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(54) **EXTERNAL DEVICE THAT CONTINUOUSLY MONITORS FOR OSDB AND DELIVERS AUDIO STIMULATION THERAPY**

EXTERNE VORRICHTUNG ZUR KONTINUIERLICHEN ÜBERWACHUNG AUF OSDB UND ZUR VERABREICHUNG EINER AUDIOSTIMULATIONSTHERAPIE

PÉRIPHÉRIQUE SURVEILLANT EN CONTINU LE SYNDROME D'APNÉE OBSTRUCTIVE DU SOMMEIL

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Description

[0001] 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.

[0002] 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.

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] DE19904260 discloses a system in which lights are used to wake a patient that is suffering from a sleep disorder. US6,363,270 discloses a system in which Apneic and hypopneic arousals are detected from heart rate and blood oxygen levels. US6,062,216 describes a sleep apnea monitor that comprises a fixed console that projects a detection beam at a sleep surface, and analyzes the returned light to detect motion associated with breathing in the patient's upper body. US2005/0061319 discloses a system for implantably monitoring external breathing therapy.

[0011] The present application provides new and improved apparatuses, which overcome the above-referenced problems and others.

[0012] With reference to one aspect, a monitoring and therapy system according to claim 1 is disclosed.

[0013] With reference to another aspect, a system for monitoring and treating obstructive sleep disordered breathing (OSIB) according to claim 9 is disclosed.

[0014] 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.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] 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.

[0019] 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.**

[0020] 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.

[0021] 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.**

[0022] 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 de-

crease. 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.

[0023] 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 I 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.

[0024] 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.**

[0025] 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.

[0026] 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.**

[0027] 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.

[0028] 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.

[0029] 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 probe **(14),** which is adapted to be disposed within 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 probe **(14),** to analyze the sensed physiological parameter and detect the physiological condition of the subject **(16);** and
a stimulating device **(20),** which is adapted to stimulate, based on the detection and analysis of the physiological condition of the subject **(16),** the subject **(16)** via the probe **(14)** within 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 probe **(14)** is adapted to sense a respiration rate of the subject **(16)** and the stimulating device **(20)** is adapted to stimulate the subject **(16)** via the probe to resume respiration, when a cessation of the respiration is detected.

3. The system as set forth in claim 2, wherein the analyzing device **(48)** is adapted to compare the sensed respiration rate with one of a default value and a predetermined parameter and to determine the respiration cessation based on the comparison, and the stimulating device **(20)** is adapted to stimulate the subject **(16)** via the probe so that the subject **(16)** resumes respiration.

4. The system as set forth in claim 2, wherein the probe **(14)** further is adapted to sense 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)** is adapted to compare 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 to detect the respiration cessation based on the combined analysis and minimizing a number of erroneous detections, and the stimulating device **(20)** is adapted to stimulate the subject **(16)** via the probe so that the subject **(16)** resumes respiration.

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

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

7. The system as set forth in claim 1, wherein the probe **(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 adapted to be inserted into the ear canal of the subject **(16)**;
a first sensing device **(42, 44),** disposed about the tube **(30)** and adapted to be inserted with the tube **(30)** into the ear canal of the subject **(16),** which first sensing device **(42, 44)** is adapted to sense at least a respiration rate of the subject **(16)**; and
a second sensing device **(42, 46)**, disposed about the tube (30) and adapted to be inserted with the tube **(30)** into the ear canal of the subject **(16),** which second sensing device **(42, 46)** is adapted to produce an audible signal, when a cessation of the respiration is detected, to stimulate the subject **(16)** to resume respiration.

9. A system **(10)** for monitoring and treating obstructive

sleep disordered breathing (OSDB) comprising:

an in-the-ear sensing device **(14)** which is adapted to be 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 is adapted to analyze the sensed physiological parameter and to detect an OSDB event; and
a device **(42, 46)** disposed in the in-the-ear sensing device **(14),** which device is adapted to stimulate **(42, 46),** based on the detected OSDB event, the subject **(16)** to mitigate the OSDB event.

10. The system as set forth in claim 9, wherein the in-the-ear sensing device **(14)** is adapted to sense at least one of a respiration rate, blood oxygen level and pulse rate of the subject **(16).**

11. The system as set forth in claim 9, wherein the analyzing device **(48)** is adapted to is adapted to detect 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.

12. The system as set forth in claim 9, wherein the in-the-ear sensing device **(14)** includes at least:

at least one sensing device **(42, 44)** which is adapted to sense 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 is adapted to generate a subconsciously audible signal hearable by the subject to urge the subject to resume breathing or to turn onto a subject side.

13. The system as set forth in claim 9, further including:

a wireless transceiver **(22),** operationally coupled with the monitoring device **(12)**, adapted to wirelessly transmit 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 is adapted to record at least one of an entire sleep activity and a number and severity of the OSDB events.

14. The system as set forth in claim 13, wherein the computerized unit (**24**) is adapted to one of perform polysomnographic diagnostic analysis of the recorded OSDB events, and electronically transfer one of the recorded and analyzed data to a Polysomnography Lab.

Patentansprüche

1. Überwachungs- und Therapiesystem (10), das Folgendes umfasst:

eine Sonde (14), die dafür ausgelegt ist, innerhalb eines Gehörgangs einer Person (16) angeordnet zu werden, um nicht-invasiv mindestens einen physiologischen Parameter der Person zu erspüren, wobei der eine physiologische Parameter mit mindestens einem physiologischen Zustand der Person zusammenhängt;
eine Analysevorrichtung (48), die betriebsfähig mit der Sonde (14) gekoppelt ist, um den erspürten physiologischen Parameter zu analysieren und den physiologischen Zustand der Person (16) zu detektieren; und
eine Stimulationsvorrichtung (20), die dafür ausgelegt ist, die Person (16) über die Sonde (14) innerhalb des Gehörgangs der Person (16) auf der Basis der Detektion und Analyse des physiologischen Zustands der Person (16) zu stimulieren, um den physiologischen Zustand der Person (16) zu mildem.

2. System nach Anspruch 1, wobei die Sonde (14) dafür ausgelegt ist, eine Atemfrequenz der Person (16) zu erspüren und die Stimulationsvorrichtung (20) dafür ausgelegt ist, die Person (16) über die Sonde zu stimulieren, um das Atmen fortzusetzen, wenn ein Einstellen der Atmung detektiert wurde.

3. System nach Anspruch 2, wobei die Analysevorrichtung (48) dafür ausgelegt ist, die erspürte Atemfrequenz mit entweder einem Standardwert oder einem vorgegebenen Parameter zu vergleichen und das Einstellen der Atmung basierend auf dem Vergleich zu ermitteln, und wobei die Stimulationsvorrichtung (20) dafür ausgelegt ist, die Person (16) über die Sonde zu stimulieren, so dass die Person (16) das Atmen fortsetzt.

4. System nach Anspruch 2, wobei die Sonde (14) weiterhin dafür ausgelegt ist, mindestens entweder die partielle Blutsauerstoffsättigung (SpO_2), eine Pulsfrequenz oder einen Blutdruck zu erspüren.

5. System nach Anspruch 4, wobei die Analysevorrichtung (48) dafür ausgelegt ist, entweder die erspürte Atemfrequenz, die partielle Blutsauerstoffsättigung

(SpO_2) oder die Pulsfrequenz oder eine Kombination hiervon mit entweder den Standardwerten oder vorgegebenen Parametern oder einer Kombination hiervon zu vergleichen, und um das Einstellen der Atmung basierend auf der kombinierten Analyse zu detektieren und eine Anzahl von fehlerhaften Detektionen zu minimieren, und wobei die Stimulationsvorrichtung (20) dafür ausgelegt ist, die Person (16) über die Sonde zu stimulieren, so dass die Person (16) das Atmen fortsetzt.

6. System nach Anspruch 2, wobei das System weiterhin Folgendes umfasst:

einen Lautsprecher (46), der dafür ausgelegt ist, ein akustisches Signal zu liefern, um die Person im Unterbewusstsein und ohne sie aufzuwekken an das Atmen zu erinnern oder sich auf eine Seite zu drehen.

7. System nach Anspruch 1, wobei die Sonde (14) eine In-dem-Ohr-Sonde umfasst.

8. System nach Anspruch 7, wobei die In-dem-Ohr-Sonde (14) Folgendes umfasst:

einen Schlauch (30), der dafür ausgelegt ist, in den Gehörgang der Person (16) eingeführt zu werden;
eine erste Sensorvorrichtung (42, 44), die um den Schlauch (30) herum angeordnet ist und dafür ausgelegt ist, mit dem Schlauch (30) in den Gehörgang der Person (16) eingeführt zu werden, wobei die erste Sensorvorrichtung (42, 44) dafür ausgelegt ist, eine Atemfrequenz der Person (16) zu erspüren; und
eine zweite Sensorvorrichtung (42, 46), die um den Schlauch (30) herum angeordnet ist und dafür ausgelegt ist, mit dem Schlauch (30) in den Gehörgang der Person (16) eingeführt zu werden, wobei die zweite Sensorvorrichtung (42, 46) dafür ausgelegt ist, ein akustisches Signal zu erzeugen, wenn ein Einstellen der Atmung detektiert wird, um die Person (16) zu stimulieren, das Atmen fortzusetzen.

9. System (10) zum Überwachen und Behandeln einer obstruktiven schlafbezogenen Atmungsstörung (obstructive sleep disordered breathing, OSDB), wobei das System Folgendes umfasst:

eine In-dem-Ohr-Sensorvorrichtung (14), die dafür ausgelegt ist, innerhalb eines Gehörgangs einer Person (16) angeordnet zu werden, um nicht-invasiv mindestens einen physiologischen Parameter der Person (16) zu erspüren, wobei der eine physiologische Parameter mit mindestens der obstruktiven schlafbezogenen Atmungsstörung (OSDB) zusammenhängt;
eine Überwachungsvorrichtung (12), die betriebsfähig mit der In-dem-Ohr-Sensorvorrichtung (14) gekoppelt ist, um mit der In-dem-Ohr-Sensorvorrichtung (14) zu kommunizieren;
eine Analysevorrichtung (48), die dafür ausgelegt ist, den erspürten physiologischen Parameter zu analysieren und ein OSDB-Ereignis zu detektieren; und
eine Vorrichtung (42, 46), die in der In-dem-Ohr-Sensorvorrichtung (14) angeordnet ist, wobei die Vorrichtung (42, 46) dafür ausgelegt ist, die Person (16) basierend auf dem detektierten SODB-Ereignis zu stimulieren, um das OSDB-Ereignis zu mildem.

10. System nach Anspruch 9, wobei die In-dem-Ohr-Sensorvorrichtung (14) dafür ausgelegt ist, mindestens entweder die Atemfrequenz, die partielle Blutsauerstoffsättigung oder eine Pulsfrequenz der Person (16) zu erspüren.

11. System nach Anspruch 9, wobei die Analysevorrichtung (48) dafür ausgelegt ist, das OSDB-Ereignis basierend auf dem Vergleich von der erspürten Atemfrequenz und mindestens entweder der partiellen Blutsauerstoffsättigung, der Pulsfrequenz oder dem Blutdruck oder einer Kombination hiervon zu detektieren.

12. System nach Anspruch 9, wobei die In-dem-Ohr-Sensorvorrichtung (14) mindestens Folgendes umfasst:

mindestens eine Sensorvorrichtung (42, 44), die dafür ausgelegt ist, mindestens entweder eine Atemfrequenz, die partielle Blutsauerstoffsättigung oder eine Pulsfrequenz der Person (16) zu erspüren; und
eine Vorrichtung (42, 46), die dafür ausgelegt ist, ein unterbewusstes akustisches Signal zu erzeugen, das durch die Person hörbar ist, um die Person zu veranlassen, das Atmen fortzusetzen oder sich auf eine Seite zu drehen.

13. System nach Anspruch 9, das weiterhin Folgendes umfasst:

einen drahtlosen Transceiver (22), der betriebsfähig mit der Überwachungsvorrichtung (12) gekoppelt ist und dafür ausgelegt ist, mindestens entweder den physiologischen Parameter oder das detektierte OSDB-Ereignis entweder kontinuierlich, periodisch mit einer vorgegebenen Frequenz, auf Anfrage oder bei Detektion des OSDB-Ereignisses drahtlos zu übertragen; und
eine Computereinheit (24), die betriebsfähig mit dem Transceiver (22) gekoppelt ist und dafür

ausgelegt ist, mindestens entweder eine gesamte Schlafaktivität oder eine Anzahl und Ausgeprägtheit der OSDB-Ereignisse aufzuzeichnen.

14. System nach Anspruch 13, wobei die Computereinheit (24) dafür ausgelegt ist, entweder eine polysomnographische diagnostische Analyse der aufgezeichneten OSDB-Ereignisse durchzuführen oder die entweder aufgezeichneten oder analysierten Daten elektronisch an ein Polysomnographie-Labor zu übertragen.

Revendications

1. Système de surveillance et de thérapie (10) comprenant :

une sonde (14), qui est adaptée pour être disposée à l'intérieur d'un canal auriculaire d'un sujet (16), pour détecter, de façon non effractive, au moins un paramètre physiologique du sujet, lequel paramètre physiologique est associé à au moins une condition physiologique du sujet ;
un dispositif d'analyse (48), qui est couplé fonctionnellement à la sonde (14), pour analyser le paramètre physiologique détecté et détecter la condition physiologique du sujet (16) ; et
un dispositif de stimulation (20), qui est adapté pour stimuler, en fonction de la détection et de l'analyse de la condition physiologique du sujet (16), le sujet (16) par l'intermédiaire de la sonde (14) à l'intérieur du canal auriculaire du sujet (16) pour réduire la condition physiologique du sujet (16).

2. Système selon la revendication 1, dans lequel la sonde (14) est adaptée pour détecter un rythme respiratoire du sujet (16) et le dispositif de stimulation (20) est adapté pour stimuler le sujet (16) par l'intermédiaire de la sonde pour recommencer la respiration, lorsqu'une cessation de la respiration est détectée.

3. Système selon la revendication 2, dans lequel le dispositif d'analyse (48) est adapté pour comparer le rythme respiratoire détecté à une valeur par défaut ou un paramètre prédéterminé et pour déterminer la cessation de respiration en fonction de la comparaison, et le dispositif de stimulation (20) est adapté pour stimuler le sujet (16) par l'intermédiaire de la sonde pour que le sujet (16) recommence à respirer.

4. Système selon la revendication 2, dans lequel la sonde (14) est en outre adaptée pour détecter au moins un parmi un niveau d'oxygène sanguin (Sp02), une fréquence du pouls, et une pression artérielle.

5. Système selon la revendication 4, dans lequel le dispositif d'analyse (48) est adapté pour comparer un parmi au moins le rythme respiratoire détecté, le niveau d'oxygène sanguin (Sp02) et la fréquence du pouls, ou une quelconque combinaison d'au moins un de ceux-ci, à un parmi des valeurs par défaut et des paramètres prédéterminés, ou une combinaison de ceux-ci, et pour détecter la cessation de respiration en fonction de l'analyse combinée et minimiser un nombre de détections erronées, et le dispositif de stimulation (20) est adapté pour stimuler le sujet (16) par l'intermédiaire de la sonde pour que le sujet (16) recommence à respirer.

6. Système selon la revendication 2, comprenant en outre :

un haut-parleur (46), qui est adapté pour fournir un signal auditif pour, de façon subconsciente et sans réveiller le sujet, rappeler au sujet de respirer, ou pour qu'il se tourne sur son côté.

7. Système selon la revendication 1, dans lequel la sonde (14) comprend une sonde intra-auriculaire.

8. Système selon la revendication 7, dans lequel la sonde intra-auriculaire (14) comprend :

un tube (30), qui est adapté pour être inséré dans le canal auriculaire du sujet (16) ;
un premier dispositif de détection (42, 44), disposé autour du tube (30) et adapté pour être inséré avec le tube (30) dans le canal auriculaire du sujet (16), lequel premier dispositif de détection (42, 44) est adapté pour détecter au moins un rythme respiratoire du sujet (16) ; et
un second dispositif de détection (42, 46), disposé autour du tube (30) et adapté pour être inséré avec le tube (30) dans le canal auriculaire du sujet (16), lequel second dispositif de détection (42, 46) est adapté pour produire un signal audible, lorsqu'une cessation de la respiration est détectée, pour stimuler le sujet (16) pour recommencer respiration.

9. Système (10) pour surveiller et traiter l'apnée obstructive du sommeil (« Obstructive Sleep Disordered Breathing » ou OSDB) comprenant :

un dispositif de détection intra-auriculaire (14) qui est adapté pour être disposé à l'intérieur d'un canal auriculaire d'un sujet (16) pour détecter, de façon non effractive, au moins un paramètre physiologique du sujet (16), lequel paramètre physiologique est associé à l'OSDB ;
un dispositif de surveillance (12) qui est couplé fonctionnellement au dispositif de détection intra-auriculaire (14) pour communiquer avec le

dispositif de détection intra-auriculaire (14) ;
un dispositif d'analyse (48) qui est adapté pour analyser le paramètre physiologique détecté et pour détecter un événement d'OSDB ; et
un dispositif (42, 46) disposé dans le dispositif de détection intra-auriculaire (14), lequel dispositif (42, 46) est adapté pour stimuler, en fonction de l'événement d'OSDB détecté, le sujet (16) pour réduire l'événement d'OSDB.

10. Système selon la revendication 9, dans lequel le dispositif de détection intra-auriculaire (14) est adapté pour détecter au moins un parmi un rythme respiratoire, un niveau d'oxygène sanguin et une fréquence du pouls du sujet (16).

11. Système selon la revendication 9, dans lequel le dispositif d'analyse (48) est adapté pour détecter l'événement d'OSDB en fonction de la comparaison d'un parmi le rythme respiratoire détecté, et au moins un parmi le niveau d'oxygène sanguin, la fréquence du pouls, et la pression artérielle, ou d'une quelconque combinaison de ceux-ci.

12. Système selon la revendication 9, dans lequel le dispositif de détection intra-auriculaire (14) comprend au moins :

au moins un dispositif de détection (42, 44) qui est adapté pour détecter au moins un parmi un rythme respiratoire, un niveau d'oxygène sanguin et une fréquence du pouls du sujet (16) ; et un dispositif (42, 46) qui est adapté pour générer un signal audible de façon subconsciente, audible par le sujet, pour inciter le sujet à recommencer de respirer ou à se tourner sur son côté.

13. Système selon la revendication 9, comprenant en outre :

un émetteur-récepteur sans fil (22), fonctionnellement couplé au dispositif de surveillance (12), adapté pour émettre sans fil au moins un parmi le paramètre physiologique et l'événement d'OSDB détecté, de façon continue, ou de façon périodique à une fréquence prédéterminée, ou à la demande ou lors de la détection de l'événement d'OSDB ; et
une unité informatisée (24) fonctionnellement couplée à l'émetteur-récepteur (22), qui est adaptée pour enregistrer au moins un parmi une activité entière du sommeil et un nombre, et une sévérité, des événements d'OSDB.

14. Système selon la revendication 13, dans lequel l'unité informatisée (24) est adaptée pour réaliser une analyse diagnostique polysomnographique des événements d'OSDB enregistrés, ou pour transférer électroniquement les données enregistrées ou les données analysées à un laboratoire polysomnographique.

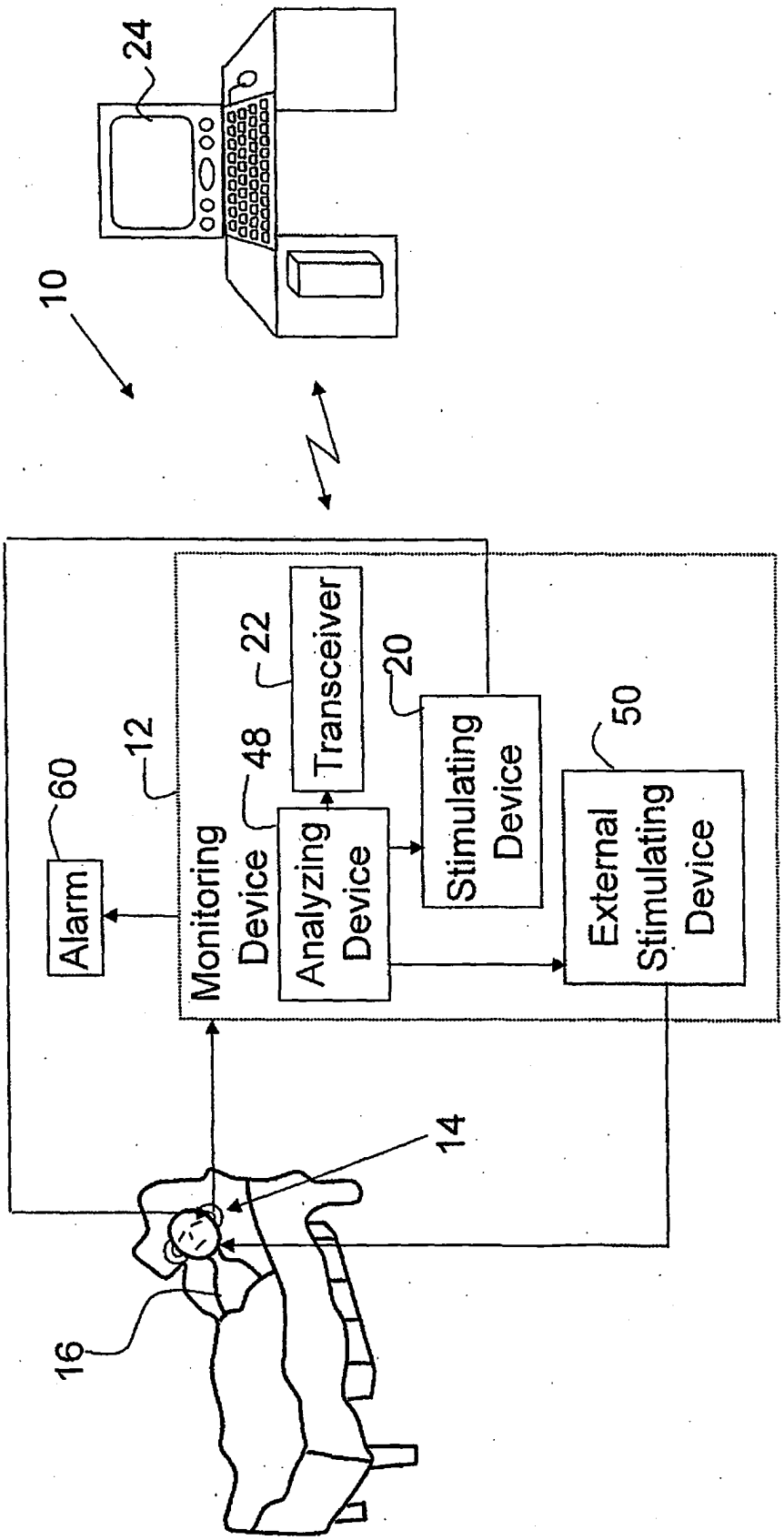

24
10
22
Transceiver
20
Stimulating Device
50
External Stimulating Device
12
60
Alarm
48
Monitoring Device
Analyzing Device
14
16

FIG 1

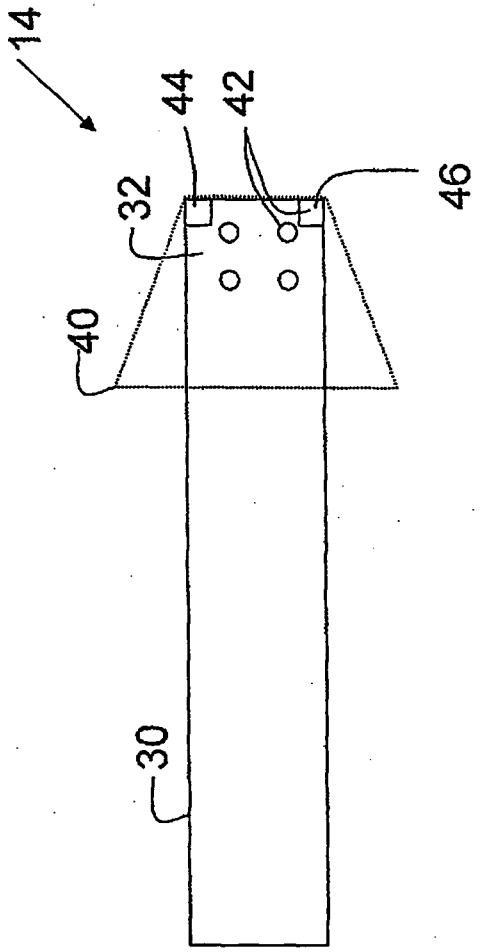
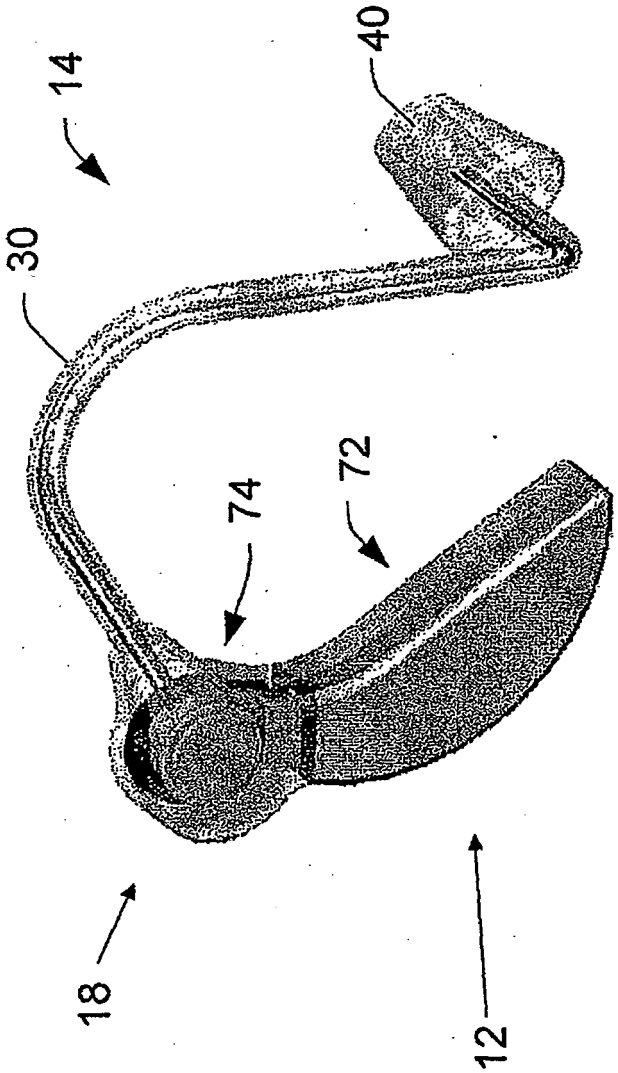


FIG 2

FIG 3



REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- DE 19904260 **[0010]**
- US 6363270 B **[0010]**
- US 6062216 A **[0010]**
- US 20050061319 A **[0010]**

专利名称(译)	外部设备持续监控OSDB并提供音频刺激治疗		
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[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
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[标]发明人	NIELSEN LARRY		
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IPC分类号	A61B5/0205 A61B5/0215 A61B5/00 A61B5/022 A61B5/08 A61M21/00 A61F5/56		
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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）。

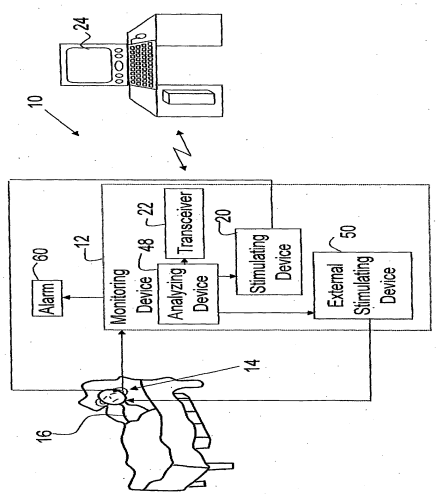

FIG 1