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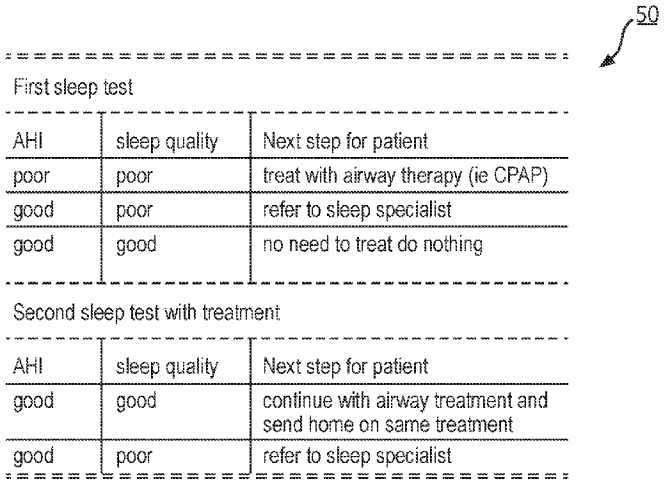

FIG. 3

(57) Abstract: Sleep related conditions of a subject are monitored and/or diagnosed based on both sleep quality and apnea hypopnea index. A first sleep test is performed in which a sleep quality of the subject and an apnea-hypopnea index are determined. A determination is made as to whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test. Responsive to the results of the first sleep test failing to meet the first condition, a recommendation of a treatment for the subject is provided. An efficacy of the treatment is confirmed in a second sleep test involving the treatment by determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea- hypopnea index of the subject associated with the second sleep test.

SLEEP QUALITY AND APNEA HYPOPNEA INDEX MONITORING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[01] This patent application claims the priority benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 62/277,647 filed on January 12, 2016, the contents of which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[02] The present disclosure pertains to systems and methods for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index.

2. Description of the Related Art

[03] Patients in a hospital, as well as in other clinical settings, are typically monitored using a variety of monitoring systems. For example, the current standard for diagnosing sleep disorder breathing involves seven to twenty two sensors, which is not practical in a routine hospital environment. In addition, while measured parameters provide valuable information, when considered individually, they do not provide sufficient information about the condition of the patient in order to optimize treatment of the patient for multiple disorders. If a patient is given an optimal treatment, the likelihood that the patient will need to be readmitted in a relatively short time after being discharged from the hospital decreases. It should be noted that because readmission of a patient for the same condition within a certain number of days following discharge is generally not reimbursed by U.S. insurance policies, readmission is costly to the hospital. As a result, hospitals endeavor to avoid such readmissions. In sum, known systems that monitor the varied health-related parameters of a patient lack a sufficient level of sophistication needed in order optimize the treatment of the patient thereby avoiding unreimbursed hospital readmissions.

SUMMARY OF THE INVENTION

[04] Accordingly, one or more aspects of the present disclosure relate to a system configured for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index. The system comprises one or more sleep quality sensors, one or more respiratory sensors, one or more hardware processors, and/or other components. The one or more sleep quality sensors are configured to provide sleep quality signals conveying information related to a sleep quality measurement of the subject. The one or more respiratory sensors are configured to provide respiratory signals conveying information related to a breathing measurement of the subject. The one or more hardware processors are configured by machine-readable instructions to: receive, in connection with a first sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determine a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals; determine an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; determine whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test; and responsive to the results of the first sleep test failing to meet the first condition, provide a recommendation of a treatment for the subject and confirm an efficacy of the treatment in a second sleep test involving the treatment. The efficacy is confirmed by: receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; and determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

[05] Another aspect of the present disclosure relates to a method for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and

apnea hypopnea index. The method comprises: receiving, in connection with a first sleep test, sleep quality signals conveying information related to a sleep quality measurement of the subject and respiratory signals conveying information related to a breathing measurement of the subject; determining a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; determining whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test; responsive to the results of the first sleep test failing to meet the first condition, providing a recommendation of a treatment for the subject; and confirming an efficacy of the treatment in a second sleep test involving the treatment. The efficacy is confirmed by: receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; and determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

[06] Still another aspect of the present disclosure relates to a system configured for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index. The system comprises: means for receiving, in connection with a first sleep test, sleep quality signals conveying information related to a sleep quality measurement of the subject and respiratory signals conveying information related to a breathing measurement of the subject; means for determining a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals; means for determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; means for determining whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test; means for, responsive to the results of

the first sleep test failing to meet the first condition, providing a recommendation of a treatment for the subject; and means for confirming an efficacy of the treatment in a second sleep test involving the treatment. The efficacy is confirmed by: receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; and determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

[07] These and other objects, features, and characteristics of the present disclosure, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[08] FIG. 1 illustrates a system configured for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, in accordance with one or more embodiments;

[09] FIG. 2 illustrates exemplary sensor configuration, in accordance with one or more embodiments;

[10] FIG. 3 illustrates a condition matrix, in accordance with one or more embodiments; and

[11] FIG. 4 illustrates a method for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, in accordance with one or more embodiments.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[12] As used herein, the singular form of "a", "an", and "the" include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are "coupled" shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or components, so long as a link occurs. As used herein, "directly coupled" means that two elements are directly in contact with each other. As used herein, "fixedly coupled" or "fixed" means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.

[13] As used herein, the word "unitary" means a component is created as a single piece or unit. That is, a component that includes pieces that are created separately and then coupled together as a unit is not a "unitary" component or body. As employed herein, the statement that two or more parts or components "engage" one another shall mean that the parts exert a force against one another either directly or through one or more intermediate parts or components. As employed herein, the term "number" shall mean one or an integer greater than one (i.e., a plurality).

[14] Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

[15] FIG. 1 illustrates a system 10 configured for monitoring and/or diagnosing sleep related conditions of a subject 12 based on both sleep quality and apnea hypopnea index (AHI), in accordance with one or more embodiments. For purposes of this disclosure, the term "sleep quality" may refer to a measure of overall stable sleep, while the term "AHI" may refer to any form of measuring disrupted sleep due to an unstable airway (e.g., respiratory disturbance index (RDI), probability of obstructive sleep apnea (OSA), and/or other measurements).

[16] Commonly, when a subject (e.g., subject 12) is admitted to a hospital, he/she is hooked up to an electrocardiogram (ECG) monitor and, occasionally, an oxygen

saturation (S_PO_2) monitor, primarily in order to detect arrhythmias to ensure the subject is not going to have a heart attack or showing any ventricular problems that could cause cardiac arrest. According to exemplary embodiments, from a raw ECG signal, a probability of sleep apnea (or apnea-hypopnea index) may be determined as well as sleep quality. In embodiments including oxygen saturation measurement, respiratory problems may also be identified. Contrasted with standard sleep monitoring for sleep disorder breathing, exemplary embodiments have reduced cost at least because there are significantly less sensors. That is, there are only the standard monitoring sensors (e.g., ECG and/or S_PO_2), according to some embodiments. In standard sleep monitoring, there are commonly electrodes on the subject's head measuring brain waves and electrodes on the subject's feet measuring leg kicks—all of which are generally highly impractical for a standard hospital-monitored subject. Accordingly, exemplary embodiments utilize what is most typically already available—the ECG electrodes that are routinely connected to the subject upon hospital admission—and identify sleep disorder breathing. In situations where disruptive breathing and quality of sleep is so poor therapy is needed, exemplary embodiments provide an ability to monitor whether the therapy is valid.

[17] Accordingly, according to one or more embodiments, system 10 includes one or more of one or more sleep quality sensors 14, one or more respiratory sensors 16, one or more oxygen saturation sensors 18, one or more user interfaces 20, one or more processors 22, and/or other components.

[18] Sleep quality sensor(s) 14 are configured to provide sleep quality signals conveying information related to a sleep quality measurement of the subject. Generally speaking, sleep quality may be described subjectively and/or objectively. A subjective description may include tiredness on waking and throughout the day or feeling rested and restored on waking. An objective description may include the number of awakenings experienced in the night. Awakenings may be determined by motion detection and/or other techniques. In some embodiments, sleep quality sensor(s) may include an accelerometer, a visual motion detector, and/or other sensors configured to detect motion. An objective description may include efficiency of sleep. In some embodiments, sleep

quality sensor(s) 14 include an electrocardiogram (ECG) configured to monitor heart activity. In such embodiments, the sleep quality signal may convey information related to heart activity of the subject. The heart activity of the subject may be used to determine one or more indices for sleep quality. Examples of such indices may include one or more of sleep efficiency index, delta-sleep efficiency index, sleep onset latency, respiratory arousals, and/or other indices of sleep quality. Other sensors useful for determining sleep quality are contemplated as sleep quality sensor(s) 14 and are within the scope of the disclosure.

[19] Respiratory sensor(s) 16 are configured to provide respiratory signals conveying information related to a breathing measurement of the subject. The breathing measurement may convey inspiration and/or expiration volume as a function of time, a number of breaths as a function of time, and/or other breathing measurements. In some embodiments, respiratory sensor(s) 16 may include one or more of a flow meter, an effort belt, a chest impediment, a thermocouple, an air pressure sensor, and/or other sensors suitable for measuring respiration of the subject.

[20] Oxygen saturation sensor(s) 18 may be configured to provide oxygen saturation signals conveying information related to an oxygen saturation (S_PO_2) of the subject. In some embodiments, oxygen saturation sensor(s) 18 may include one or more of a pulse oximeter and/or other sensors suitable for measuring oxygen saturation.

[21] FIG. 2 illustrates exemplary sensor configuration 200, in accordance with one or more embodiments. As shown in FIG. 2, a subject 202 may be fitted with one or more sensors. Such sensors may include one or more of electrocardiogram (ECG) sensors 204, effort belt 206, pulse oximeter 208, and/or other sensors. ECG sensors 204 are disposed at one or more positions near the heart of subject 202. In some embodiments, sleep quality sensor(s) 14 (shown in FIG. 1) includes an electrocardiogram (ECG) that is the same as or similar to ECG sensors 204. Effort belt 206 is disposed about the chest of subject 202. In some embodiments, respiratory sensor(s) 16 (shown in FIG. 1) includes an effort belt that is the same as or similar to effort belt 206. Pulse oximeter 208 is disposed on a finger of subject 202. In some embodiments, oxygen saturation sensor(s) 18 (shown

in FIG. 1) includes a pulse oximeter that is the same as or similar to pulse oximeter 208. While sensor configuration 200 shows three specific sensors, this is not intended to be limiting as other configurations are contemplated and are within the scope of the disclosure. For example, sensor configuration 200 may include one or more additional sensors not described, and/or without one or more of the sensors discussed.

[22] User interface(s) 20 is configured to provide an interface between system 10 and caregivers, subject 12, and/or other users through which caregivers, subject 12, and/or other users may provide information to and receive information from system 10. This enables data, cues, results, and/or instructions and any other communicable items, collectively referred to as "information," to be communicated between a user (e.g., a caregiver, subject 12, and/or other users) and processor 18, and/or other components of system 10. For example, sleep quality information, apnea-hypopnea index, oxygen saturation, and/or other information about subject 12 may be communicated from a caregiver to system 10 via user interface(s) 20.

[23] Examples of interface devices suitable for inclusion in user interface(s) 20 comprise a graphical user interface, a display, a touchscreen, a keypad, buttons, switches, a keyboard, knobs, levers, speakers, a microphone, an indicator light, an audible alarm, a printer, a haptic feedback device, and/or other interface devices. In some embodiments, user interface(s) 20 comprises a plurality of separate interfaces. For example, user interface(s) 20 may comprise a plurality of different interfaces associated with a plurality of computing devices associated with different caregivers. User interface(s) 20 is configured such that the plurality of caregivers may provide information to and receive information from (e.g., treatment information, etc.) system 10 via the individual ones of the plurality of user interfaces. In some embodiments, user interface(s) 20 comprises at least one interface that is provided integrally with processor 18 and/or other components of system 10.

[24] It is to be understood that other communication techniques, either hard-wired or wireless, are also contemplated by the present disclosure as user interface(s) 20. For example, the present disclosure contemplates that user interface(s) 20 may be

integrated with a removable storage interface provided by electronic storage 40. In this example, information may be loaded into system 10 from removable storage (e.g., a smart card, a flash drive, a removable disk, etc.) that enables the user(s) to customize the implementation of system 10. Other exemplary input devices and techniques adapted for use with system 10 as user interface(s) 20 comprise, but are not limited to, an RS-232 port, RF link, an IR link, modem (telephone, cable or other). In short, any technique for communicating information with system 10 is contemplated by the present disclosure as user interface(s) 20.

[25] Processor(s) 22 are configured to provide information processing capabilities in system 10. As such, processor(s) 22 may comprise one or more of a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information. Although processor(s) 22 is shown in FIG. 1 as a single entity, this is for illustrative purposes only. In some embodiments, processor(s) 22 may comprise a plurality of processing units. These processing units may be physically located within the same device, or processor(s) 22 may represent processing functionality of a plurality of devices operating in coordination.

[26] As shown in FIG. 1, processor(s) 22 are configured by machine-readable instructions 24. Machine-readable instructions 24 may be executed by processor(s) 22 to cause processor(s) 22 to perform one or more functions. Machine-readable instructions 22 may include one or more of a user input/output component 26, a sensor information component 28, an analysis component 30, a treatment determination component 32, and/or other components. Processor(s) 22 may be configured to execute components 26, 28, 30, 32, and/or other components by software; hardware; firmware; some combination of software, hardware, and/or firmware; and/or other mechanisms for configuring processing capabilities on processor(s) 22.

[27] It should be appreciated that although components 26, 28, 30, and 32 are illustrated in FIG. 1 as being co-located within a single processing unit, in embodiments in which processor(s) 22 comprises multiple processing units, one or more of components 26,

28, 30, and/or 32 may be located remotely from the other components. The description of the functionality provided by the different components 26, 28, 30, and/or 32 described herein is for illustrative purposes, and is not intended to be limiting, as any of components 26, 28, 30, and/or 32 may provide more or less functionality than is described. For example, one or more of components 26, 28, 30, and/or 32 may be eliminated, and some or all of its functionality may be provided by other components 26, 28, 30, and/or 32. As another example, processor(s) 22 may be configured to execute one or more additional components that may perform some or all of the functionality attributed below to one of components 26, 28, 30, and/or 32.

[28] User input/output component 26 is configured to facilitate entry and/or selection of information by subject 12, caregivers, and/or other users. User input/output component 26 facilitates entry and/or selection of information via user interface(s) 20 and/or other interface devices. For example, user input/output component 26 may cause user interface(s) 20 to display one or more views of a graphical user interface to a caregiver which facilitate entry and/or selection of information by the caregiver. In some embodiments, user input/output component 26 is configured to facilitate entry and/or selection of information via one or more user interfaces 16 associated with one or more caregivers. In some embodiments, user input/output component 26 is be configured to facilitate entry and/or selection of information through a website, a mobile app, a bot through which text messages and/or emails are sent, and/or via other methods. In some embodiments, user input/output component 26 is configured to prompt subject 12, caregivers, and/or other users to answer specific questions, and/or provide other information. In some embodiments, user input/output component 26 is configured to associate a time of day, a duration of time, and/or other time information with the entered and/or selected information.

[29] Sensor information component 28 is configured to receive one or more signals from one or more sensors. Such signal may be received in connection with one or more sleep tests. In some embodiments, sensor information component 28 is configured to receive one or more of sleep quality signals from sleep quality sensor(s) 14, respiratory

signals from respiratory sensor(s) 16, oxygen saturation signals from oxygen saturation sensor(s) 18, and/or other signals.

[30] Analysis component 30 is configured to determine various quantities associated with subject 12. Such determinations may be made in connection with one or more sleep tests. The quantities may be determined based on information conveyed by signals received by sensor information component 28. In some embodiments, analysis component 30 is configured to determine a sleep quality of subject 12. The sleep quality may be determined based on the sleep quality signals. In some embodiments, analysis component 30 is configured to determine an apnea-hypopnea index of subject 12. The apnea-hypopnea index may be determined based on the respiratory signals. In some embodiments, analysis component 30 is configured to determine an oxygen saturation (S_PO_2) of subject 12. The oxygen saturation may be determined based on the oxygen saturation signals.

[31] In some embodiments, analysis component 30 is configured to determine whether results of a given sleep test meet a first condition. The determination of whether results of the given sleep test meet the first condition may be based on one or more of the sleep quality of subject 12, the apnea-hypopnea index of subject 12, the oxygen saturation of subject 12, neuro arousals connected to the respirator effort, and/or other information. In some embodiments, a first condition is met when two or more results of the given sleep test are considered “good”.

[32] Treatment determination component 32 is configured to provide a recommendation of a treatment for subject 12. Such determination may be made responsive to the results of a given sleep test failing to meet the first condition (as determined by analysis component 30. The treatment may be provided by one or more treatment devices 34. In some embodiments, treatment device(s) 34 may include one or more of a smart (e.g., auto-titrating) continuous positive airway pressure (CPAP) device, bi-level PAP, volume-guaranteed PAP, and/or other devices that treat sleep disordered breathing.

[33] Referring again to analysis component 30, it may be configured to confirm an efficacy of the treatment in a second (or successive) sleep test involving the treatment. Such confirmation may be performed in conjunction with one or more other machine-readable instruction components. For example, in exemplary embodiments, confirming the efficacy of the treatment may include: receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; and determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

[34] FIG. 3 illustrates a condition matrix 50, in accordance with one or more embodiments. The condition matrix 50 shows various combinations of sleep test outcomes. More specifically, condition matrix 50 shows combinations of AHI and sleep quality being either "poor" or "good." According to some embodiments, in connection with a first sleep test, if both AHI and sleep quality are poor, then subject 12 is treated with an airway treatment (e.g., CPAP); if AHI is good and sleep quality is poor, then subject 12 is referred to a sleep specialist; and if both AHI and sleep quality are good, then there is no need for treatment. In connection with a second sleep test where treatment is provided to subject 12 in response to the outcome of the first sleep test, if AHI is good and sleep quality is poor, then subject 12 is referred to a sleep specialist; and if both AHI and sleep quality are good, then the provided treatment is continued and may be used in a home setting, in accordance with some embodiments.

[35] Electronic storage 40 comprises electronic storage media that electronically stores information. The electronic storage media of electronic storage 40 may comprise one or both of system storage that is provided integrally (i.e., substantially non-removable) with system 10 and/or removable storage that is removably connectable to system 10 via, for example, a port (e.g., a USB port, a firewire port, etc.) or a drive (e.g., a disk drive,

etc.). Electronic storage 40 may comprise one or more of optically readable storage media (e.g., optical disks, etc.), magnetically readable storage media (e.g., magnetic tape, magnetic hard drive, floppy drive, etc.), electrical charge-based storage media (e.g., EPROM, RAM, etc.), solid-state storage media (e.g., flash drive, etc.), and/or other electronically readable storage media. Electronic storage 40 may store software algorithms, information determined by processor(s) 22, information received via user interface(s) 20 and/or external computing systems, information received from sleep quality sensor(s) 14, information received from respiratory sensor(s) 16, information received from saturation sensor(s) 18, and/or other information that enables system 10 to function as described herein. Electronic storage 40 may be (in whole or in part) a separate component within system 10, or electronic storage 40 may be provided (in whole or in part) integrally with one or more other components of system 10 (e.g., user interface(s) 20, processor(s) 22).

[36] FIG. 4 illustrates a method 400 for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, in accordance with one or more embodiments. The operations of method 400 presented below are intended to be illustrative. In some embodiments, method 400 may be accomplished with one or more additional operations not described, and/or without one or more of the operations discussed. Additionally, the order in which the operations of method 400 are illustrated in FIG. 4 and described below is not intended to be limiting.

[37] In some embodiments, one or more operations of method 400 may be implemented in one or more processing devices (e.g., a digital processor, an analog processor, a digital circuit designed to process information, an analog circuit designed to process information, a state machine, and/or other mechanisms for electronically processing information). The one or more processing devices may include one or more devices executing some or all of the operations of method 400 in response to instructions stored electronically on an electronic storage medium. The one or more processing devices may include one or more devices configured through hardware, firmware, and/or

software to be specifically designed for execution of one or more of the operations of method 400.

[38] At an operation 402, in connection with a first sleep test, sleep quality signals and respiratory signals are received. The sleep quality signals may convey information related to a sleep quality measurement of the subject. The respiratory signals may convey information related to a breathing measurement of the subject. Operation 402 may be performed by one or more processors configured by a machine-readable instruction component that is the same as or similar to sensor information component 28 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[39] At an operation 404, in connection with the first sleep test, a sleep quality of the subject is determined based on the sleep quality signals. Operation 404 may be performed by one or more processors configured by a machine-readable instruction component that is the same as or similar to analysis component 30 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[40] At an operation 406, in connection with the first sleep test, an apnea-hypopnea index of the subject is determined based on the respiratory signals. Operation 406 may be performed by one or more processors configured by a machine-readable instruction component that is the same as or similar to analysis component 30 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[41] At an operation 408, a determination is made as to whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test. Operation 408 may be performed by one or more processors configured by a machine-readable instruction component that is the same as or similar to analysis component 30 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[42] At an operation 410, responsive to the results of the first sleep test failing to meet the first condition, a recommendation is provided of a treatment for the subject. Operation 410 may be performed by one or more processors configured by a machine-readable instruction component that is the same as or similar to treatment determination

component 32 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[43] At an operation 412, an efficacy of the treatment in a second sleep test involving the treatment is confirmed. In some embodiments, the efficacy is confirmed by: receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors; determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals; determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals; and determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test. Operation 402 may be performed by one or more processors configured by one or more machine-readable instruction components that is/are the same as or similar to one or more of sensor information component 28, analysis component 30, and/or treatment determination component 32 (shown in FIG. 1 and described herein), in accordance with one or more embodiments.

[44] In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word "comprising" or "including" does not exclude the presence of elements or steps other than those listed in a claim. In a device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The word "a" or "an" preceding an element does not exclude the presence of a plurality of such elements. In any device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The mere fact that certain elements are recited in mutually different dependent claims does not indicate that these elements cannot be used in combination.

[45] Although the disclosure has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the disclosure is not limited to the disclosed embodiments, but, on the contrary, is intended to

cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

What is Claimed is:

1. A system (10) configured for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, the system comprising:

(a) one or more sleep quality sensors (14) configured to provide sleep quality signals conveying information related to a sleep quality measurement of the subject;

(b) one or more respiratory sensors (16) configured to provide respiratory signals conveying information related to a breathing measurement of the subject; and

(c) one or more hardware processors (22) configured by machine-readable instructions to:

(1) receive, in connection with a first sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors,

(2) determine a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals,

(3) determine an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals,

(4) determine whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test, and

(5) responsive to the results of the first sleep test failing to meet the first condition, provide a recommendation of a treatment for the subject and confirm an efficacy of the treatment in a second sleep test involving the treatment by:

(i) receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors,

(ii) determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals,

(iii) determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals, and

(iv) determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

2. The system of claim 1, wherein the one or more sleep quality sensors include an electrocardiogram (ECG) configured to monitor heart activity, and wherein the sleep quality signal conveys information related to heart activity of the subject.

3. The system of claim 1, further comprising one or more oxygen saturation sensors configured to provide oxygen saturation signals conveying information related to an oxygen saturation (S_PO_2) of the subject.

4. The system of claim 3, wherein the one or more hardware processors are further configured by machine-readable instructions to:

receive, in connection with the first sleep test, the oxygen saturation signals from the one or more oxygen saturation sensors; and

determine an oxygen saturation of the subject, in connection with the first sleep test, based on the oxygen saturation signals, and wherein determining whether the results of the first sleep test meet the first condition is further based on the oxygen saturation of the subject.

5. The system of claim 1, wherein the treatment includes utilizing a continuous positive airway pressure (CPAP) device.

6. A method for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, the method comprising:

(a) receiving, in connection with a first sleep test, sleep quality signals conveying information related to a sleep quality measurement of the subject and respiratory signals conveying information related to a breathing measurement of the subject;

(b) determining a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals;

(c) determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals;

(d) determining whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test;

(e) responsive to the results of the first sleep test failing to meet the first condition, providing a recommendation of a treatment for the subject; and

(f) confirming an efficacy of the treatment in a second sleep test involving the treatment by:

(1) receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors,

(2) determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals,

(3) determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals, and

(4) determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

7. The method of claim 6, wherein the sleep quality signal conveys information related to heart activity of the subject.

8. The method of claim 6, further comprising receiving, in connection with the first sleep test, oxygen saturation signals conveying information related to an oxygen saturation (S_PO_2) of the subject.

9. The method of claim 8, further comprising determining an oxygen saturation of the subject, in connection with the first sleep test, based on the oxygen saturation signals, and wherein determining whether the results of the first sleep test meet the first condition is further based on the oxygen saturation of the subject.

10. The method of claim 6, wherein the treatment includes utilizing a continuous positive airway pressure (CPAP) device.

11. A system configured for monitoring and/or diagnosing sleep related conditions of a subject based on both sleep quality and apnea hypopnea index, the system comprising:

(a) means (22,28) for receiving, in connection with a first sleep test, sleep quality signals conveying information related to a sleep quality measurement of the subject and respiratory signals conveying information related to a breathing measurement of the subject;

(b) means (22,30) for determining a sleep quality of the subject, in connection with the first sleep test, based on the sleep quality signals;

(c) means (22,30) for determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals;

(d) means (22,30) for determining whether results of the first sleep test meet a first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the first sleep test;

(e) means (22,32) for, responsive to the results of the first sleep test failing to meet the first condition, providing a recommendation of a treatment for the subject; and

(f) means (22,30) for confirming an efficacy of the treatment in a second sleep test involving the treatment by:

(1) receiving, in connection with a second sleep test, the sleep quality signals from the one or more sleep quality sensors and the respiratory signals from the one or more respiratory sensors,

(2) determining a sleep quality of the subject, in connection with the second sleep test, based on the sleep quality signals,

(3) determining an apnea-hypopnea index of the subject, in connection with the first sleep test, based on the respiratory signals, and

(4) determining whether results of the second sleep test meet the first condition based on both the sleep quality and apnea-hypopnea index of the subject associated with the second sleep test.

12. The system of claim 11, wherein the sleep quality signal conveys information related to heart activity of the subject.

13. The system of claim 11, further comprising means (22,28) for receiving, in connection with the first sleep test, oxygen saturation signals conveying information related to an oxygen saturation (S_PO_2) of the subject.

14. The system of claim 13, further comprising means (22,30) for determining an oxygen saturation of the subject, in connection with the first sleep test, based on the oxygen saturation signals, and wherein determining whether the results of the first sleep test meet the first condition is further based on the oxygen saturation of the subject.

15. The system of claim 11, wherein the treatment includes utilizing a continuous positive airway pressure (CPAP) device.

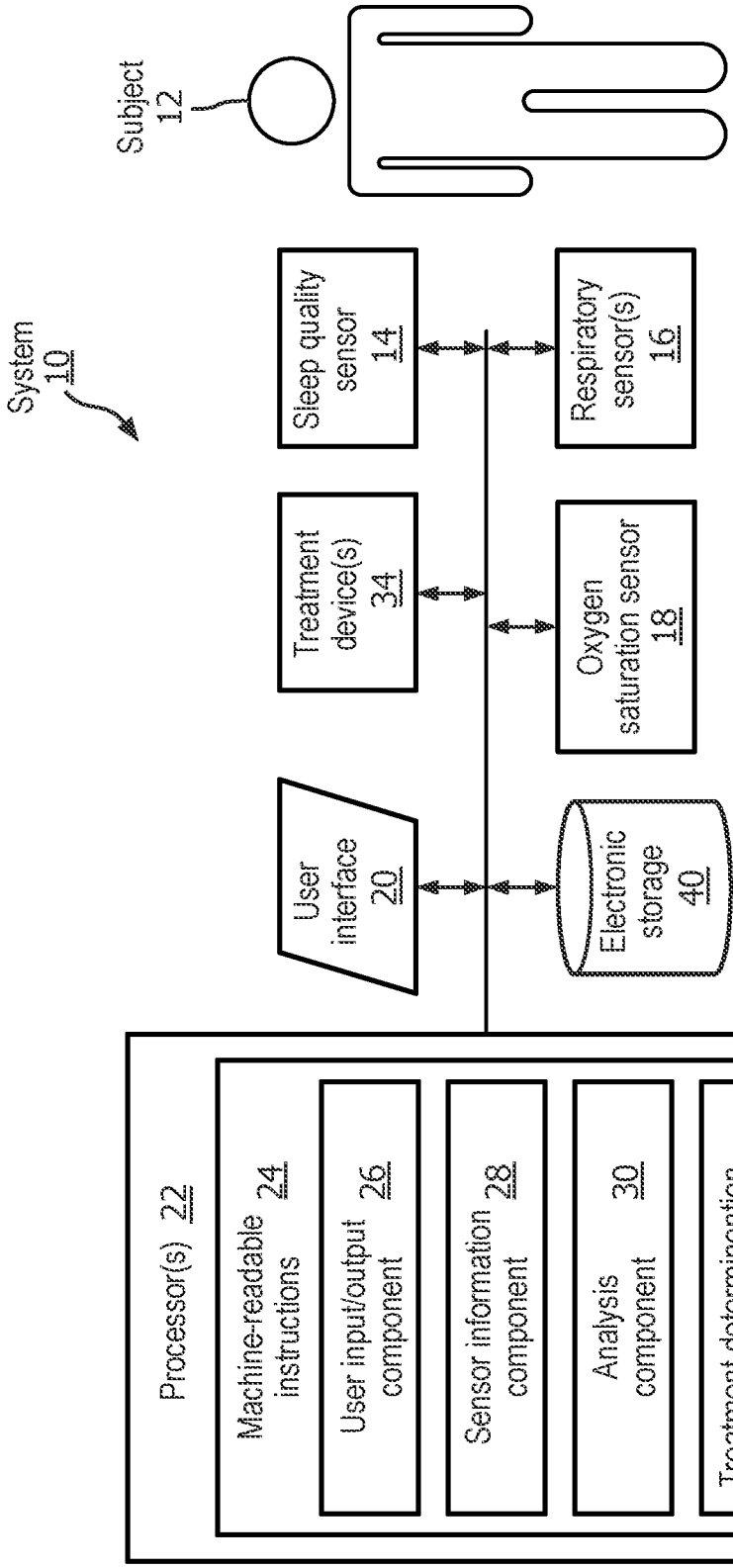
Subject
12
System
10
Sleep quality sensor
14
Respiratory sensor(s)
16
Treatment device(s)
34
Oxygen saturation sensor
18
User interface
20
Electronic storage
40
Processor(s)
22
Machine-readable instructions
24
User input/output component
26
Sensor information component
28
Analysis component
30
Treatment determination component
32

FIG. 1

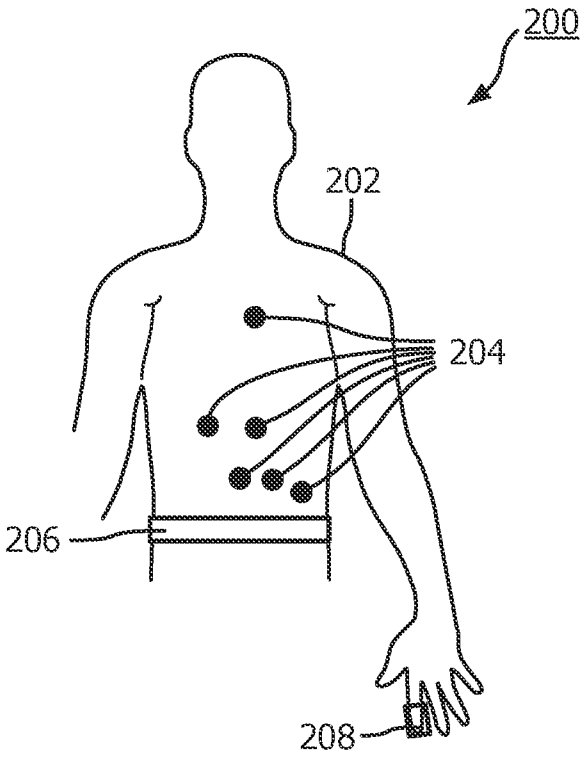

FIG. 2

50

First sleep test

AHI	sleep quality	Next step for patient
poor	poor	treat with airway therapy (ie CPAP)
good	poor	refer to sleep specialist
good	good	no need to treat do nothing

Second sleep test with treatment

AHI	sleep quality	Next step for patient
good	good	continue with airway treatment and send home on same treatment
good	poor	refer to sleep specialist

FIG. 3

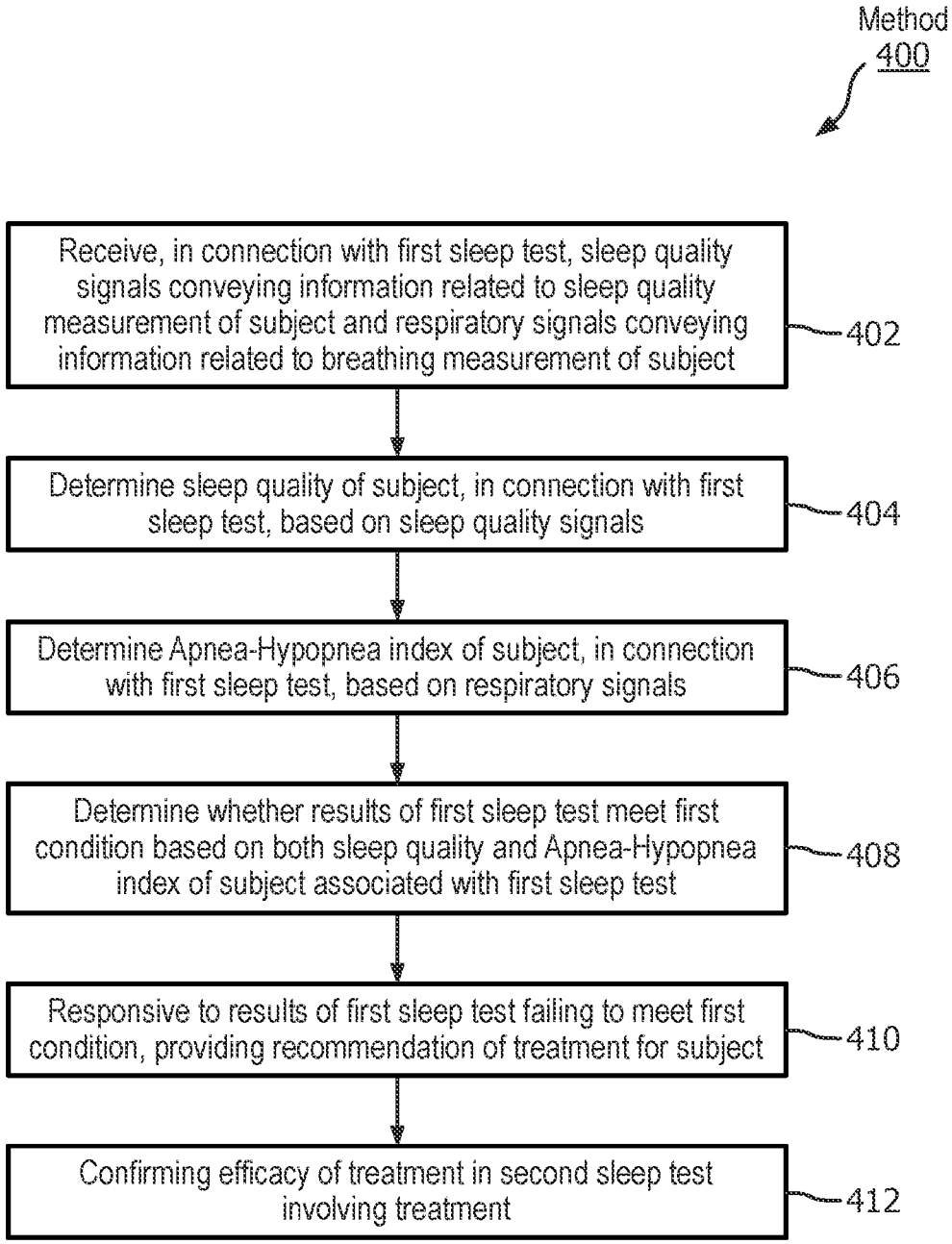
Method
400
Receive, in connection with first sleep test, sleep quality signals conveying information related to sleep quality measurement of subject and respiratory signals conveying information related to breathing measurement of subject
402
Determine sleep quality of subject, in connection with first sleep test, based on sleep quality signals
404
Determine Apnea-Hypopnea index of subject, in connection with first sleep test, based on respiratory signals
406
Determine whether results of first sleep test meet first condition based on both sleep quality and Apnea-Hypopnea index of subject associated with first sleep test
408
Responsive to results of first sleep test failing to meet first condition, providing recommendation of treatment for subject
410
Confirming efficacy of treatment in second sleep test involving treatment
412

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/050140

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0402 A61B5/08 A61B5/1455
ADD.

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

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/061315 A1 (LEE KENT [US] ET AL) 24 March 2005 (2005-03-24) paragraph [0054] - paragraph [0058] paragraph [0114] paragraph [0164] paragraph [0180] paragraph [0212] - paragraph [0213] table 1 figure 24 -----	1-5, 11-15
X	US 2011/306850 A1 (HATLESTAD JOHN D [US] ET AL) 15 December 2011 (2011-12-15) paragraph [0080] paragraph [0128] - paragraph [0139] paragraph [0160] claim 20 ----- -/--	1-5, 11-15

[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 application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 April 2017	13/04/2017

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, Fax: (+31-70) 340-3016	Gooding Arango, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2017/050140

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/046151 A1 (BSOUL MAJDI [US] ET AL) 21 February 2013 (2013-02-21) paragraph [0054] paragraph [0062] - paragraph [0065] paragraph [0077] figure 2 claim 9 -----	1-5, 11-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2017/050140

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

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

1. [X] Claims Nos.: 6-10
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 accordanoe with the second and third sentences of Rule 6.4(a).

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

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

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 fees, this Authority did not invite payment of additional fees.

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

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

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

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

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 6-10

Method claim 6 constitutes a diagnostic method (Rule 39.1(iv) PCT), as it is performed on the human body and includes all the necessary steps for the diagnosis, namely the collection of the data ("receiving, in connection with a first sleep test, sleep quality signals... and respiratory signals"), the comparison of these data with standard values, the finding of a significant deviation ("determining a sleep quality...; determining an apnea-hypopnea index...; determining whether results... meet a first condition) and the attribution to a clinical picture (implied by "providing a recommendation of a treatment"). Additionally, method claim 6 also constitutes a method of treatment of the human body by therapy (Rule 39.1(iv) PCT), as the method aims to provide a "recommendation of a treatment" which is then performed ("confirming an efficacy of the treatment in a second sleep test involving the treatment"). That is, the treatment step is essential for the claimed invention to work and therefore is considered to be part of the claim.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2017/050140

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2005061315 A1	24-03-2005	NONE	
US 2011306850 A1	15-12-2011	US 2005042589 A1	24-02-2005
		US 2011306850 A1	15-12-2011
US 2013046151 A1	21-02-2013	NONE	

专利名称(译)	睡眠质量和呼吸暂停低通气指数监测系统		
公开(公告)号	EP3402389A1	公开(公告)日	2018-11-21
申请号	EP2017701010	申请日	2017-01-12
[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N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	SCARBERRY EUGENE NELSON		
发明人	SCARBERRY, EUGENE NELSON		
IPC分类号	A61B5/00 A61B5/0402 A61B5/08 A61B5/1455		
CPC分类号	A61B5/4815 A61B5/0205 A61B5/0402 A61B5/08 A61B5/0816 A61B5/091 A61B5/14551 A61B5/4818 A61B5/4836 A61B5/4848 A61M16/024 A61M2230/04 A61M2230/205 A61M2230/42		
优先权	62/277647 2016-01-12 US		
外部链接	Espacenet		

摘要(译)

基于睡眠质量和呼吸暂停低通气指数监测和/或诊断受试者的睡眠相关病症。进行第一次睡眠测试，其中确定受试者的睡眠质量和呼吸暂停 - 呼吸不足指数。基于与第一睡眠测试相关联的受试者的睡眠质量和呼吸暂停 - 呼吸不足指数，确定第一睡眠测试的结果是否满足第一条件。响应于第一次睡眠测试的结果未能满足第一条件，提供了对受试者的治疗建议。在第二次睡眠测试中确认治疗功效，所述第二次睡眠测试涉及通过基于与第二次睡眠测试相关的受试者的睡眠质量和呼吸暂停低通气指数确定第二次睡眠测试的结果是否满足第一条件来进行治疗。