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(54) **ADMINISTERING A SLEEP DISORDER**

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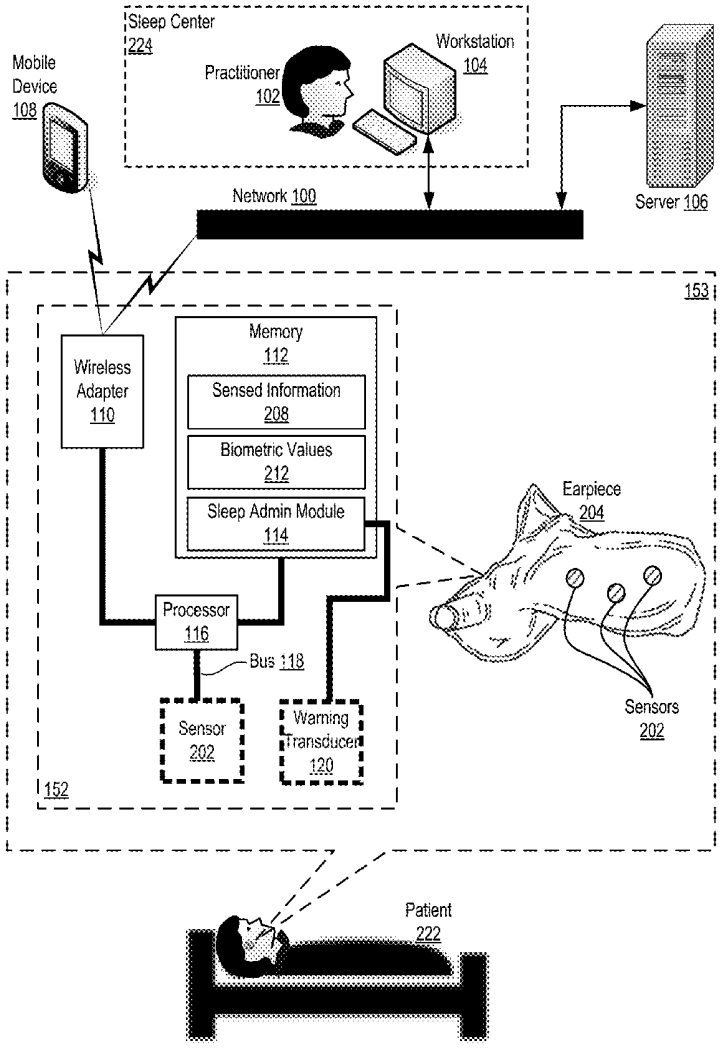
CPC ***A61B 5/4818*** (2013.01)

(57) **ABSTRACT**

Methods and apparatuses for administering a sleep disorder are provided. Embodiments include receiving, in a sleep administration module through one or more sensors of an earpiece worn within an ear of a sleeping patient, information regarding the sleep of the patient; deriving, by the sleep administration module from the information regarding the sleep of the patient, one or more biometric values capable of indicating the existence of a sleep disorder; and determining, by the sleep administration module, whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder.



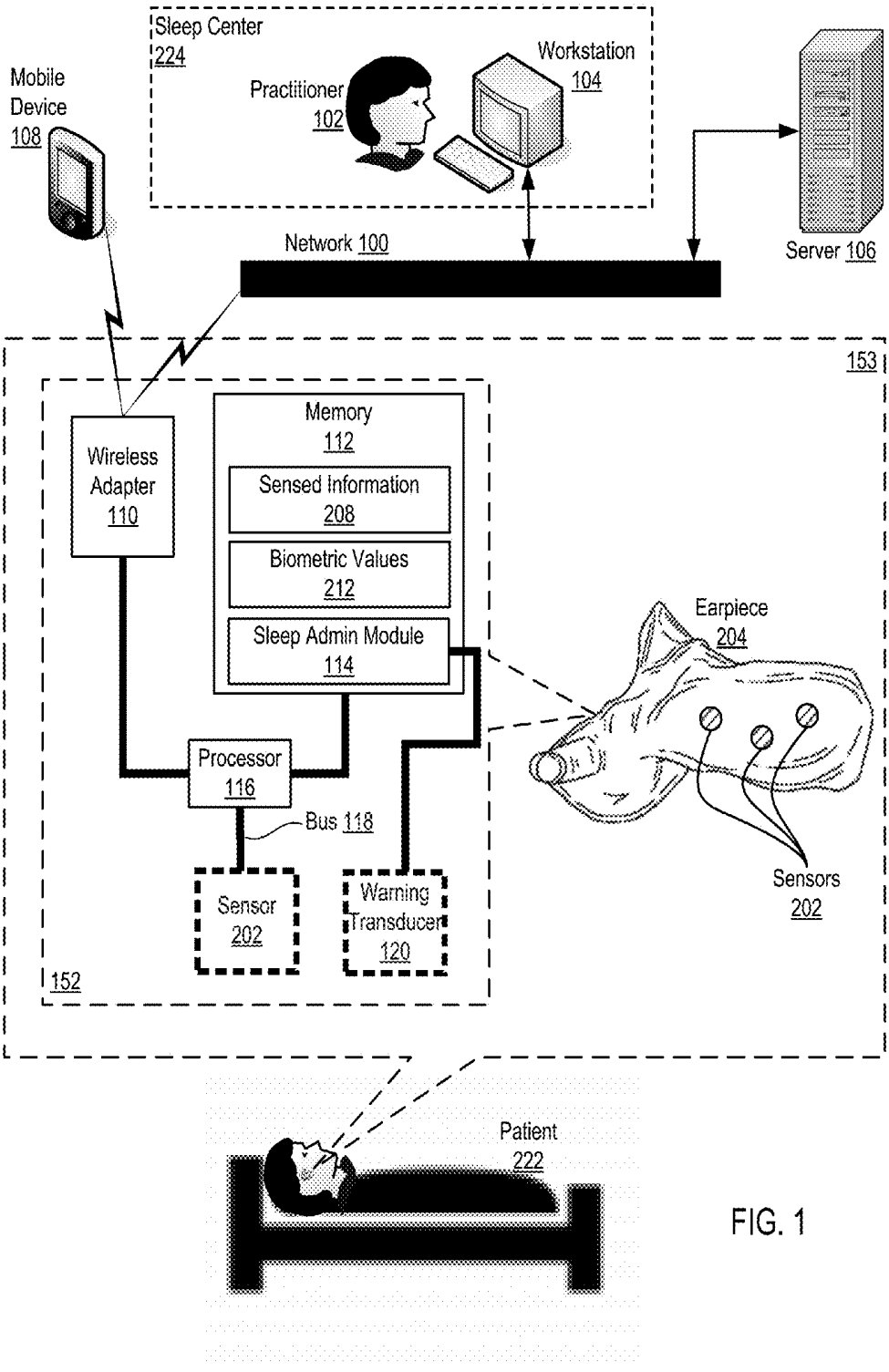

Sleep Center
224
Practitioner
102
Workstation
104
Mobile
Device
108
Network 100
Server 106
153
Wireless
Adapter
110
Memory
112
Sensed Information
208
Biometric Values
212
Sleep Admin Module
114
Earpiece
204
Processor
116
Bus 118
Sensor
202
Warning
Transducer
120
Sensors
202
152
Patient
222

FIG. 1

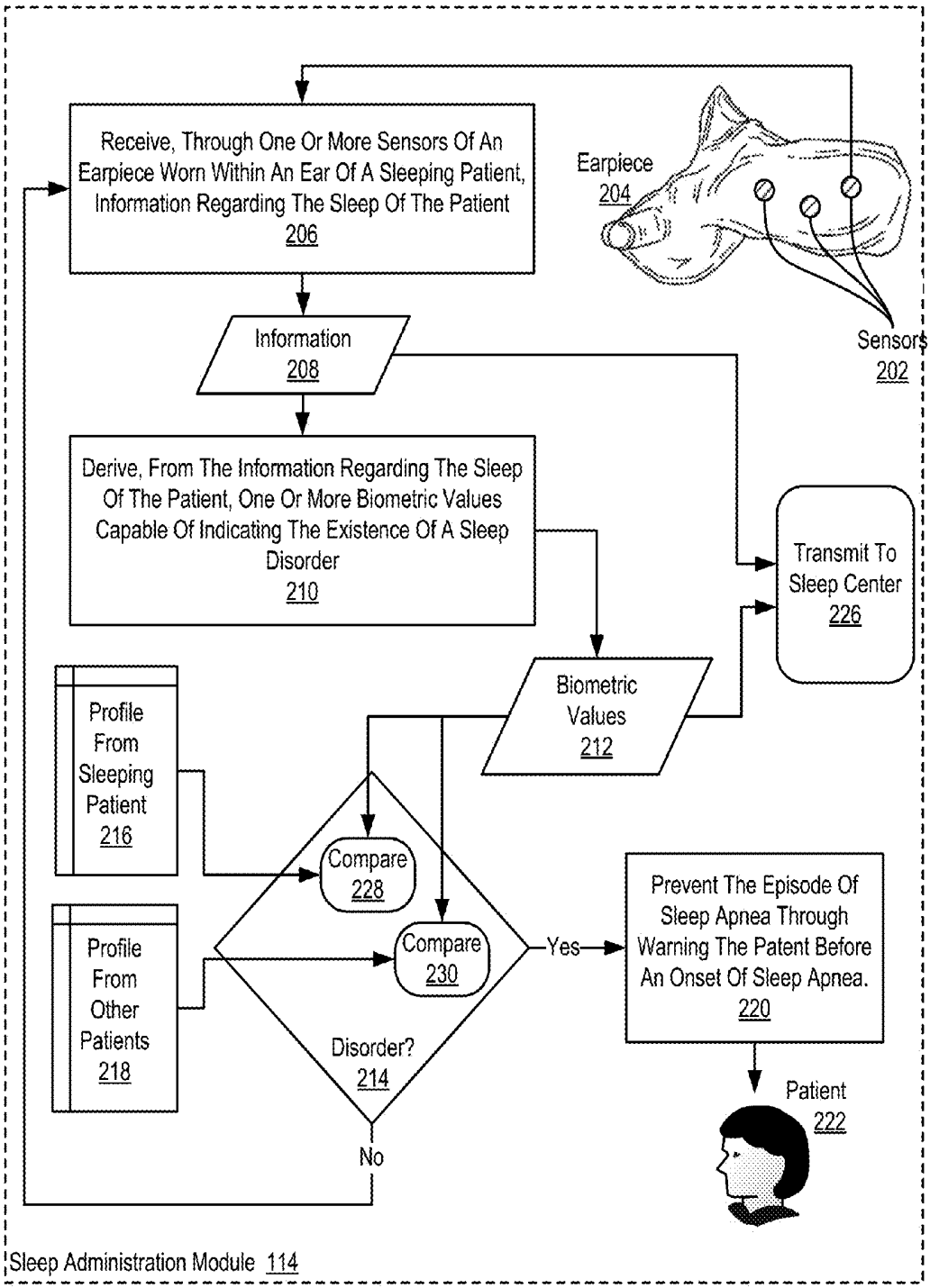

Receive, Through One Or More Sensors Of An Earpiece Worn Within An Ear Of A Sleeping Patient, Information Regarding The Sleep Of The Patient
206
Earpiece
204
Sensors
202
Information
208
Derive, From The Information Regarding The Sleep Of The Patient, One Or More Biometric Values Capable Of Indicating The Existence Of A Sleep Disorder
210
Transmit To Sleep Center
226
Biometric Values
212
Profile From Sleeping Patient
216
Profile From Other Patients
218
Compare
228
Compare
230
Disorder?
214
Yes
No
Prevent The Episode Of Sleep Apnea Through Warning The Patent Before An Onset Of Sleep Apnea.
220
Patient
222
Sleep Administration Module 114

FIG. 2

ADMINISTERING A SLEEP DISORDER

BACKGROUND

[0001] A sleep disorder is a medical disorder of the sleep patterns of a person or animal. Some sleep disorders are serious enough to interfere with normal physical, mental, and emotional functioning. Disruptions in sleep can be caused by a variety of issues, from teeth grinding (bruxism), sleep apnea, sleep hypopnea, night terrors, and many others. In many cases, sleep disorders can interfere with a person being able to function effectively.

SUMMARY

[0002] Methods and apparatuses for administering a sleep disorder are provided. Embodiments include receiving, in a sleep administration module through one or more sensors of an earpiece worn within an ear of a sleeping patient, information regarding the sleep of the patient; deriving, by the sleep administration module from the information regarding the sleep of the patient, one or more biometric values capable of indicating the existence of a sleep disorder; and determining, by the sleep administration module, whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder.

[0003] The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular descriptions of exemplary embodiments of the invention as illustrated in the accompanying drawings wherein like reference numbers generally represent like parts of exemplary embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] FIG. **1** sets forth a line drawing of example apparatus for administration of a sleep disorder.

[0005] FIG. **2** sets forth a flow chart illustrating an example method of administering a sleep disorder.

DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS

[0006] Example methods and apparatus or systems for administration of a sleep disorder are described with reference to the accompanying drawings, beginning with FIG. **1**. FIG. **1** sets forth a line drawing of example apparatus for administration of a sleep disorder. The example apparatus of FIG. **1** includes an earpiece (**204**). The earpiece has sensors (**202**) integrated into the earpiece, and the sensors are capable of sensing, when the earpiece is worn within an ear of a sleeping patient (**222**), information (**208**) regarding the sleep of the patient.

[0007] The earpiece (**204**) in this example is manufactured from a 3D image derived from an optical scan of the interior of the patient's ear canal. Creating a 3D image derived from an optical scan of the interior of the patient's ear canal can be carried out using methods and systems described in U.S. patent application Ser. Nos. 13/417,649; 13/417,767, 13/586,471; 13/586.411; 13/586,459; 13/546,448; 13/586,448; 13/586,474; 14/040,973, 14/041,943; 14/049,666; 14/049,530; 14/049,687, all incorporated by reference herein in their entirety.

[0008] The example apparatus of FIG. **1** also includes a sleep administration module (**114**) operably coupled to the sensors (**202**). The sleep administration module is configured to derive from the sensed information (**208**) one or more biometric values (**212**). The biometric values are capable of indicating the existence of a sleep disorder, and the sleep administration module is further configured to determine whether the biometric values (**212**) indicate that the sleeping patient is presently experiencing a sleep disorder. In the example of FIG. **1**, the sensed information (**208**) can include electroencephalography, electromyography, electrooculography, electrocardiography, accelerometry, reflective pulse oximetry, audio, temperature, and other sensed information as may occur to those of skill in the art. Also in the example of FIG. **1**, the biometric values (**212**) can include pulse rate, body temperature, blood oxygen level, rapid eye movement sleep, non-rapid eye movement sleep, snoring, blood pressure, muscle tension, and other values derived from sensed information as may occur to those of skill in the art. In this example, the sleep administration module (**114**) is also configured to transmit, through a wireless data communications adapter (**110**) and a data communications network (**100**), the sensed information (**208**) as well as the biometric values (**212**) to a sleep center (**224**).

[0009] Examples of sleep disorders administrable by the example apparatus of FIG. **1** include sleep hypopnea, sleep apnea, and a sleep disorder that is a precursor to an episode of sleep apnea. This paper tends to focus on apnea and hypopnea, but there are many more sleep disorders and related disorders amenable to administration, including, for example, epileptiform discharges, seizures, RBD, REM without atonia, multiple parasomnias (sleep terrors, sleep walking, sleep talking, catathrenia, exploding head syndrome, confusional arousals, hypnogogic hallucinations, hypnopompic hallucinations, sleep paralysis, etc. . . .), nocturnal movement disorders (bruxism, RLS, PLMD, muscle cramps, myoclonus, etc. . . .), multiple causes for sleep fragmentation (pain-related insomnia, excessive cortical and sub-cortical arousal, hyperhidrosis, etc. . . .), sleep-disordered breathing (all types including pediatric and adult), narcolepsy, cataplexy, delayed sleep phase, advanced sleep phase, idiopathic hypersomnolence, recurrent hypersomnolence, and day/night PSG testing also provides a host of other measures that are important such as EKG arrhythmias, peripheral O2/CO2 levels, respiratory drive via direct measures (RIP bands, intercostal EMG) and indirect measures (nasal airflow, air temperature flow, snoring), and periodic muscle analysis with EMG.

[0010] The sleep administration module (**114**) in the example of FIG. **1** is also configured to prevent an episode of sleep apnea through a warning (**120**) to the patient before an onset of sleep apnea when the sleep administration module determines that a precursor condition is present. Examples of warnings include audible tones provided through a speaker or earphone on the earpiece, a vibration warning through a buzzer or the like, integrated within the earpiece, a prerecorded voice warning, and so on.

[0011] For further explanation, FIG. **2** sets forth a flow chart illustrating an example method of administering a sleep disorder. The method of FIG. **2** includes receiving (**206**), in a sleep administration module (**114**) through one or more sensors (**202**) of an earpiece (**204**) worn within an ear of a sleeping patient (**222**), information (**208**) regarding the sleep of the patient.

[0012] The example method of FIG. **2** also includes deriving (**210**), by the sleep administration module (**114**) from the information (**208**) regarding the sleep of the patient (**222**), one or more biometric values (**212**) capable of indicating the

existence of a sleep disorder. In the example of FIG. **2**, the sensed information (**208**) can include electroencephalography, electromyography, electrooculography, electrocardiography, accelerometry, reflective pulse oximetry, audio, temperature, and other sensed information as may occur to those of skill in the art. In the example of FIG. **2**, the biometric values (**212**) can include pulse rate, body temperature, blood oxygen level, rapid eye movement sleep, non-rapid eye movement sleep, snoring, blood pressure, muscle tension, and other values derived from sensed information as may occur to those of skill in the art. The method of FIG. **2** also includes an optional step of transmitting (**404**), by the sleep administration module (**114**), the sensed information (**208**) and/or the biometric values (**212**) to a sleep center (**224** on FIG. **1**).

[0013] The example of FIG. **2** includes determining (**214**), by the sleep administration module (**114**), whether the one or more biometric values (**212**) indicate that the sleeping patient (**222**) is presently experiencing a sleep disorder. Examples of sleep disorders administrable by the example method of FIG. **2** include sleep hypopnea, sleep apnea, and a sleep disorder that is a precursor to an episode of sleep apnea. The method of FIG. **2** includes preventing (**220**), by the sleep administration module (**114**), an episode of sleep apnea through warning the patient (**222**) before an onset of sleep apnea when it is determined (**214**) that a precursor condition is present.

[0014] The method of FIG. **2** includes sleep administration module (**114**) is configured to prevent an episode of sleep apnea through a warning (**120**) to the patient before an onset of sleep apnea when the sleep administration module determines that a precursor state is present.

[0015] In the method of FIG. **2**, determining (**214**) whether the biometric values (**212**) indicate that the sleeping patient is presently experiencing a sleep disorder can be carried out by comparing (**228**) the biometric values (**212**) with a predetermined sleep disorder profile (**216**) personalized for the sleeping patient. Also in the method of FIG. **2**, determining (**214**) whether the biometric values (**212**) indicate that the sleeping patient is presently experiencing a sleep disorder can alternatively be carried out by comparing (**230**) the one or more biometric values (**212**) with a predetermined sleep disorder profile (**218**) derived from sleep disorder data of a number of other patients.

[0016] Administration of sleep disorders is carried out generally in embodiments by use of electroencephalography ('EEG'), electromyography ('EMG') and electrooculography ('EOG') information from sensors on an earpiece within the ear. The stage of sleep typically is taken from EEG and EMG information, from measures of the power of signals at certain frequencies. Stage 2 sleep will give sudden, short high-voltage wave bursts occurring at 12-14 Hz. Stage 3 sleep will show theta (4-7 Hz) and delta waves (1-4 Hz) with skeletal muscles very relaxed. Stage 4 is "slow wave sleep" because of delta waves, with a body turn approximately every 20 minutes. Rapid eye movement ('REM') sleep is indicated after the first four stages when frequency goes back to alpha waves, body temperature increases, heart rate increases, respiratory rate increases, blood pressure increases, the brain uses even more oxygen than when awake, eyes move rapidly. This particular signal from eye movement may be classified as EMG rather than EOG and is easily detected with information from the earpiece sensors.

[0017] Regarding REM sleep, sleep alternates between REM and non-REM or NREM; REM occurs about every 90 minutes and increases in length from 5-10 minutes to 20-50 minutes. The amount of REM sleep typically is determined in embodiments from sensor information by detecting eye movement using EOG and EMG. A person feels most rested when awakened just after a REM cycle, so that warnings can signal a person to awaken when apparatus in embodiments detects that REM is finished.

[0018] Clenching and grinding of teeth is detected in embodiments by use of EMG. For each skeletal muscle, there is an optimal longitudinal length at which the maximum muscle activation can occur; muscle activation of the muscles of mastication can be measured using EMG. When placing a sleep disorder appliance into the mouth, the teeth become separated, slightly lengthening the muscles of mastication, preventing the electrical signal from the muscles of mastication from being as intense as having no teeth separation. For a patient that is prone to clenching, the clenching intensity will be decreased when wearing the oral appliance. Warnings to the patient in embodiments effectively implements relaxation training. Some embodiments play music or tones only when a patient is relaxed (or vice versa) using EMG detection of nearby muscle activity (muscles of mastication).

[0019] Accelerometry from within the ear includes in embodiments nine degrees of freedom (9DOF accelerometry). 9DOF accelerometry includes multiple axes of detection from which, based on acceleration due to gravity, a patient's resting head position can be determined. Then embodiments can alert the patient to changes into nonoptimal sleep positions.

[0020] Oximetry typically is implemented as reflection pulse oximetry from within the ear or transmission pulse oximetry around the pinna. Embodiments can use both red (600-750 nm) and infrared light (850-1000 nm) to illuminate blood and use a photosensor to measure either transmission or reflection. Red light at 660 nm reflects off of hemoglobin when it is saturated (HbO2) and infrared light at 940 nm reflects off of de-oxygenated hemoglobin (Hb).

$$\text{Ratio of Ratios} \sim \frac{\ln\left(\frac{Red_{systole}}{Red_{diastole}}\right)}{\ln\left(\frac{IR_{systole}}{IR_{diastole}}\right)} \qquad \text{Formula 1}$$

[0021] The 'ratio of ratios' according to Formula 1 is calibrated in embodiments to determine peripheral capillary oxygen saturation or SpO_2 in percentage, using a lookup table to determine the actual percentage. SpO_2 (%) can be measured, a value that decreases during an apneic episode. Pulse rate (beats per minute) can be measured in embodiments with oximetry because there is variable light absorption due to pulsatile volume of arterial blood. When measuring from within the ear canal, direct reflective pulse oximetry towards the superficial temporal artery, which runs anterior to the canal, or associated vasculature. When measuring in locations requiring light transmission detection (instead of reflection), such as through the pinna or ear lobe, embodiments use a clip that places lights on one side of tissue and photosensor on the other side. While using an oral appliance for obstructive sleep apnea, there are no acute decreases in oxygen saturation unless sleep apnea occurs via central sleep apnea where there is no respiratory effort by the patient. Embodiments therefore can alert a patient when oxygen saturation decreases below a threshold.

[0022] Sensors in embodiments can include a microphone to sense or record snoring sounds. Snoring sounds decrease with use of an obstructive sleep apnea oral appliance. Snoring sounds can also be used to indicate oral appliance (mandibular advancement appliance) effectiveness at maintaining pharyngeal patency. Audio from snoring in embodiments can complement accelerometer information to determine patient movements during sleep, alerting a patient to change positions when snoring indicates nonoptimal body position.

[0023] Additional warning-type technology in embodiments can include a speaker or earphone integrated in the earpiece that delivers information directly into a patient's ear without disrupting others nearby. Audible warnings can include alerts to change sleeping position, alerts to wake a patient, music or relaxation sounds, including playing slow breathing sounds for breath matching, to aid a patient in falling asleep. These alerts and sounds in embodiments are implemented with a phone paired via Bluetooth with a source of soothing sounds or music and, in some embodiments, are supportive of sleep-related training such as EMG relaxation training.

[0024] An embodiment includes a piezo sensor to detect pulse from within the ear. This is in addition to pulse oximetry which in some embodiments may have too low measurement/calculation frequency or too low noise for pulse detection. A piezo sensor is mounted on the earpiece so as to contact skin in the ear canal and detect pulse through impulses affecting skin pressure on the sensor. In at least one embodiment, skin pressure noise from snoring, movement, and the like, is canceled with audio noise from a microphone.

[0025] In some embodiments, earpiece sensors can include one or more active in-ear readers for sensors mounted on an oral appliance and directed to sleep disorder appliance compliance, including a passive RadioFrequency Identification (RFID) tag, a Near Field Communications ('NFC') tag, a contactless smart card, or the like, attached to the oral appliance and registered with the active in-ear reader in an earpiece when in use to determine appliance compliance. A passive tag in an embodiment is switched on only when the oral appliance is locked into the patient's mouth, working only when two pieces of the RFID tag are connected to each other via electrodes to the gums. One part of such an RFID tag is attached to the patient, making electrical contact to a second part of the RFID tag mounted on the oral appliance only when the appliance is worn. In another embodiment, a passive RFID tag is split into two parts as an open circuit, and the act of placing the oral appliance in the mouth and pressing it onto the teeth mechanically connects the two for further operation with an active RFID reader.

[0026] The active in-ear reader in the earpiece sends an RF signal to power a passive RFID or NFC tag installed on the oral appliance. The active in-ear reader can send an RF signal that powers a passive tag on the oral appliance, with the passive tag connected to one or more physiological sensors, temperature, O2, pressure against teeth, electrical conduction, and so on, with the sensor data then sent back to the active reader in the ear. A force sensor may be embedded in an oral appliance to be pressed against tooth during use, with force data be transferred to the in-ear reader to determine appliance compliance. A temperature sensor may be embedded into an oral appliance, with temperature data transferred to the in-ear reader to determine appliance compliance.

[0027] In some embodiments, an oral appliance contains a piezo or bone conduction transducer, with audio vibrations received by microphone in the ear or on the appliance, with a connection to the earpiece by RFID, ultrasound, vibration, and so on. An ultrasound signal in such embodiments is sent from the ear device through the body and makes contact with the oral appliance. The signal is then passively modulated and reflected through the body and back to the ear device. The modified signal received by the ear device confirms proper placement of the oral appliance in the mouth.

[0028] It will be understood from the foregoing description that modifications and changes may be made in various embodiments of the present invention without departing from its true spirit. The descriptions in this specification are for purposes of illustration only and are not to be construed in a limiting sense. The scope of the present invention is limited only by the language of the following claims.

What is claimed is:

1. A method of administering a sleep disorder, the method comprising:

receiving, in a sleep administration module through one or more sensors of an earpiece worn within an ear of a sleeping patient, information regarding the sleep of the patient;

deriving, by the sleep administration module from the information regarding the sleep of the patient, one or more biometric values capable of indicating the existence of a sleep disorder;

determining, by the sleep administration module, whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder.

2. The method of claim **1** wherein the information comprises electroencephalography, electromyography, electrooculography, accelerometry, reflective pulse oximetry, audio, and temperature.

3. The method of claim **1** further comprising transmitting, by the sleep administration module, the sensed information to a sleep center.

4. The method of claim **1** wherein the biometric values comprise pulse rate, body temperature, blood oxygen level, rapid eye movement sleep, non-rapid eye movement sleep, snoring, blood pressure, and muscle tension.

5. The method of claim **1** further comprising transmitting, by the sleep administration module, the biometric values to a sleep center.

6. The method of claim **1** wherein the sleep disorder is sleep apnea.

7. The method of claim **1** wherein the sleep disorder is sleep hypopnea.

8. The method of claim **1** wherein the determined sleep disorder is a precursor to an episode of sleep apnea, and the method further comprises preventing, by the sleep administration module, the episode of sleep apnea through warning the patient before an onset of sleep apnea.

9. The method of claim **1** wherein determining whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder further comprises comparing the one or more biometric values with a predetermined sleep disorder profile personalized for the sleeping patient.

10. The method of claim **1** wherein determining whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder further comprises comparing the one or more biometric values with a predetermined sleep disorder profile derived from sleep disorder data of a plurality of other patients.

11. Apparatus for administration of a sleep disorder, the apparatus comprising:

an earpiece having integrated sensors capable of sensing, when the earpiece is worn within an ear of a sleeping patient, information regarding the sleep of the patient; and

a sleep administration module operably coupled to the sensors and configured to derive from the sensed information one or more biometric values capable of indicating the existence of a sleep disorder and to determine whether the one or more biometric values indicate that the sleeping patient is presently experiencing a sleep disorder.

12. The apparatus of claim **11** wherein the information comprises electroencephalography, electromyography, electrooculography, accelerometry, reflective pulse oximetry, audio, and temperature.

13. The apparatus of claim **11** wherein the sleep administration module is further configured to transmit the sensed information to a sleep center.

14. The apparatus of claim **11** wherein the biometric values comprise pulse rate, body temperature, blood oxygen level, rapid eye movement sleep, non-rapid eye movement sleep, snoring, blood pressure, and muscle tension.

15. The apparatus of claim **11** wherein the sleep administration module is further configured to transmit the biometric values to a sleep center.

16. The apparatus of claim **11** wherein the sleep disorder is sleep apnea.

17. The apparatus of claim **11** wherein the sleep disorder is sleep hypopnea.

18. The apparatus of claim **11** wherein the determined sleep disorder is a precursor to an episode of sleep apnea, and the sleep administration module is further configured to prevent the episode of sleep apnea through a warning to the patient before an onset of sleep apnea.

19. The apparatus of claim **11** wherein the earpiece is manufactured from a 3D image derived from an optical scan of the interior of the patient's ear canal.

* * * * *

专利名称(译)	管理睡眠障碍		
公开(公告)号	US20150150499A1	公开(公告)日	2015-06-04
申请号	US14/094210	申请日	2013-12-02
申请(专利权)人(译)	UNITED科学，LLC		
[标]发明人	GEORGE EOHAN HATZILIAS KAROL PATEL MAYOOR PINGALI GOVINDA POZGAY BRIAN RAUBOLT JIM SHARPE WESS ERIC THOMPSON JACOB		
发明人	GEORGE, EOHAN HATZILIAS, KAROL PATEL, MAYOOR PINGALI, GOVINDA POZGAY, BRIAN RAUBOLT, JIM SHARPE, WESS ERIC THOMPSON, JACOB		
IPC分类号	A61B5/00		
CPC分类号	A61B5/4818 A61B5/0022 A61B5/6817 A61B5/746		
外部链接	Espacenet USPTO		

摘要(译)

提供了用于施用睡眠障碍的方法和装置。实施例包括在睡眠管理模块中通过佩戴在睡眠患者耳朵内的耳机的一个或多个传感器接收关于患者睡眠的信息;睡眠管理模块从关于患者睡眠的信息中得出一个或多个能够指示睡眠障碍存在的生物特征值;并且由睡眠管理模块确定一个或多个生物特征值是否指示睡眠患者当前正在经历睡眠障碍。