution.

In yet another approach, the nerves are stimulated by a high voltage shock to the sleeper to condition the sleeper to resume breathing. Such method is painful and might result in a nervous injury.

The present application provides new and improved imaging apparatuses and methods, which overcome the above-referenced problems and others.

With reference to one aspect, a monitoring, therapy, and polysomnography testing system is disclosed. A physiological parameter measuring device is disposed within or near an ear canal of a subject to non-invasively sense at least one physiological parameter of the subject which one physiological parameter is associated with at least one physiological condition of the subject. An analyzing device is operatively coupled to the physiological parameter measuring device to analyze the sensed physiological parameter and detect the physiological condition of the subject. Based on the detection and analysis of the physiological condition of the subject, a

stimulating device stimulates the subject with the physiological parameter measuring device within or near the ear canal of the subject to mitigate the physiological condition of the subject.

With reference to another aspect, a method is disclosed. At least one physiological parameter of a sleeping subject is non-invasively sensed via an auditory canal of the subject, the physiological parameter being associated with at least one physiological condition of the subject. The sensed physiological parameter is analyzed to detect the physiological condition of the subject. In response to the detection of the physiological condition of the subject, the subject is stimulated so that the physiological condition of the subject is mitigated.

With reference to another aspect, a system for monitoring and treating obstructive sleep disordered breathing (OSDB) is disclosed. An in-the-ear sensing device is disposed within an ear canal of a subject to non-invasively sense at least one physiological parameter of the subject which one physiological parameter is associated with the OSDB. A monitoring device is operatively coupled to the in-the-ear sensing device to communicate with the in-the-ear sensing device. An analyzing device analyzes the sensed physiological parameter and detects an OSDB event. A device is disposed in the in-the-ear sensing device, which device, based on the detected OSDB event, stimulates the subject to mitigate the OSDB event.

Still further advantages and benefits of the present application will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

The following may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting.

FIGURE 1 is a diagrammatical illustration of a monitoring and therapy system,

FIGURE 2 is a diagrammatical illustration of an in-the-ear probe; and

FIGURE 3 is an image of an in-the-ear probe attached to a behind-the-ear device.

With reference to FIGURES 1, 2 and 3, a monitoring or therapy or Polysomnography testing system **10** includes a monitoring device **12** that is configured to communicate with physiological measuring devices, such as an in-the-ear probe (ITE) **14**, inserted in an ear or auditory canal of a subject or sleeper **16**, for measuring one or more physiological parameters or signals, such as respiration, blood pressure, pulse oximetry or a level of blood oxygen (SpO_2), heart or pulse rate, perfusion, and temperature, from within an ear or auditory canal. As described in detail below, the monitoring device **12** monitors one or more physiological signals provided by the probe **14** to detect signs of Obstructive Sleep Disordered Breathing (OSDB) such as the signs of sleep apnea. If the signs of sleep apnea are detected, a stimulating device **20** applies stimulus to the subject **16** via the probe **14** so that a normal breathing pattern is restored. The examples of the monitoring device **12** are a behind-the-ear (BTE) OSDB monitoring device **18** as shown in FIGURE 3, an on-a-collar (OAC) device, and any other device suitable for interpreting the measurements and providing a suitable therapy as described below.

For example, the physiological parameters may be wirelessly transmitted by a wireless transceiver **22**, for example, continuously, periodically at a predetermined rate, on-demand, and upon occurrence of an event, from the monitoring device **12** to a computerized unit or central station **24**. The computerized unit **24** may be used to record the entire sleep activity and/or only the number and severity of OSDB events. Diagnostic analysis may be performed as data is received, or the recorded activity may be logged within a clinical or home environment and then physically or electronically returned to the Polysomnography Lab the next day for diagnostic analysis. The number of stimulation corrected OSDB events, non-corrected OSDB events, along with event severities may additionally be recorded.

With continuing reference to FIGURE 2, the probe **14** includes a tube **30** that inserts into the ear canal of the subject **16**. The tube **30** is suitably dimensioned to enter the ear canal to a suitable depth and adapts to various shaped ear canals, e.g., different diameter or contours.

In one embodiment, the tube **30** includes an end portion **32**, which resides in the ear canal. An inflatable balloon **40** surrounds the end portion **32** of the tube **30** or any other suitable portion of the tube **30**. The inflatable balloon **40** supports one or more sensors **42** that are operatively coupled to a surface of the balloon **40** to measure

physiological signals. The examples of sensors include light emitting diodes (LEDs), an infrared (IR) source, light detecting sensors, a pressure transducer, a microphone, a speaker, and a thermistor. For example, the light detecting sensor is used to minimize or prevent absorption of light not indicative of the physiological process under measurement such as light from outside the ear or light emitted from another sensor located on the balloon **40**. The inflatable balloon **40** is inflated to position the sensors **42** proximate to an appropriate tissue within the ear canal with adequate force and pressure to ensure close coupling of sensors with the tissue but without causing decreased perfusion or blanching of the tissue. Alternatively, the balloon is omitted and replaced with a spongy material that expands to correctly position the sensors. The sensors **42** are mounted about the end portion **32** of the tube **30** and could be moved into contact with the tissue once the tube **30** is inserted into the ear canal of the subject **16**.

Typically, sensors for measuring pulse rate and/or blood oxygen are positioned proximate to the ear canal tissue that is perfused with arterial blood supplied by branches of the External as well as the Internal Carotid Arteries, thus serving as a well perfused physiological site even if the body is experiencing peripheral shutdown due to shock or other conditions. Such sensors include an energy emitting means, such as an LED, which emits light into the tissue, and an energy detecting means that detects light transmission through the vascular tissue to determine pulse rate and/or blood oxygen levels. In another example, a temperature sensor, such as a thermistor, is positioned proximate to the vascular tissue. In yet another example, sensors for sensing audio signals such as a microphone **44** are suitably positioned in relatively quite regions of the ear canal to mitigate sensing erroneous audio signals. For example, microphone **44** can sense pulse pressure sounds and respiration. As another example, sensor(s) for producing audio signals, such as a speaker **46**, are positioned in the ear canal to produce audio signals to restore the sleeper's breathing pattern as described below.

The inflatable balloon **40** is also used to facilitate non-invasive measuring of the blood pressure. For the non-invasive blood pressure measurement, the inflatable balloon **40** is inflated until it occludes blood flow in a portion of the ear proximate a blood pressure sensor(s), such as a pressure transducer, operatively connected to the inflatable balloon **40**. The pressure in the inflatable balloon **40** is then suitably released to deflate the inflatable balloon **40**. A systolic and a diastolic blood pressure are obtained during inflation

and/or deflation using an auscultatory approach via the microphone **42** operatively connected to the balloon **40** and/or an oscillometric approach via optical sensing components attached to the balloon **40**.

With reference again to FIGURE 1, the probe **14** senses at least a respiration rate of the sleeper **16**. In one preferred embodiment, in addition to sensing the respiration of the sleeper **16**, the probe **14** senses at least one of a blood oxygen level (SpO_2) and the pulse rate of the sleeper **16**. In another preferred embodiment, the probe **14** senses at least one of SpO_2 and a blood pressure of the sleeper **16**. Although blood oxygen level is highly correlated with the severity of the sleep apnea due to the cyclic depression of blood oxygen as the sleeper experiences repeated cycles of oxygen deprivation, analyzing the combination of the respiration rate, blood oxygen level and pulse rate substantially enhances diagnostics of the sleep apnea as compared to analyzing a single signal. An analyzing device **48** analyses the sensed information for sleep apnea, e.g. for absence of breathing. Typically, as the sleeper **16** goes into the sleep apnea, the respiration ceases and SpO_2 begins to decrease. The pulse rate typically begins to decrease also. In one embodiment, the analyzing device or algorithm or means **48** analyses combination of data which is received by measuring respiration, SpO_2 and the pulse rate, which makes the analysis less susceptible to noise and mistake. The analysis might vary from one sleeper to another depending on that sleeper's personal data and medical history. For example, the pulse rate and SpO_2 can be compared with thresholds, e.g. a sudden slowing of the pulse rate by 10 beats per minute and a SpO_2 dropping below 90. Based on the analysis, the simulating device **20** applies the stimulus to the sleeper **16**. For example, for some subjects the stimulus is given after the respiration cessation of 10 seconds, while for others, the stimulus is given after the respiration cessation of 5 seconds, and in yet for others after a longer duration such as 30 or 45 seconds. As another example, for some sleepers the stimulus is given if the sleeper's pulse rate drops below a predetermined value. As another example, the respiration threshold varies dynamically with SpO_2 level or decreases in the pulse rate, e.g. carbon dioxide builds up in the blood shorter respiration cessations are tolerated.

The stimulus is given via the speaker **46**, which is, for example, a low power speaker which produces audible sounds that are loud enough to be heard by the user of the device, e.g. the sleeper **16**, but are not audible outside of the ear canal of the sleeper **16**. For example, the stimulus is a sound or a person's voice that tells the sleeper **16** to start

breathing, or to move, e.g. to turn on the side. As about 50% of sleepers with OSDB only show signs of OSDB when sleeping in a supine position, simply telling the sleepers to turn on the side is highly effect for this group. Such stimulus is given subconsciously, by barely waking up the sleeper **16**, if at all, only to resume breathing. Such stimulus occurs only a few seconds into the sleep apnea, thus significantly reducing the sleep apnea time. If the apnea persists, a louder voice or noise may be applied. Alternatively, the stimulating device **20** provides an external stimulus to the sleeper **16**, e.g. near the sleeper's ear. If the monitoring device **12** determines that after the stimulus is given there has been no breathing for a predetermined period of time, such as 1 minute or more, and the saturation levels are decreasing, the stimulating device **20** progressively increases the intensity of the audio signal. If, after reaching the maximum stimulation signal strength, the monitoring device **12** still does not detect that the breathing has been resumed, in one embodiment, an external stimulating device **50** applies a shock to the neck area or behind the ear via, for example, the on-a-collar device. In another embodiment, an external alarm **60** is provided which awakens, for example, a care provider.

With reference again to FIGURE 2, the tube **30** includes one or more passageways (not shown) that extend through the tube **30**. Such passageways house sensor data, power, and control wires, provide a hermetically sealed channel for inflating/deflating the balloon **40**, and/or allow pressure inside the ear to equalize with the environment during balloon inflation/deflation. The passageways isolate the wires from the inner ear environment, mitigating contamination of both the ear and the sensor wiring and provide a pressurized air conduit to the balloon **40**.

With reference again to FIGURE 3, the ITE probe **14** is mechanically and electrically coupled to the exemplary behind-the-ear (BTE) device **18**, together forming the complete OSDB monitoring device **12**. In one instance, the tube **30** and the BTE device **12** are formed as a single unit, while in another instance the tube **30** and the BTE device **12** are detachably connected. Such attachment can be through a fastening means including a threaded connector, a snap, a setscrew, an adhesive, a rivet, etc. An arm **72** provides support behind the ear and a battery **74** powers both devices. An optional sheath (not shown) can be placed over the tube **30** and/or balloon **40** to protect the ear and the structure/balloon/sensor assembly from contamination. In one aspect, the sheath can be semi-permeable to allow airflow, but prevent fluid from moving from one side of the sheath

to the other side. In another aspect, the sheath prevents substantially all matter from moving from one side of the sheath to the other side. The structure/balloon/sensor assembly can be disposable, washable, and/or sterilizeable.

In one embodiment, the monitoring device **12** communicates with the central station or computerized unit **24** to receive, display, analyze, validate and forward via wire or wirelessly physiological measurements continuously over a network, spot-check received physiological measurements obtained by the in-the-ear probe and download such measurements to the central monitoring station **24**, send information such as, physiological measurements, patient history, medical history, messages, notifications, alarms, and the like to an authorized individual, the central monitoring station, the polysomnography testing center, and the like. Of course, it is contemplated that a plurality of the monitoring devices **12**, each associated with a corresponding subject, communicates with the central station or computerized unit **24**.

In the manner described above, all necessary physiological signals needed for monitoring OSDB are obtained from one site within the ear. The described embodiments have the ability to treat OSDB from within the ear using audio stimulation therapy. The audio stimulation therapy signal may be programmed to become progressive louder and louder until the sleeper either subconsciously or consciously is momentarily semi-awakened causing the sleeper to breath. The audio stimulation therapy signal can be directed at the sleeper only, allowing others to not be awakened. Monitoring and delivery of therapy for OSDB can be provided that does not consciously arouse the sleeper or cause discomfort or stress that leads to the person's incompliance and non-acceptance. An apnea prone sleeper's discomfort is greatly reduced because the annoying breathing mask is no longer required while sleeping. The detection and treatment of OSDB can be performed without tethered connections (air hose, physiological measurement cables) between the sleeper and external contraptions thus enabling sleeper's movement and position changes during the night. The need for an implanted electrical stimulator or surgical procedures to treat OSDB is eliminated.

The polysomnography diagnostic testing is simplified by eliminating all tethered attachments from external devices to the sleeper and by having all physiological measurements performed from a single site. The cost and complexity of Polysomnography is reduced, making it more practical for screening large numbers of people in

Polysomnography Labs. Polysomnography diagnostic testing becomes practical to be performed within the homes of people allowing them to sleep and be tested in their normal sleeping environment. Additionally, it becomes practical to record the number and severity of OSDB events (corrected and non-corrected) within the home environment to evaluate the need for continuous monitoring for OSDB as well as evaluating the performance of such corrective devices.

The application has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the application be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS

1. A monitoring and therapy system **(10)** comprising:

a physiological parameter measuring device **(14)**, which is disposed within or near an ear canal of a subject **(16)**, to non-invasively sense at least one physiological parameter of the subject, which one physiological parameter is associated with at least one physiological condition of the subject;

an analyzing device **(48)**, which is operatively coupled to the physiological parameter measuring device **(14)**, to analyze the sensed physiological parameter and detect the physiological condition of the subject **(16)**; and

a stimulating device **(20)**, which, based on the detection and analysis of the physiological condition of the subject **(16)**, stimulates the subject **(16)** with the physiological parameter measuring device **(14)** within or near the ear canal of the subject **(16)** to mitigate the physiological condition of the subject **(16)**.

2. The system as set forth in claim 1, wherein the physiological parameter measuring device **(14)** senses a respiration rate of the subject **(16)** and, when a cessation of the respiration is detected, the stimulating device **(20)** stimulates the subject **(16)** to resume respiration.

3. The system as set forth in claim 2, wherein the analyzing device **(48)** compares the sensed respiration rate with one of a default value and a predetermined parameter and determines the respiration cessation based on the comparison, and the stimulating device **(20)** stimulates the subject **(16)** so that the subject **(16)** resumes respiration.

4. The system as set forth in claim 2, wherein the physiological parameter measuring device **(14)** further senses at least one of a blood oxygen level (SpO_2), a pulse rate, and a blood pressure.

5. The system as set forth in claim 4, wherein the analyzing device **(48)** compares one or any combination of at least the sensed respiration rate, the blood oxygen level (SpO_2) and the pulse rate with one of or a combination of default values and predetermined parameters, and detects the respiration cessation based on the combined analysis and minimizing a number of

erroneous detections, and the stimulating device **(20)** stimulates the subject **(16)** so that the subject **(16)** resumes respiration.

6. The system as set forth in claim 2, further including:

a speaker **(46)**, which provides an auditory, signal which, subconsciously and without waking the subject, reminds the subject to breathe, or to turn onto a side of the subject.

7. The system as set forth in claim 1, wherein the physiological parameter measuring device **(14)** includes an in-the-ear probe.

8. The system as set forth in claim 7, wherein the in-the-ear probe **(14)** includes:

a tube **(30)**, which is inserted into the ear canal of the subject **(16)**;

a first sensing device **(42, 44)**, disposed about the tube **(30)** and inserted with the tube **(30)** into the ear canal of the subject **(16)**, which first sensing device **(42, 44)** senses at least a respiration rate of the subject **(16)**; and

a second sensing device **(42, 46)**, disposed about the tube **(30)** and inserted with the tube **(30)** into the ear canal of the subject **(16)**, which second sensing device **(42, 46)** produces an audible signal when a cessation of the respiration is detected, which audible signal stimulates the subject **(16)** to resume respiration.

9. A method comprising:

non-invasively sensing at least one physiological parameter of a sleeping subject **(16)** via an auditory canal of the subject, the physiological parameter being associated with at least one physiological condition of the subject;

analyzing the sensed physiological parameter to detect the physiological condition of the subject; and

in response to the detection of the physiological condition of the subject, stimulating the subject so that the physiological condition of the subject is mitigated.

10. The method as set forth in claim 9, further including:

sensing a respiration rate of the subject;

detecting a cessation of the respiration; and

stimulating the subject so that the subject resumes respiration.

11. The method as set forth in claim 10, wherein the step for detecting the respiration cessation includes:

comparing the sensed respiration rate with one of a default value and a predetermined parameter; and

based on the comparison, determining the respiration cessation.

12. The method as set forth in claim 10, further including:

sensing physiological parameters including at least one of a blood oxygen level (SpO_2), a pulse rate and blood pressure;

analyzing combination of the sensed respiration rate and the sensed physiological parameters;

detecting the respiration cessation based on the combined analysis; and

minimizing a number of erroneous stimulations.

13. The method as set forth in claim 12, wherein the step of detecting the respiration cessation includes:

comparing the sensed respiration rate, blood oxygen level (SpO_2) and pulse rate with one or a combination of default values and predetermined parameters; and

based on a comparison, determining the respiration cessation.

14. The method as set forth in claim 10, wherein the stimulating step includes at least one of:

providing a subconscious message to the sleeping subject;

reminding the subject to breathe; and

reminding the subject to turn onto a subject side.

15. The method as set forth in claim 9, further including:

inserting a first sensing device **(42, 44)** into the auditory canal of the subject;

sensing a respiration rate of the subject with the first sensing device;

inserting a second sensing device **(42, 46)** into the auditory canal of the subject;

producing an audible signal with the second sensing device, which audible signal is audible to an associated subject; and

stimulating the associated subject with the audible signal so that the subject resumes respiration.

16. The method as set forth in claim 9, further including:

detecting obstructive sleep disordered breathing (OSDB) events;

transmitting at least one of the sensed physiological parameter and detected OSDB events to a computerized unit; and

recording at least one of an entire sleep activity and a number and severity of the OSDB events.

17. The system as set forth in claim 16, further including one of:

performing polysomnographic diagnostic analysis of the recorded OSDB events, and

transferring at least one of the collected and the analyzed data to a Polysomnography Lab.

18. An apparatus for performing the method of claim 9.

19. A system **(10)** for monitoring and treating obstructive sleep disordered breathing (OSDB) comprising:

an in-the-ear sensing device **(14)** which is disposed within an ear canal of a subject **(16)** to non-invasively sense at least one physiological parameter of the subject **(16)** which one physiological parameter is associated with the OSDB;

a monitoring device **(12)**, which is operatively coupled to the in-the-ear sensing device **(14)** to communicate with the in-the-ear sensing device **(14)**;

an analyzing device **(48)** which analyzes the sensed physiological parameter and detects an OSDB event; and

a device **(42, 46)** disposed in the in-the-ear sensing device **(14)**, which device **(42, 46)**, based on the detected OSDB event, stimulates the subject **(16)** to mitigate the OSDB event.

20. The system as set forth in claim 19, wherein the in-the-ear sensing device **(14)** senses at least one of a respiration rate, blood oxygen level and pulse rate of the subject **(16)**.

21. The system as set forth in claim 19, wherein the analyzing device **(48)** detects the OSDB event based on comparing one or any combination of the sensed respiration rate, and at least one of blood oxygen level, pulse rate, and blood pressure.

22. The system as set forth in claim 19, wherein the in-the-ear sensing device **(14)** includes at least:

at least one sensing device **(42, 44)** which senses at least one of a respiration rate, a blood oxygen level and a pulse rate of the subject **(16)**; and

a device **(42, 46)** which generates a subconsciously audible signal hearable by the subject which audible signal urges the subject to resume breathing or to turn onto a subject side.

23. The system as set forth in claim 19, further including:

a wireless transceiver **(22)**, operationally coupled with the monitoring device **(12)**, that wirelessly transmits at least one of the physiological parameter and detected OSDB event, one of continuously, periodically at a predetermined rate, on-demand, and upon detection of the OSDB event; and

a computerized unit **(24)** operationally coupled to the transceiver **(22)**, which records at least one of an entire sleep activity and a number and severity of the OSDB events.

24. The system as set forth in claim 23, wherein the computerized unit **(24)** one of performs polysomnographic diagnostic analysis of the recorded OSDB events, and electronically transfers one of the recorded and analyzed data to a Polysomnography Lab.

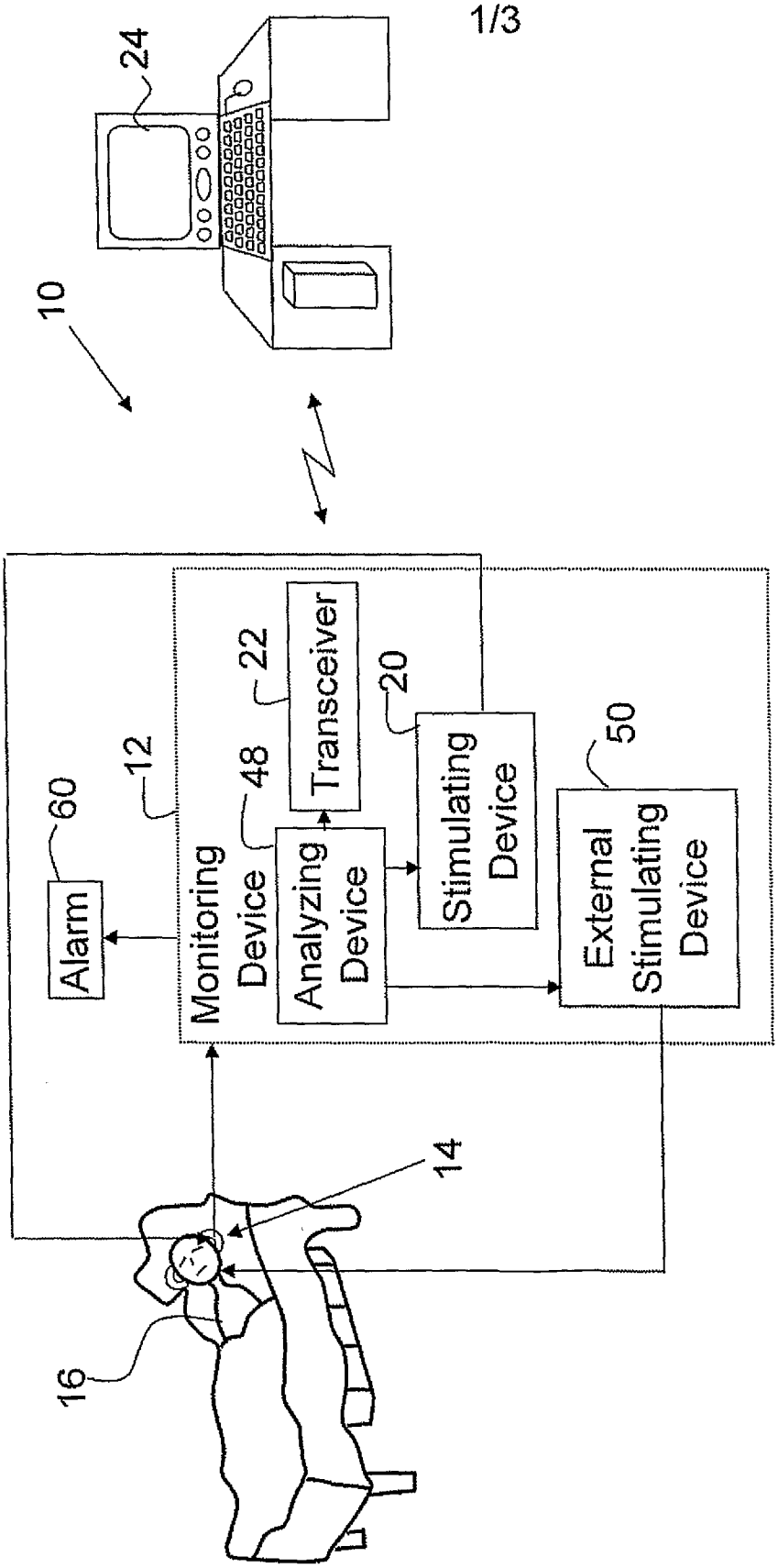

24
10
Alarm
60
12
Monitoring Device
48
Analyzing Device
Transceiver
22
20
Stimulating Device
50
External Stimulating Device
14
16

FIG 1

FIG 2

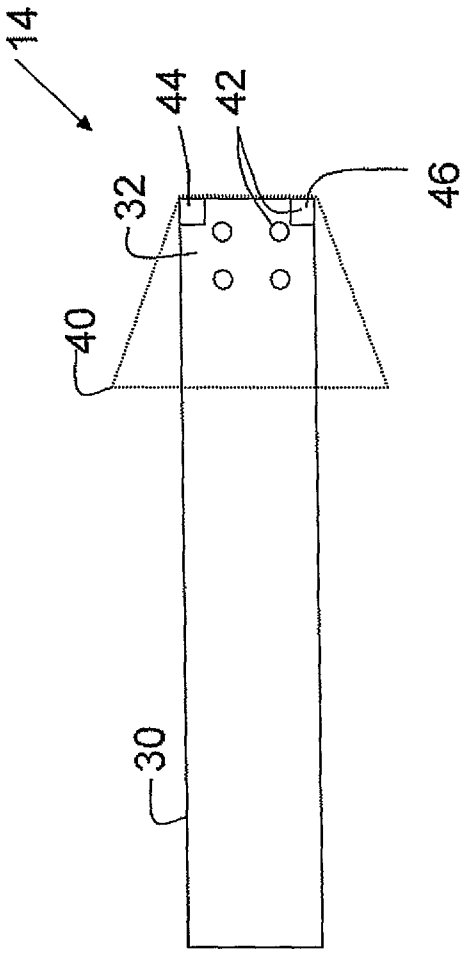
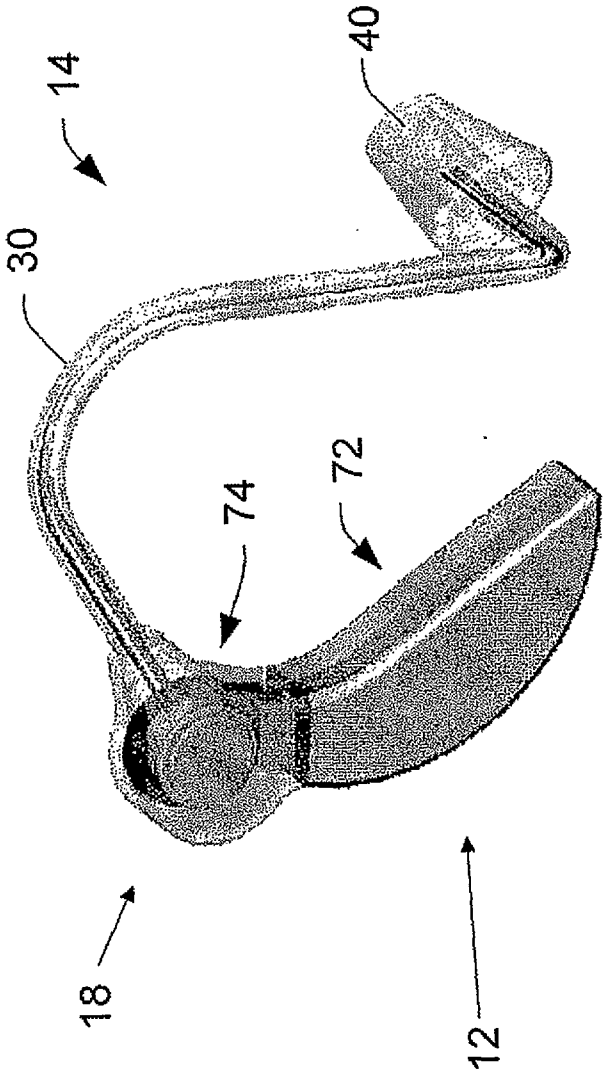


FIG 3



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/061638

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0205 A61B5/0215 A61B5/00 A61B5/022 A61B5/08
A61M21/00
ADD. A61F5/56
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 A61M A61F

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	DE 199 04 260 A1 (ENDERLEIN DIETMAR [DE]) 2 November 2000 (2000-11-02) column 2, lines 9-27 column 3, lines 54-60,65,66 column 4, lines 5-10,22-42 figures 1,4	1-3,18 4-8, 19-24
Y	US 6 363 270 B1 (COLLA GREGORY ALAN [AU] ET AL) 26 March 2002 (2002-03-26) abstract column 2, lines 57-60	4,5, 20-24

-/--

[X] Further documents are listed in the continuation of Box C.

[X] 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 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
11 May 2007	22/05/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Willig, Hendrik

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/061638

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 062 216 A (CORN STEPHEN B [US]) 16 May 2000 (2000-05-16) abstract column 2, lines 51-54 figure 1	6-8, 19-24
Y	US 2005/061319 A1 (HARTLEY JESSE W [US] ET AL) 24 March 2005 (2005-03-24) abstract paragraph [0068]	23,24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/061638

Box 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. [X] Claims Nos.: 9-17
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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 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:

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 an additional fee, this Authority did not invite payment of any additional fee.

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.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 9-17

As it becomes apparent from the whole content of the application, the methods of claims 9-17 are methods for the symptomatic treatment of obstructive sleep disordered breathing (see, e.g. p. 1, l. 14-26, p. 8, l. 15-16, claim 16). Consequently, claims 9-17 relate to methods for treatment of the human body by therapy (Rule 39.1(iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2007/061638

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19904260 A1	02-11-2000	NONE	
US 6363270 B1	26-03-2002	NONE	
US 6062216 A	16-05-2000	NONE	
US 2005061319 A1	24-03-2005	NONE	

专利名称(译)	外部设备持续监控OSDB并提供音频刺激治疗		
公开(公告)号	EP1991115A1	公开(公告)日	2008-11-19
申请号	EP2007717561	申请日	2007-02-06
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	NIELSEN LARRY		
发明人	NIELSEN, LARRY		
IPC分类号	A61B5/0205 A61B5/0215 A61B5/00 A61B5/022 A61B5/08 A61M21/00 A61F5/56		
CPC分类号	A61B5/14552 A61B5/0215 A61B5/022 A61B5/0816 A61B5/14542 A61B5/4818 A61B5/6815 A61B5/6817 A61B5/6838		
优先权	60/777480 2006-02-28 US		
其他公开文献	EP1991115B1		
外部链接	Espacenet		

摘要(译)

生理参数测量装置（14）设置在受试者（16）的耳道内或附近，以非侵入性地感测受试者的至少一个生理参数，其中一个生理参数与受试者的至少一个生理状况相关联。。分析装置（48）可操作地连接到生理参数测量装置（14），以分析所感测的生理参数并检测受试者的生理状况（16）。基于受试者（16）的生理状况的检测和分析，刺激装置（20）利用受试者（16）的耳道内或附近的生理参数测量装置（14）刺激受试者（16）。减轻受试者的生理状况（16）。