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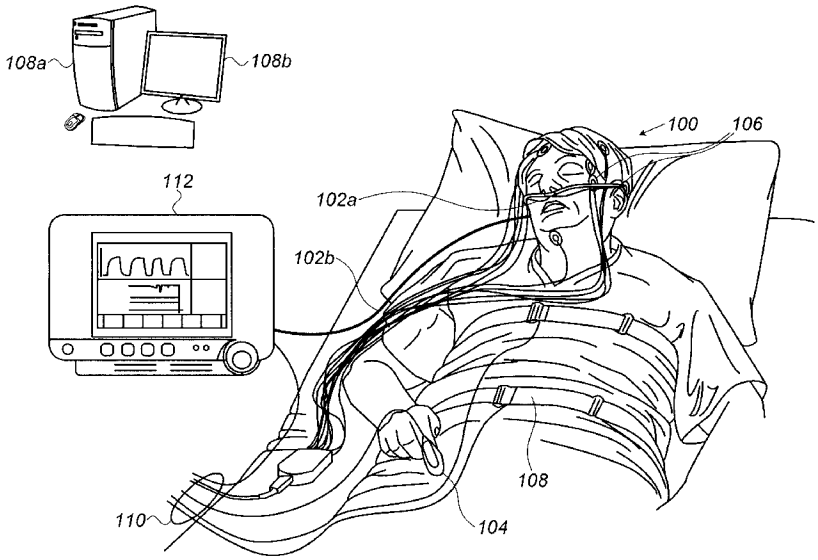

FIG. 1

(57) Abstract: A system for automatic sleep test analysis, the system comprising: a pulse oximeter for continuously monitoring oxygen saturation values of a patient; a capnograph for continuously monitoring exhaled carbon dioxide (C02) values of the patient; and a computing unit configured to compute a continuous integrated sleep score based on a sequential analysis of the oxygen saturation values and the exhaled C02 values, wherein the continuous integrated sleep score is indicative of the patient's breathing-related sleep quality during at least a portion of the sleep test.

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METHOD AND SYSTEM FOR SLEEP DISTURBANCE ANALYSIS

FIELD OF THE INVENTION

The invention relates to a method and system for sleep disturbance analysis.

BACKGROUND OF THE INVENTION

A significant number of individuals are prone to brief interruptions (apneas) of breathing during sleep due to a common sleep disorder known as obstructive sleep apnea (OSA). OSA is believed to affect approximately 18 million people in the US and has been linked to an increased risk of heart disease, high blood pressure, stroke, and impotency. Spurred by an increase in the OSA diagnosis rate, the American Academy of Sleep Medicine (AASM) estimates that "the number of patients seeking treatment will grow at a calculated annual growth rate (CAGR) of 16% from 2005-2010."

OSA is a common disease in the United States. The prevalence of OSA, as indicated by data from the Wisconsin Cohort Study (adults aged 30-60 years), is 9-24% for men and 4-9% for women. The estimated prevalence of OSAHS (obstructive sleep apnea-hypopnea syndrome) is 2% in women and 4% in men.

The exact cause of OSA remains unclear. The site of obstruction in most patients is the soft palate, extending to the region at the base of the tongue. There are no rigid structures, such as cartilage or bone, in this area to hold the airway open. During the day, muscles in the region keep the passage wide open. But as a person with OSA falls asleep, these muscles relax to a point where the airway collapses and becomes obstructed. When the airway closes, breathing stops and the sleeper awakens to open the airway. The arousal from sleep usually lasts only a few seconds, but brief arousals disrupt continuous sleep and prevent the person from reaching the deep stages of slumber, such as rapid eye movement (REM) sleep, which the body needs in order to rest and replenish its strength.

Many types of abnormal breathing during sleep have been described as apneas. Partial airway obstruction can lead to a reduction in tidal volume, referred to as progressive increases in respiratory effort, reflecting increasing upper airway resistance. Some patients have periods of hypoventilation during sleep, most commonly seen in REM, and not always associated with apneic events.

Another type of breathing abnormality consists of those apneic events that are not associated with inspiratory effort, indicating reduced central respiratory drive, referred to as central apneas.

As different types of disordered breathing events during sleep have been described, it has been recognized that signs and symptoms could be used to describe several syndromes.

Guilleminault introduced the term obstructive sleep apnea syndrome (OSAS) with its central feature of daytime hyper-somnolence and polysomnographically proven obstructive apneas. Hypopneas were first described as events of shallow breathing causing oxygen desaturation. In 1988, cases with Hypopneas and no or few apneas were described, with clinical symptoms similar to OSAS, and introduced the sleep hypopnea syndrome. Subsequently the OSAS began to be referred to as the obstructive sleep apnea-hypopnea syndrome (OSAHS).

The initial description of OSAS by Guilleminault included a criterion of a minimum duration of 10 seconds for an apnea to be scored. Based on a study of healthy subjects it was also suggested that more than 30 apneas per night should be considered abnormal. This was later standardized as the apnea index, which reflects the number of apneas per hour of sleep.

Since the initial descriptions of these different types of abnormal breathing events and their related syndromes, technology has changed and original definitions have been modified.

Today, the diagnosis of sleep disorders commonly includes both a patient clinical assessment and an overnight recording session, where several patient parameters are recorded. The recorded data is later analyzed by an expert and/or dedicated software program to detect and provide a score to the level of sleep disorder.

Two of the basic patient parameters used to determine the severity of the sleep disorder is the apnea-hypopnea index (AHI) and the oxygen desaturation index, both indicative of a fall in respiratory effort or drive. Though an apnea event is the result of a total cessation of breathing, for a hypopnea event, it is sufficient that the patient breath flow drops measurably (for example, by more than 50%). It is generally accepted that detection of hypopnic events even without total apnea is sufficient for OSA diagnosis. Though the hypopnea index and the many correlating arousals are a

clear indicator of the disorder, it is believed that the resulting periods of hypoxia are the main reason for the increased patient health risks.

During a sleep study, many parameters relating to the patient's sleep are recorded and later analyzed, either by an expert and/or an appropriate software package. All the hypopnea and apnea events during the night are counted, and indexes for each separately and also together are calculated, based on the average number of events per hour. It is accepted that the higher the index calculated is, the severity of OSA is greater, where three levels are often defined: mild, moderate and severe. The medical decision or diagnosis does not rely only on this value, but it is considered as one of the main parameters for decision making.

Though as mentioned above, it is felt by many experts that it is the resulting periods of hypoxia that are the main reason for the increased patient health risks, an oxygen desaturation index is not always calculated by itself, but is taken into consideration via the hypopnea index, which, as defined, requires a subsequent desaturation event in order for it to be counted (though, according to the AASM definition, an arousal could replace the need for the desaturation).

Many studies have been made over the years to correlate sleep scores using the AHI (apnea hypopnea index) with OSA severity, patient populations, outcomes like hypertension etc., with often conflicting results.

Although sleep medicine, its understanding and knowledge have increased exponentially over the past 20 years, many inherent drawbacks in the technical definition and method of measurement of the AHI exist. The mere fact that the AHI is created by calculating the number of events per hour, where all events are weighted equally, is believed to be a major drawback. One event may be far stronger than another, both per patient and relative to different patients, and the equal treatment these events receive may cause numerous inherent errors in the diagnosis of sleep disorders.

Further, the AHI index is based mainly upon measurements of the patient flow, where the measure of flow is an indirect manner of measuring tidal volumes. Where it is the tidal volume, which truly indicates the effectiveness of the ventilation and oxygenation, and as explained, will dictate the sleep quality. The correlation between volume and flow is often poor, and is further dependent on the duration of the breath and how it changes over the breath cycle. Still further, when patient breath flow is

measured, what is normally being measured is relative flow without any absolute measurements. This, since it may be virtually impossible to measure total flow without closing off the entire oral/nasal cavities to permit the total breath to pass via the flow sensor. In reality, one samples only a part of the air flowing from the nasal and/or oral nasal cavity, in order to provide a value that is supposed to be proportional to the entire flow and that, proportional to tidal volume. However, as explained, one can change a level of flow without changing volume, by changing the pattern or length of the breath, mouth aperture or mode of breathing, i.e. nasal, oral or oral nasal.

Currently, in many sleep test settings, assessment of sleep quality, as related to effective breathing, is carried out by calculating an Apnea Index (AI) and a Hypopnea Index (HI), and/or their sum, the Apnea-Hypopnea Index (AHI). These indices are based on counting events during sleep period and averaging them over time (e.g., number of events per hour). The calculation of events is based on parameters collected using flow sensors (pressure and or thermocouple sensors), oximeter and or EEG. The events are in general a change (usually, a decrease) in the level of the parameter from a base-line for at least a predefined amount of time, followed by a change in the opposite direction (usually, an increase). For example an Apnea event as defined by the American Association of Sleep Medicine may be a decrease to 90% in the pressure level, as compared to its base-line, that lasted 10 seconds as measured by a thermistor. The indices are quantitative, as all events are counted equal, disregarding their severity and their duration (e.g., a de-saturation event that lasts 60 seconds, with a drop of SpO_2 from 95% to 85%, has the same weight as a de-saturation event that lasts 6 seconds with a drop of SpO_2 from 100% to 95%).

The common diagnostic criteria of a sleep disorder is that the individual fulfills criterion A or B, plus criterion C, as presented below, to be regarded as suffering from a sleep disorder:

A. Excessive daytime sleepiness that is not better explained by other factors;

B. Two or more of the following that are not better explained by other factors:

- choking or gasping during sleep,
- recurrent awakenings from sleep,
- unrefreshing sleep,
- daytime fatigue,
- impaired concentration;

C. Overnight monitoring demonstrates five or more obstructed breathing events per hour during sleep. These events may include any combination of obstructive apneas/hypopneas or respiratory effort related arousals, as defined below.

The American Academy of Sleep Medicine (AASM) recommends that an apnea event be detected using an oral-nasal thermal sensor, which measures the respiratory gas temperature that is proportional to the flow passing across it, while for detection of a hypopnea event they recommend the use of a pressure transducer where changes in pressure are proportional to the flow. Though the AASM recommend the use of the thermal sensor for apnea, they propose, as an alternative, the use of a pressure transducer. The pressure transducer method uses a cannula interfaced to the patient to capture the breath sample, where the pressure created from the breath flowing into the cannula is sensed by a pressure sensor positioned at the end of the cannula. Though it is not mentioned in the manual, it is normal to find that the cannula is an oral-nasal cannula, in order to sample both nasal and oral breathing. However, many sleep labs prefer to use only a nasal cannula for that purpose.

Though there are many definitions of a hypopnea event, the following is one of the most accepted definitions:

A) Medically: Hypopnea is a medical term for a disorder which involves episodes of overly shallow breathing and/or an abnormally low respiratory rate. This differs from apnea in that there still remains some flow of air. Hypopnea events may happen while asleep or while awake.

B) Technically: A reduction of airflow lasting 10 or more seconds measured by a 30 percent reduction in airflow, associated with a drop in oxygen level by 4 percent, or a 50% reduction in airflow accompanied by either a 3% drop in oxygen level or an arousal. Hypopneas are often said to have the same clinical significance as an apnea.

An apnea event (as defined for sleep studies), unlike a hypopnea event, is sometimes defined as a 90% detected reduction in flow, as measured by either a pressure or a thermal sensor, but does not require a corresponding desaturation event. Again, a 10 second period is usually required in order for it to be considered and counted as an event.

Further drawbacks are laid out below:

Drawbacks in the use of flow as the parameter to measure shallow breathing:

As defined above, a hypopnic event is often medically defined as involving episodes of overly shallow breathing and/or an abnormally low respiratory rate. These overly shallow breaths may be caused by partial obstruction of the airway, or may be of a central nature, where the source is metabolic and/or neuromuscular. This reduction in strength, effort and/or drive will normally create a drop in tidal volume of the breath and minute ventilation, and a consequent reduction of effective gas transfer (Oxygen intake and CO_2 removal). Even in normal breathing, some 20% of the breath will not take part in gas transfer; this percentage is the result of dead space, which is the volume from the mouth down to the bronchiole tubes where the breath does not make contact with the Alveoli (where breath transfer takes place). This volume is approximately 150ml in adults, relative to a normal tidal volume of some 500ml. Hence the more one breaths shallowly, the percentage of breath taking part in gas transfer will drop strongly, this, since the dead space volume will remain constant but the tidal volume will fall.

It would infer from the above, that optimally the actual changes in tidal volume or minute ventilation during sleep should be measured. Instrumentation for these purposes may be spirometry or pneumotachography, respectively, which dictates measuring volumes of the entire breath. This, however, is not very practical during sleep. Spirometry, for example, is accomplished normally in controlled measuring procedures with a cooperative patient.

The measure of flow is hence an *indirect* manner of measuring tidal volumes, where the correlation between volume and flow will be dependent on the duration of the breath and how it changes over the breath cycle.

Further, when patient breath flow is measured, what is normally being measured is relative flow without any absolute measurements. This, since it may be virtually impossible to measure total flow without closing off the entire oral/nasal cavities to permit the total breath to pass via the flow sensor. In reality, one samples only a part of the air flowing from the nasal and/or oral nasal cavity, in order to provide a value that is supposed to be proportional to the entire flow. However, as explained, one can change a level of flow without changing volume, by changing the pattern and length of the breath.

Drawbacks in the method of measurement:

As mentioned, two methods for measurement are commonly recommended by the experts and AASM: Thermal or pressure sensors. The pressure sensor method has two main drawbacks:

1. Issues relating to the sampling means and interface:

Optimally, a patient should be sampled from both his nasal and oral cavities, this, since a patient can have a mixture of nasal, oral and oral nasal breathing (though nasal breathing is most prominent in patients with OAS, who tend to open their mouths during sleep).

Sampling from both nostrils and mouth dictates a more complicated interface design, often considered cumbersome during sleep. Many marketed products are nasal alone for this reason. Further, even if an oral-nasal design is used and tolerated, the oral sampling prong must cover a substantial part of the mouth in order to capture flow and changes in order to be useful.

Further, the measured flow level will be dependent on where the patient is breathing from; if the patient changes his breathing characteristic, i.e. from pure nasal to oral-nasal etc., a change of flow will be sensed, though in reality the total flow may remain the same.

Still further, the level of flow measured will depend on the extent of the opening of the mouth. When wider open, the flow captured will naturally fall. And still further, a partially blocked nose or intermittently blocked nostril will also change the measured flow shape. All the above changes could be detected as an erroneous hypopnea, though none were the result of a partial blockage or shallow breath. Further, as mentioned, the flow levels measured are relative, with no absolute value, and will differ from patient to patient based, for instance, on the size of the patient' nostrils relative to the sampling cannula.

2. Issues related to correlating pressure measurements to actual flow:

Pressure, as mentioned, is an *indirect* measure of flow (proportional to the square root). Different sensors and systems use different methods to measure and depict the flow.

Still further, many systems prefer to use an AC coupled measuring system, which is sensitive only to changes in pressure and not constant flow. This, since the cannula may be placed under a CPAP (continuous positive airway pressure) mask, where the

high pressures would interfere with the measurements if DC coupling would be used. This AC coupling acts like a filter and hence also changes the shape of the real flow changes.

Drawbacks in the technical definition of Hypopnea when measured with flow:

As mentioned above, a technical definition of hypopnea has been provided which is relevant to when measuring flow with a pressure transducer, i.e. a reduction of airflow lasting 10 or more seconds measured by a 30 percent reduction in airflow, associated with a drop in oxygen level by 4 percent or a 50% reduction in airflow accompanied by either a 3% drop in oxygen level or an arousal. Hypopneas are usually related to as having the same clinical significance as an apnea.

In order to define a reduction in flow of 30 or 50%, one must define a baseline from where it has fallen. This baseline must be updated continuously, since not only fast changes occur, but also gradual changes. Then the question is asked, how to calculate this baseline? How often is it updated? After a fall, how does one reset it? From which point is it reset? How does one take into consideration that the change is possible caused by a change in flow pattern or breath period? From where does one count the 10 seconds?

Drawbacks based on the fact that all events are defined equally:

All events are calculated in the index as equal, though one may ask, is the effect on a patient is the same? Is an event that lasted 10 seconds the same as one that lasted 40 seconds? Is a desaturation event that had a 3% drop similar to one where it dropped by 13%? If an SpO_2 baseline was 99% or 89%? If the flow fell by 30% or fell by 80%? Is there importance to recurring patterns? And so on.

Hence, there is a long-felt need for an improved standard method with more absolute means of scoring apnea/hypopnea events.

SUMMARY OF THE INVENTION

There is provided, in accordance with an embodiment, a method for automatic sleep test analysis, the method comprising: continuously monitoring, using a pulse oximeter, oxygen saturation values of a patient; continuously monitoring, using a capnograph, exhaled carbon dioxide (CO_2) values of the patient; and computing a continuous integrated sleep score based on a sequential analysis of the oxygen saturation values and the exhaled CO_2 values, wherein the continuous integrated sleep

score is indicative of the patient's breathing-related sleep quality during at least a portion of the sleep test.

There is further provided, in accordance with an embodiment, a system for automatic sleep test analysis, the system comprising: a pulse oximeter for continuously monitoring oxygen saturation values of a patient; a capnograph for continuously monitoring exhaled carbon dioxide (CO_2) values of the patient; and a computing unit configured to compute a continuous integrated sleep score based on a sequential analysis of the oxygen saturation values and the exhaled CO_2 values, wherein the continuous integrated sleep score is indicative of the patient's breathing-related sleep quality during at least a portion of the sleep test

In some embodiments, the sequential analysis comprises applying to the oxygen saturation values and the exhaled CO_2 values an analysis method selected from the group consisting of: a linear regression model, a non-linear regression model, fuzzy logic, a Bayesian network, a decision tree, a neural network, a radial base function and an expert system.

In some embodiments, the method further comprises detecting multiple events indicative of ineffective breathing exhibited in one or more of the oxygen saturation values and the CO_2 values; and computing a weighting function for the detected events, wherein each event is assigned a suitable weight.

In some embodiments, the suitable weight for each event is based on applying an integrative function to the oxygen saturation values and CO_2 values over a duration of each event, wherein the integrative function comprises the following parameters: the oxygen saturation values and CO_2 values over the duration of the event; baseline oxygen saturation and CO_2 values measured prior to the event; and the duration of the event.

In some embodiments, the integrative function further comprises at least one parameter selected from the group consisting of: a difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values; a maximal difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values; and minimal oxygen saturation and CO_2 values over the duration of the event.

In some embodiments, the method further comprises computing, from the continuous integrated sleep score, an integrated sleep score for each of a plurality of time windows in the sleep test.

In some embodiments, the time windows are moving time windows.

In some embodiments, the moving time windows are each of a static length.

In some embodiments, the method further comprises dynamically changing a length of at least some of the moving time windows.

In some embodiments, the method further comprises monitoring one or more additional parameters selected from the group consisting of: heart rate, encephalogram (EEG), breath flow and chest movement, wherein the computing of the continuous integrated sleep score is further based on one or more of the additional parameters.

In some embodiments, the method further comprises summarizing at least a portion of the continuous integrated sleep score, to generate a summarized sleep quality score.

In some embodiments, the computing unit is further configured to: detect multiple events indicative of ineffective breathing exhibited in one or more of the oxygen saturation values and the CO_2 values; and compute a weighting function for the detected events, wherein each event is assigned a suitable weight.

In some embodiments, the computing unit is further configured to compute, from the continuous integrated sleep score, an integrated sleep score for each of a plurality of time windows in the sleep test.

In some embodiments, the computing unit is further configured to dynamically change a length of at least some of the moving time windows.

In some embodiments, the system further comprises at least one apparatus selected from the group consisting of: a heart rate monitor; an electroencephalogram (EEG) monitor; a breath flow sensor; and a chest movement sensor, wherein the computing is further based on data received by the computing unit from one or more of the apparatuses.

In some embodiments, the computing unit is further configured to summarize at least a portion of the continuous integrated sleep score, to generate a summarized sleep quality score.

BRIEF DESCRIPTION OF THE FIGURES

Exemplary embodiments are illustrated in referenced figures. Dimensions of components and features shown in the figures are generally chosen for convenience and clarity of presentation and are not necessarily shown to scale. The figures are listed below.

Fig. 1 shows a semi-pictorial illustration of a patient connected to sleep test equipment;

Fig. 2 shows a flow chart of a method for automatic sleep test analysis;

Fig. 3 shows an exemplary flowchart in which input parameters from a capnograph, a pulse oximeter and a flow meter are analyzed over a time window and applied with a transformation function;

Fig. 4 shows a flow chart in which, after calculating a continuum or a set of single, integrated sleep scores, a sleep quality score (SQS) is calculated;

Fig. 5 shows a transformation function for $EtCO_2$ with exemplary values;

Fig. 6 shows values of a continuous integrated sleep score (CISS) for $EtCO_2$ over time;

Fig. 7 shows the use of linear combination of $EtCO_2$ and SpO_2 to generate the CISS;

Fig. 8 shows CO_2 concentrations (waveforms) with continuous scoring between 0 and 10;

Fig. 9 shows SpO_2 values and a calculated score, 0 to 100; and

Fig. 10 shows an integrated score, 0 to 100.

DETAILED DESCRIPTION

An aspect of some embodiment relates to the usage of a capnograph in sleep testing, instead of or in conjunction with a flow meter. Capnography is often said to be one of the most sensitive monitors for tracking patient ventilation available today. A flow meter can often provide an erroneously higher score because changes in patient breathing patterns can be misinterpreted for a hypopnic event.

Although a capnograph may not be primarily used to detect shallow breathing, it does provide absolute measurements, not relative, which are directly linked with breathing performance and ventilation.

A capnograph may still be used in conjunction with a pulse oximeter, since the consequent hypoxia events indicated by desaturation and level of SpO_2 are linked more with the risks, than the shallow breathing, and for which reason a hypopnea event is defined as one which occurs together with a desaturation event.

A capnograph operating together with a pulse oxymeter may provide a more reliable method for not only detection of sleep disturbance but to provide a better means for evaluating the severity. Further, as mentioned, a shallow breath will likely have a corresponding effect on the CO_2 level, when falling towards dead space breathing, hence a falling CO_2 level is more indicative of a hypopnic event that is harmful to the patient than flow alone, and its absolute value corresponds more than the indirect measure of flow.

Further, an oral-nasal cannula for measuring CO_2 is not normally affected by changing breathing patterns, i.e. nasal to oral and vice versa, neither is it dependent on the opening of the mouth. Additionally, not only is the CO_2 waveform amplitude indicative of ventilation performance, but also are the inherent shapes of a single waveform and the patterns of groups of waveform. Using all these attributes together may provide a more robust means for analyzing the quality of sleep.

Reference is now made to Fig. 1, which shows a semi-pictorial illustration of a patient **100** connected to sleep test equipment. An oral-nasal cannula **102a** may be positioned on the patient's face, for collecting exhaled oral and nasal breath. The exhaled breath is drawn through a CO_2 tube **102b** towards a capnograph **112** which may be positioned next to the patient's bed. A pulse oximeter **104** may be positioned on the patient's finger, for measuring oxygen saturation values.

Optionally, various other sensors may connected to or associated with the patient. For example, one or more electrodes **106** may be attached to the patient's face and/or scalp, for measuring eye movement, brain activity and/or the like. One or more elastic belts **108** may be worn by the subject, measuring his or hers chest movement, which is indicative of breath.

Cables **110** of the different sensors may extend up to a monitoring room of the sleep lab, if the sleep test is performed in a lab. There, the cables may be connected to a computing unit **108a** which receives and analyzes the data. A monitor **108b** may be connected to computing unit **108**, for the purpose of displaying one or more of the sleep-related scores in real time, as they are being generated. Optionally, a printer (not

shown) may also be connected to computing unit **108a**, for printing a summary score at the end of the sleep test, and/or the individual scores that were generated throughout the test period. The printed scores may be laid out graphically and/or numerically. Optionally, a graphical and/or numerical report is generated as a digital file by computing unit **108** without printing.

In an embodiment, there is provided a method for automatic sleep test analysis, in which oxygen saturation is monitored by pulse oximeter **104** of Fig. 1, CO_2 is monitored by capnograph **112** of Fig. 1, and one or more sleep-related scores are computed by computing unit **108** of Fig. 1. The method is shown schematically in Fig. 2.

The method includes receiving two or more measured patient parameters at a given time window during sleep, wherein the at least two measured parameters relate to the breathing effectiveness and originate from a Capnograph and a Pulse Oximeter; and computing a single, integrated sleep score (ISS) based on the two or more measured patient parameters during that time window indicative of the sleep quality and effectiveness. Accordingly, multiple integrated sleep scores are being computed in each sleep test.

Secondly and optionally, for a period of time greater than the said time window, a continuum or set of scores may be computed, generating a continuous integrated sleep score (CISS).

Thirdly and also optionally, a summary of the continuous integrated sleep score or of the multiple integrated sleep scores of a patient, which includes receiving and using the CISS or ISSs for calculating a summary score to be referred as the Sleep Quality Score (SQS). The SQS may be computed for the whole duration of sleep test or for sub-period or sub-periods of the sleep-test (for example for periods with a specific posture or periods with a specific sleep-stage). Additional parameters may be received and used for the definition of the sub-period ranges. The method may further include providing a medical recommendation.

Advantageously, the computed CISS and/or SQS provide a measure that is based on quality rather than on quantity alone.

According to some embodiments, the single, integrated scores may be calculated by various means, such as, for example, by use of mathematical equations, algorithms,

formulas, and the like that may take into consideration one or more of the values or derivatives of the values of the parameters.

According to some embodiments, computing the single, integrated scores may include applying a mathematical model reflecting medical expert considerations, literature, clinical data, medical experience or any combination thereof that indicate the quality of the sleep as reflected by the measured parameters. Computing the single, integrated scores may include applying a linear regression model, a non-linear regression model, a fuzzy logic, a Bayesian network, a decision tree, a neural network, a radial base function, an expert system, or any combination thereof.

According to further embodiments, the at least two measured parameters may include a CO_2 related parameter and an O_2 related parameter. In addition, the heart rate, an encephalogram (EEG), breath flow (using a pressure transducer and/or a thermocouple), chest movement, or any combination thereof may optionally be used.

The O_2 related parameter may include SpO_2, change in SpO_2, slope of change in SpO_2 their variability's or any combination thereof.

Fig. 3 shows an exemplary flowchart, in which input parameters from a capnograph, a pulse oximeter and a flow meter are analyzed over a time window and a transformation function is applied to each one of them. Then, a single integrated score per parameter is calculated, followed by a synergy ruling algorithm which is used to generate a single, integrated score for that time window, based on all per-parameter scores.

Fig. 4 shows a flow chart in which, according to an embodiment, after calculating a continuum or set of single, integrated sleep scores that generates a continuous integrated sleep score (CISS), the sleep quality score (SQS) is calculated based on a mathematical assessment of the CISS for the period of interest and represented as either a single score, or a set of scores, or matrix.

According to additional embodiments, the method of calculating the single integrated sleep score and/or SQS of a subject may further include receiving one or more subject characteristics; and computing the single integrated sleep score and/or SQS based on the two or more measured patient parameters and on one or more patient characteristics. The one or more patient characteristics may include age, weight, gender, medical condition, medication, medical history or any combination thereof.

The medical history may include smoking, heart disease, lung disease or any combination thereof.

According to further embodiments, the single integrated sleep score may be on a simple scale such as the range of 1 to 100 or 1 to 10. It is therefore a unit-less score which is only indicative of the magnitude of the sleep quality as a continuous value during sleep test. Where either the lowest value indicates a high quality of sleep or the highest value indicates the high quality of sleep.

According to additional embodiments, the method of generating the single integrated sleep score and or SQS of a patient may further include computing a reliability index of the SQS.

According to further embodiments, the SQS may be calculated by various means, such as, for example by use of mathematical equations, algorithms, formulas, and the like that may take into consideration one or more of the values or derivatives of the values of CISS, such as average, median, integration, variance and the like or combination thereof.

According to some embodiments, computing the SQS may include applying a mathematical model reflecting the overall sleep quality at the period of sleep or at parts of the period of sleep.

According to a further aspect there is provided a method for calculating an overall score, the sleep quality score which is based upon the single quality sleep scores generated over a trial period. The SQS can also be calculated for a sub-period of the trial for example per hour or period of sleep mode or patient position. The SQS may be calculated using an average or any other standard statistical means for depicting and representing a set of scores over a period of time. The sleep quality score is hence a value indicative of the overall sleep quality for the period defined. The sleep disorder measure may be represented by a single value or by a set of values or even graphic representation. The set of values may include one value generated by the statistical evaluation of the single integrated scores, while a second related to number or rate of events. While a third may relate to distribution, standard distribution or any other statistical assessment of the CISS.

According to yet additional embodiments, the method may further include a graphic display of the CISS. The score can be calculated in real time, off-line, at the apparatus as is, or combined to other apparatus tool such as the polysomnograph

(PSG). Optionally, the information from the capnograph, pulse oximeter and optionally flow meter is transmitted via a communication port directly or wirelessly to a PSG or other sleep analysis tool.

According to some embodiments, there is a need to analyze the various patient related parameters that are collected during sleep, and provide the sleep test analyzers and technicians with a more concise, comprehensive, intuitive, clear and useful information about the patient's sleep quality as a result of the breathing effectiveness.

The computed CISS and SQS provide a measure that is based on quality rather than on quantity alone.

The CISS and SQS may be calculated on real-time or off-line using the parameters data. The single integrated sleep score from which the CISS and SQS are generated, at a given time point reflects the quality of sleep during a previous time window, ranging from few seconds to few minutes. The score is updated at a rate smaller than the minimal time window (moving window). The time window may be an absolute constant (static) or adaptively change (dynamic).

According to some embodiments, the single integrated sleep score computation may be a linear function or a non-linear function or a non-linear transformation of the parameters and or the parameters derivatives indicative of the breathing effectiveness. Non-linear transformations may be applied on each of the parameters separately and later to be integrated into single score or it may be applied on an integrated value of the parameters.

According to some embodiments, the single integrated sleep score computation may be a linear function or a non-linear function or transformation of a parameter in a given time-window taking into account the absolute value of the parameter at any time point in the time-window, the absolute values of the minimum and maximum of the parameter and the difference between them, the rate of change in the parameter values, or any combination thereof.

According to some embodiments, the single integrated sleep score computation may be a linear function or a non-linear function or transformation of a parameter in a given time-window taking into account also an absolute base-line calculated from a different and normally longer time window of the parameter, an absolute base-line value of the parameter whose importance and weighting depends on the subject's characteristics (such as: age, presence of heart-disease, pulmonary disease), an

absolute or a relative base-line that depends on other parameters used for the sleep test (such as: sleep stage, time since falling asleep)

According to some embodiments, the single integrated sleep score computation may be a linear function or a non-linear function or transformation of several parameters where a first parameter's value or any of its derivatives (such as: maximum, minimum, differences, rate of change, baseline) may be used in combination with a second parameter's value or its derivatives and hence creating synergy between the input parameters and their integrated effect as related to breathing effectiveness..

According to some embodiments, the single integrated sleep score computation may be event based, where an event of a parameter is detected in a time-window and a weighting function is calculated for each event. The events may include the following: no-breathing for at least Y seconds, a decrease of at least X% of SpO_2 values for at least Y seconds, a decrease or an increase of at least X mmHg of $EtCO_2$ values for at least Y seconds, a decrease to at most X mmHg of $EtCO_2$ values for at least Y seconds, an increase to at least X mmHg of $EtCO_2$ values for at least Y seconds, a decrease of successive $EtCO_2$ values with at least Z rate for at least Y seconds, an increase of successive $EtCO_2$ values with at least Z rate for at least Y seconds, a very short breath (spike), decrease in flow (pressure and or thermocouple) by at least X% for at least Y seconds or any combination thereof.

According to some embodiments, the changes in the parameter values (decrease or increase) are relative to a base line. The base-line may be calculated continuously (i.e. updated every Y seconds, where Y is 1-5 seconds) by averaging (using mean or median or other averaging function) the parameter value in a defined time window. This time-window is selected in a way that the variability of the parameter at that time period is low and no event is included. The variability can be calculated using standard-deviation, range of change, maximum, minimum, variance or the like. For example, base-line for SpO_2 may be calculated in a time-window lasting between the last 10-200 seconds, where SpO_2 values during that time varies less or equal to ±1%.

In some embodiments, a flow meter (based on, for example, pressure, thermo-couple and/or the like) may be added to the capnograph and the pulse oximeter. As mentioned, a change in the flow does not necessarily dictate any change in CO_2 – such as during a hypopnea event where shallow breathing occurs. Hence, when a reduction

in the flow is seen, without any substantial change to the CO_2, it would cause a certain drop in the score; however, if the decrease in the flow it is also coupled with a drop in CO_2, then the drop in the score may be more significant, since the reduction is now supported by two parameters and not by flow only.

In some embodiments, other one or more parameters commonly monitored in a sleep test using a polysomnograph may be added. For example, readings from a polysomnograph may be indicative on an arousal of the patient. Such arousal, if occurring following or simultaneously with an apnea and/or a hypopnea event, may cause the score to decrease, due to two reasons: Firstly, the arousal is reinforcement of the determination of a apnea/hypopnea event, since it usually occurs when the patient chokes or doesn't breath sufficiently. Secondly, the arousal itself means that the quality of the sleep is low, and, additionally, the occurrence of multiple arousals during the sleep period may consequently cause other problems, such as daytime drowsiness, sleep deprivation, headaches and/or the like.

According to some embodiments, the weighting function calculated **212** for each event may be linear or non-linear function taking into account the absolute value of the parameter at any time point during the event, the absolute values of the minimum and maximum of the parameter and the difference between them, the rate of change in the parameter values, the event's base-line, the difference between the parameters values and the event's base-line, the integral, the difference between the extreme parameter value (e.g. its minimum), the event's base-line, the duration of the event or any combination thereof.

According to some embodiments, the weighting function calculated **212** for each event may be linear or non-linear function taking into account values and or events of other parameter or parameters in a time window larger than the event duration, previous to the event, during the event and or after the event.

According to some embodiments, the single integrated sleep score during an event of a parameter or during events of more than one parameter may be computed as a linear or non-linear function of the event weighting-function value or of the events weighting-functions values. The single integrated sleep score may be a constant value during the period of event or events or it may be a continuous value that changes during the course of the event relative to the extent of the event as defined and inherent to the function used

According to some embodiments, when no event is detected, the single integrated sleep score may be computed based on the parameter's values and on the subject's characteristics (such as: age, presence of heart-disease, pulmonary disease), and or on other parameters used for the sleep test (such as: sleep stage, time since falling asleep). For example, when no events occur, the single integrated sleep score of a healthy subject may be 100 out of 100, if all his parameters are in the normal range. However, if a healthy subject has a low SpO_2 (e.g., 90%), but no event is detected his single integrated sleep score may decrease to 80. A subject with a chronic pulmonary disease, with a "normally" low SpO_2 levels (e.g., 92% as compare to 98-100% for healthy subjects), may have a single integrated sleep score of close to a 100.

According to further embodiments, the SQS i.e. the summary of the CISS, may be calculated by various means, such as, for example by use of mathematical equations, algorithms, formulas, and the like that may take into consideration one or more of the values or derivatives of the values of the parameters, such as average, median, integration, variance and the like. Hence, depicting the overall sleep quality and breathing effectiveness over the test period.

According to some embodiments, the single, integrated scores may be calculated by various means, such as, for example by use of mathematical equations, algorithms, formulas, and the like that may take into consideration one or more of the values or derivatives of the values of the parameters.

According to some embodiments, computing the single, integrated scores may include applying a mathematical model reflecting medical expert considerations, literature, clinical data, medical experience or any combination thereof that indicate the quality of the sleep as reflected by the measured parameters. Computing the single, integrated scores may include applying a linear regression model, a non-linear regression model, a fuzzy logic, a Bayesian network, a decision tree, a neural network, a radial base function, an expert system, or any combination thereof.

The CO_2 related parameter may include a CO_2 waveform related parameter, an expired air CO_2 concentration, respiratory rate or any combination thereof. The CO_2 waveform related parameter may include $EtCO_2$, changes in $EtCO_2$, a slope of the increase in the CO_2 concentration, a change in a slope of the increase in the CO_2 concentration, time to rise to a predetermined percentage of a maximum value of CO_2 concentration, a change in time to rise to a predetermined percentage of a maximum

value of CO_2 concentration, an angle of rise to a predetermined percentage of a maximum value of CO_2 concentration, a change in an angle of rise to a predetermined percentage of a maximum value of CO_2 concentration, breath to breath correlation, a change in breath to breath correlation, a CO_2 duty cycle, a change in CO_2 duty cycle breath duration, change in cycle breath duration or their variability's or any combination thereof.

EXAMPLE 1

An example of functions and generation of the CISS for the *continuous type* of calculation are presented below.

A trapezoidal-shaped membership function, which is a nonlinear function (which is used commonly with Fuzzy-Logic) may be applied on any value of $EtCO_2$ and/or SpO_2. The function is designed in a way that input values at the normal range of that parameter will have a score of 1; as the value gets farther from the normal range, the score will decrease.

The general function:

$$f(x,a,b,c,d) = max\left(min\left(\frac{x-a}{b-a}, 1, \frac{d-x}{d-c}\right), 0\right)$$

Fig. 5 shows a transformation function for $EtCO_2$ with the exemplary values of a=20, b=35,c=45 and d=70. Fig. 6 shows the values of the CISS (here only for $EtCO_2$) over time. The parameters may depend on the subject's age, medical history and/or the like.

The use of linear combination of the two values, $EtCO_2$ and SpO_2, to generate CISS, is demonstrated in Fig. 7.

EXAMPLE 2

An example of functions and generation of sleep scores for the event-based type of calculation are presented below.

An integrative function is applied over the range of the detected event. Its parameters are the parameter's value (x), the base-line (prior to the event) (BL), the length of the event (t), the differences between the minimum value and the base-line, the maximal differences and the minimum value. In the following are several examples for such function:

$$f = (max(BL - x))t^{0.5}$$

$$f = \frac{(BL - X)^2}{t}$$

$$f = \frac{(BL - X)^2 g(min(x))}{t}$$

$$g(x) = \begin{cases} 1, & x > 94 \\ 1.5, & 89 \le x \le 94 \\ 2, & x < 89 \end{cases}$$

Fig. 8 shows CO_2 concentrations (waveforms) with continuous scoring between 0 and 10.

Fig. 9 shows SpO_2 values and the calculated score, 0 to 100.

Fig. 10 shows the integrated score, 0 to 100.

In the description and claims of the application, each of the words “comprise” “include” and “have”, and forms thereof, are not necessarily limited to members in a list with which the words may be associated.

CLAIMS

What is claimed is:

1. A method for automatic sleep test analysis, the method comprising:

continuously monitoring, using a pulse oximeter, oxygen saturation values of a patient;

continuously monitoring, using a capnograph, exhaled carbon dioxide (CO_2) values of the patient; and

computing a continuous integrated sleep score based on a sequential analysis of the oxygen saturation values and the exhaled CO_2 values, wherein the continuous integrated sleep score is indicative of the patient's breathing-related sleep quality during at least a portion of the sleep test.

2. The method according to claim 1, wherein the sequential analysis comprises applying to the oxygen saturation values and the exhaled CO_2 values an analysis method selected from the group consisting of: a linear regression model, a non-linear regression model, fuzzy logic, a Bayesian network, a decision tree, a neural network, a radial base function and an expert system.

3. The method according to claim 1, further comprising

detecting multiple events indicative of ineffective breathing exhibited in one or more of the oxygen saturation values and the CO_2 values; and

computing a weighting function for the detected events, wherein each event is assigned a suitable weight.

4. The method according to claim 3, wherein the suitable weight for each event is based on applying an integrative function to the oxygen saturation values and CO_2 values over a duration of each event,

wherein the integrative function comprises the following parameters:

the oxygen saturation values and CO_2 values over the duration of the event;

baseline oxygen saturation and CO_2 values measured prior to the event; and

the duration of the event;

5. The method according to claim 4, wherein the integrative function further comprises at least one parameter selected from the group consisting of:

a difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values;

a maximal difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values; and

minimal oxygen saturation and CO_2 values over the duration of the event.

6. The method according to claim 1, further comprising computing, from the continuous integrated sleep score, an integrated sleep score for each of a plurality of time windows in the sleep test.

7. The method according to claim 6, wherein the time windows are moving time windows.

8. The method according to claim 7, wherein the moving time windows are each of a static length.

9. The method according to claim 7, further comprising dynamically changing a length of at least some of the moving time windows.

10. The method according to claim 1, further comprising:

monitoring one or more additional parameters selected from the group consisting of: heart rate, encephalogram (EEG), breath flow and chest movement,

wherein the computing of the continuous integrated sleep score is further based on one or more of the additional parameters.

11. The method according to claim 1, further comprising summarizing at least a portion of the continuous integrated sleep score, to generate a summarized sleep quality score.

12. A system for automatic sleep test analysis, the system comprising:

a pulse oximeter for continuously monitoring oxygen saturation values of a patient;

a capnograph for continuously monitoring exhaled carbon dioxide (CO_2) values of the patient; and

a computing unit configured to compute a continuous integrated sleep score based on a sequential analysis of the oxygen saturation values and the exhaled CO_2 values, wherein the continuous integrated sleep score is indicative of the patient's breathing-related sleep quality during at least a portion of the sleep test

13. The system according to claim 12, wherein the sequential analysis comprises applying to the oxygen saturation values and the exhaled CO_2 values an analysis method selected from the group consisting of: a linear regression model, a non-linear regression model, fuzzy logic, a Bayesian network, a decision tree, a neural network, a radial base function and an expert system.

14. The system according to claim 12, wherein the computing unit is further configured to:

detect multiple events indicative of ineffective breathing exhibited in one or more of the oxygen saturation values and the CO_2 values; and

compute a weighting function for the detected events, wherein each event is assigned a suitable weight.

15. The system according to claim 14, wherein the suitable weight for each event is based on applying an integrative function to the oxygen saturation values and CO_2 values over a duration of each event,

wherein the integrative function comprises the following parameters:

the oxygen saturation values and CO_2 values over the duration of the event;

baseline oxygen saturation and CO_2 values measured prior to the event; and

the duration of the event;

16. The system according to claim 16, wherein the integrative function further comprises at least one parameter selected from the group consisting of:

a difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values;

a maximal difference between minimum oxygen saturation and CO_2 values over the duration of the event and the baseline oxygen saturation and CO_2 values; and

minimal oxygen saturation and CO_2 values over the duration of the event.

17. The system according to claim 12, wherein the computing unit is further configured to compute, from the continuous integrated sleep score, an integrated sleep score for each of a plurality of time windows in the sleep test.

18. The system according to claim 17, wherein the time windows are moving time windows.

19. The system according to claim 18, wherein the moving time windows are each of a static length.

20. The system according to claim 18, wherein the computing unit is further configured to dynamically change a length of at least some of the moving time windows.

21. The system according to claim 12, further comprising at least one apparatus selected from the group consisting of:

a heart rate monitor;

an electroencephalogram (EEG) monitor;

a breath flow sensor; and

a chest movement sensor,

wherein the computing is further based on data received by the computing unit from one or more of the apparatuses.

22. The system according to claim 12, wherein the computing unit is further configured to summarize at least a portion of the continuous integrated sleep score, to generate a summarized sleep quality score.

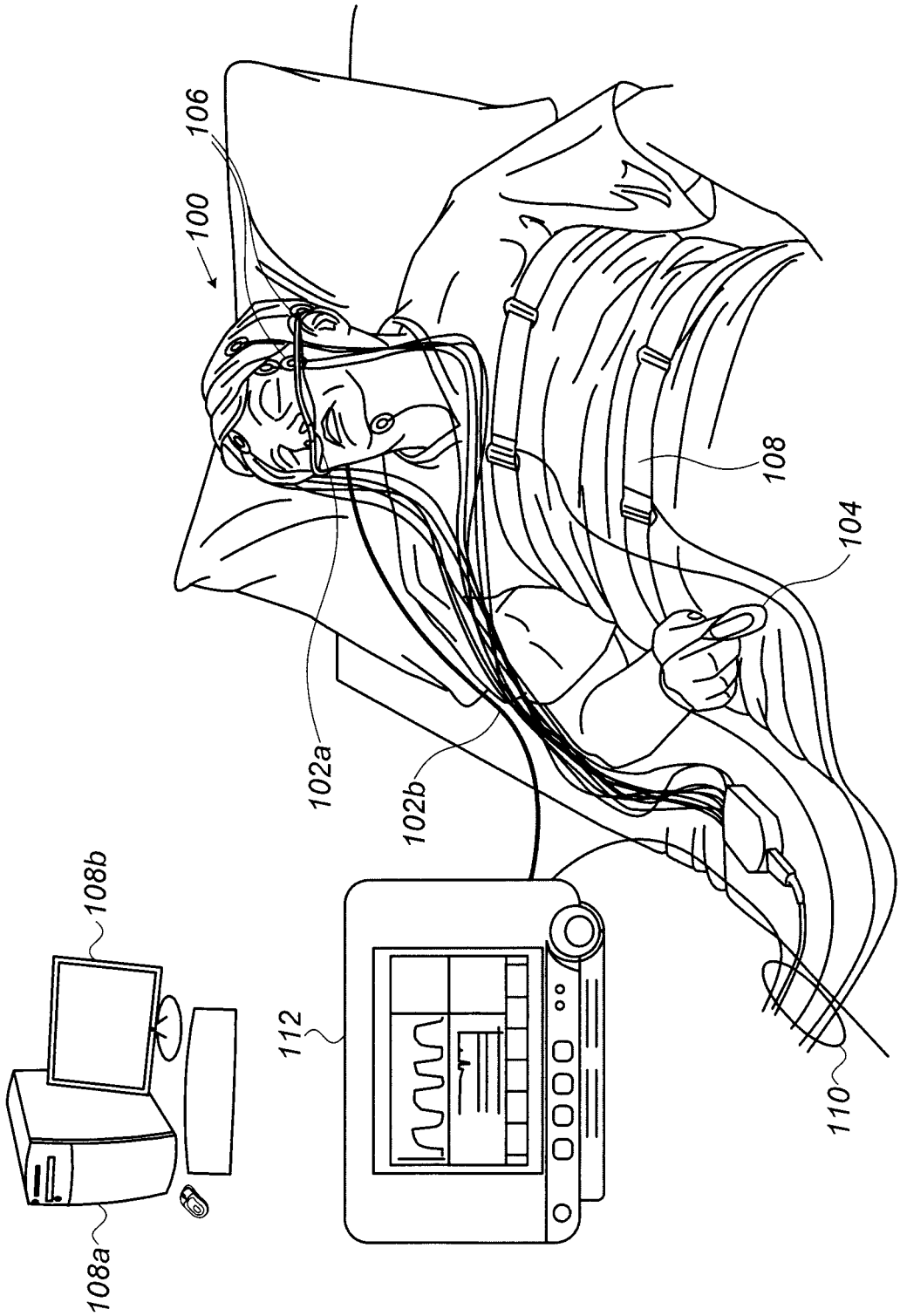

FIG. 1

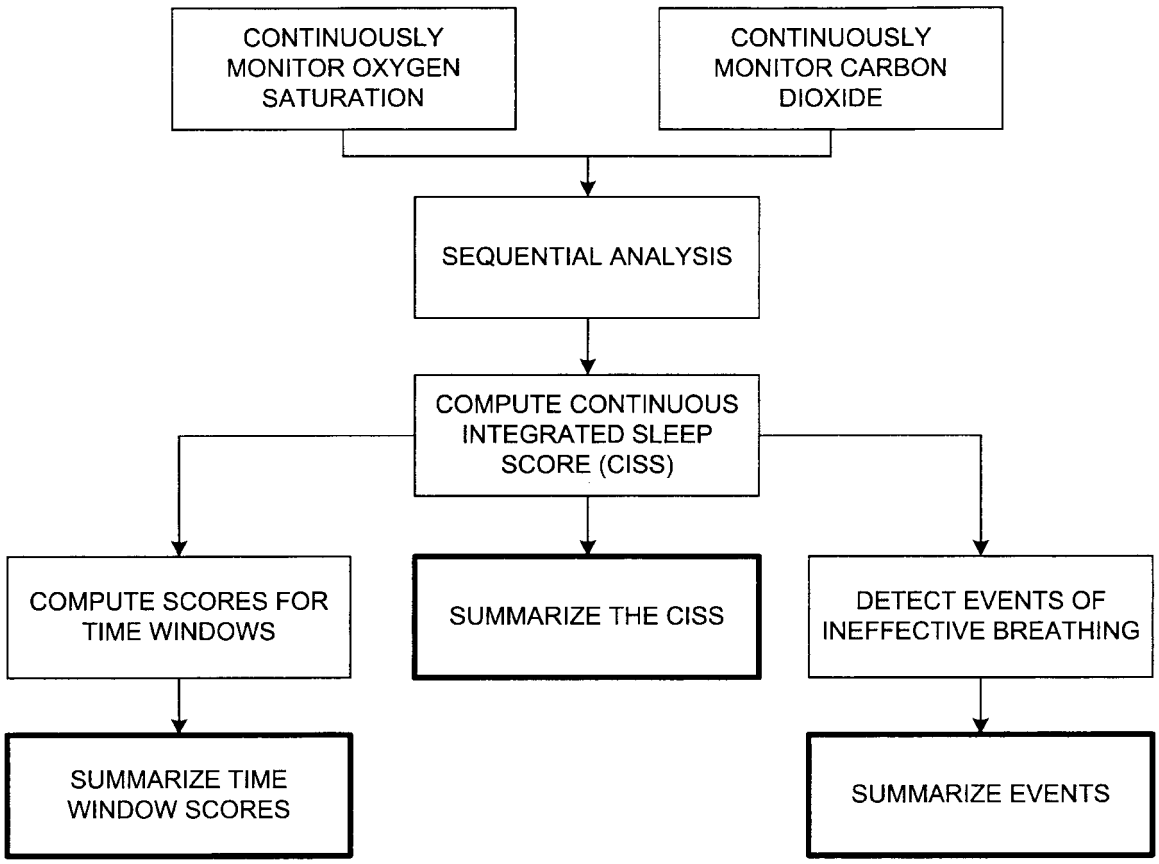
CONTINUOUSLY MONITOR OXYGEN SATURATION
CONTINUOUSLY MONITOR CARBON DIOXIDE
SEQUENTIAL ANALYSIS
COMPUTE CONTINUOUS INTEGRATED SLEEP SCORE (CISS)
COMPUTE SCORES FOR TIME WINDOWS
SUMMARIZE THE CISS
DETECT EVENTS OF INEFFECTIVE BREATHING
SUMMARIZE TIME WINDOW SCORES
SUMMARIZE EVENTS

FIG. 2

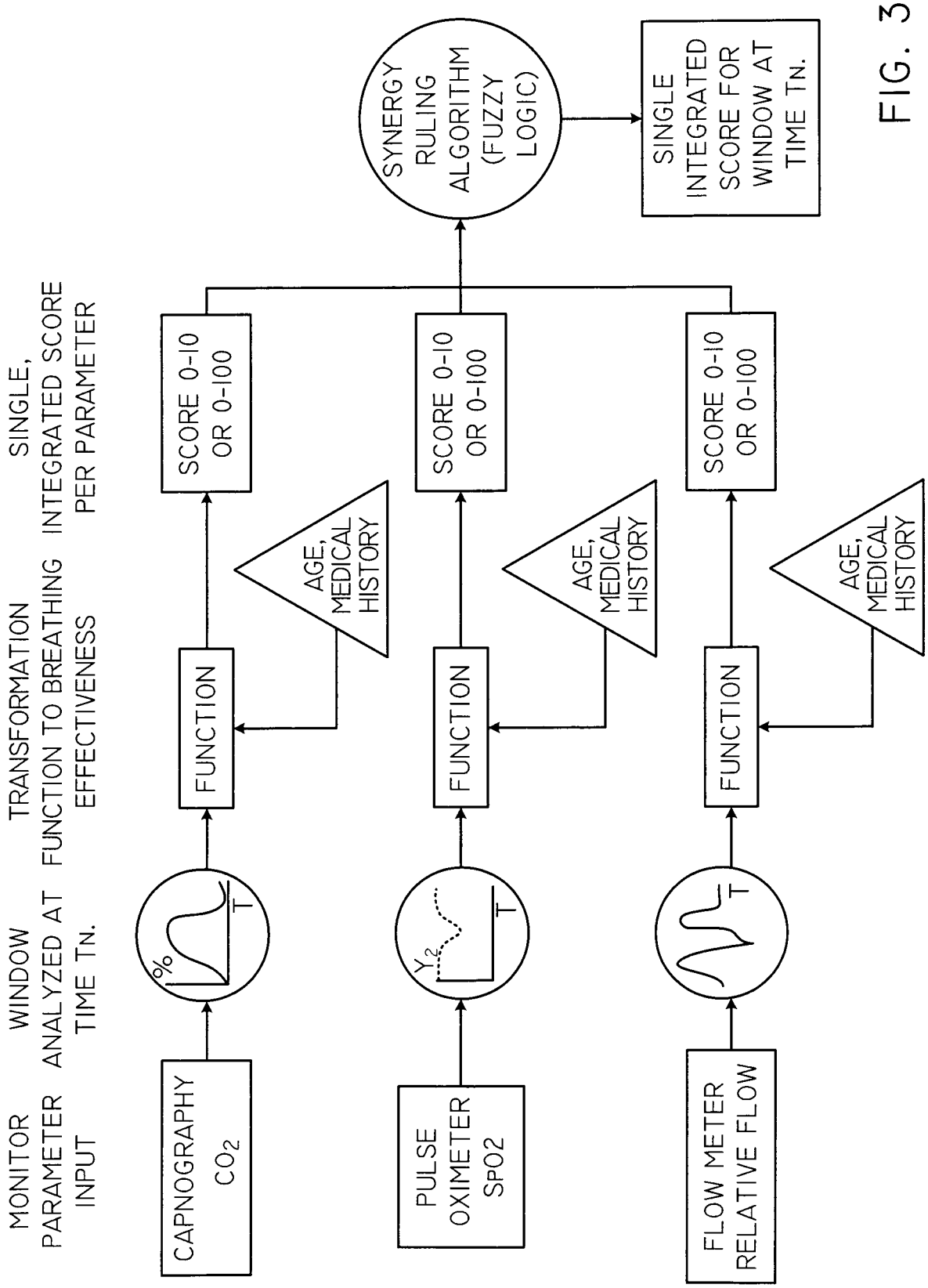
MONITOR PARAMETER INPUT
WINDOW ANALYZED AT TIME TN.
TRANSFORMATION FUNCTION TO BREATHING EFFECTIVENESS
SINGLE, INTEGRATED SCORE PER PARAMETER
CAPNOGRAPHY CO_2
%
T
FUNCTION
AGE, MEDICAL HISTORY
SCORE 0-10 OR 0-100
PULSE OXIMETER SPO2
Y_2
T
FUNCTION
AGE, MEDICAL HISTORY
SCORE 0-10 OR 0-100
FLOW METER RELATIVE FLOW
T
FUNCTION
AGE, MEDICAL HISTORY
SCORE 0-10 OR 0-100
SYNERGY RULING ALGORITHM (FUZZY LOGIC)
SINGLE INTEGRATED SCORE FOR WINDOW AT TIME TN.

FIG. 3

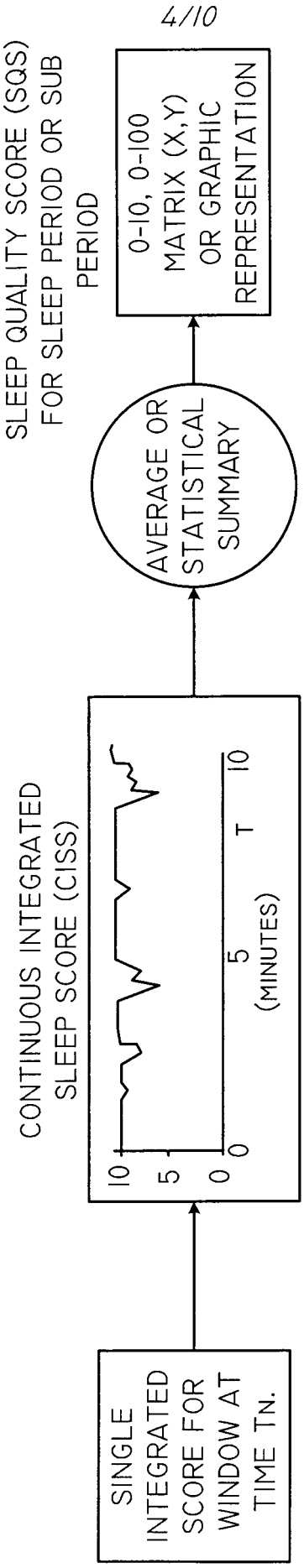
SINGLE INTEGRATED SCORE FOR WINDOW AT TIME TN.
CONTINUOUS INTEGRATED SLEEP SCORE (CISS)
10
5
0
0
5
10
T
(MINUTES)
AVERAGE OR STATISTICAL SUMMARY
SLEEP QUALITY SCORE (SQS) FOR SLEEP PERIOD OR SUB PERIOD
0-10, 0-100 MATRIX (X,Y) OR GRAPHIC REPRESENTATION

FIG. 4

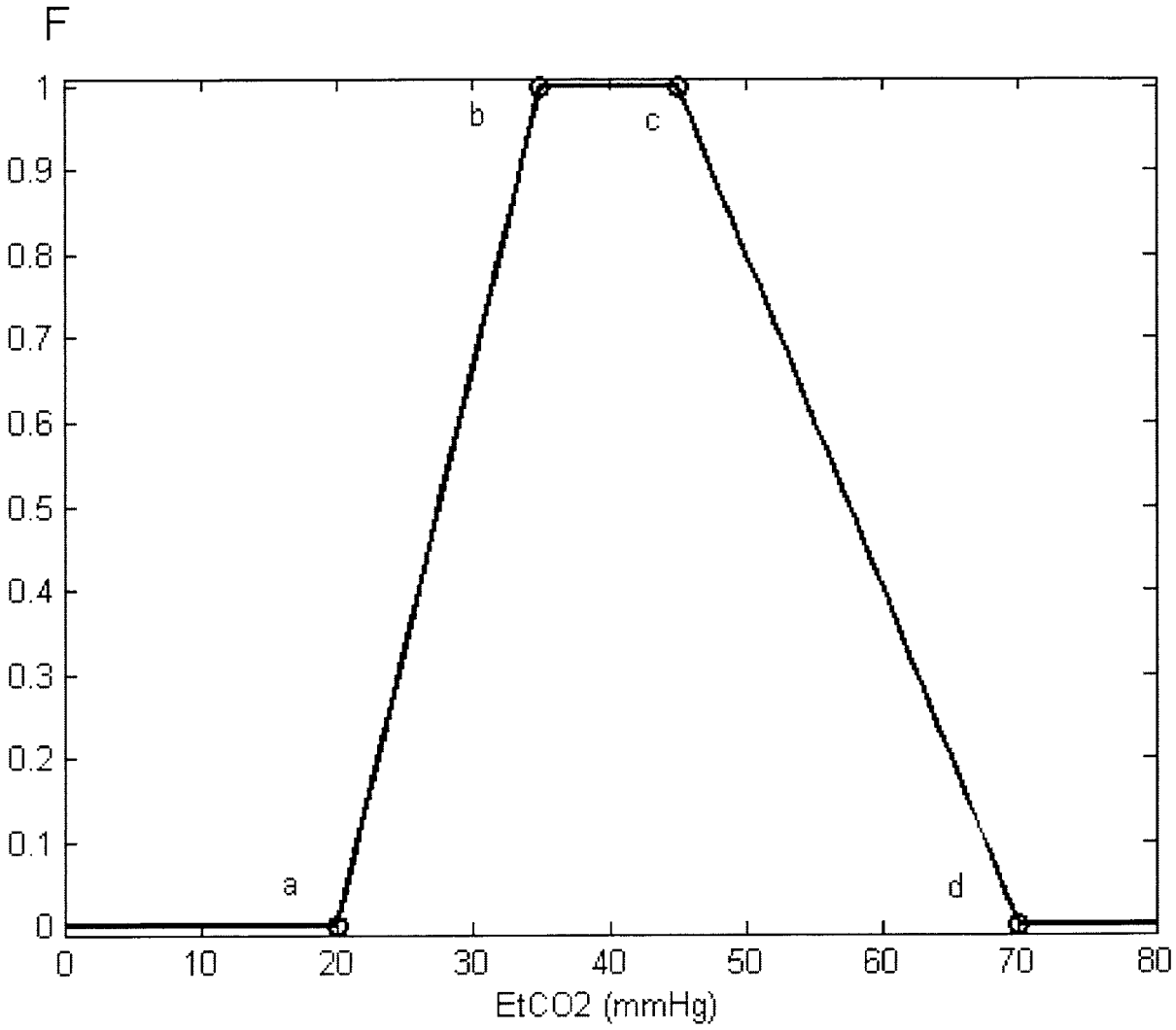
F
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
a
b
c
d
0
10
20
30
40
50
60
70
80
EtCO2 (mmHg)

FIG. 5

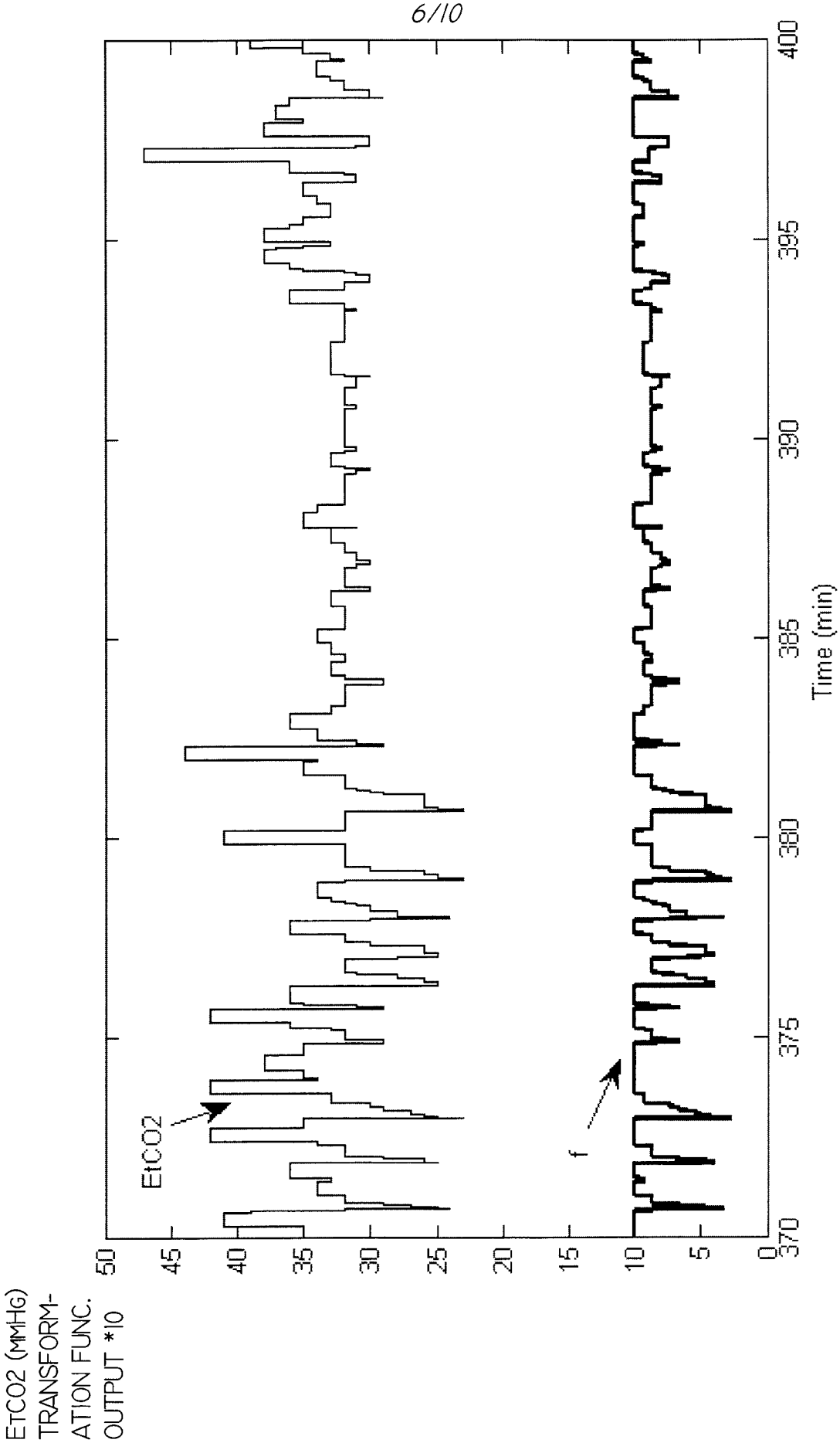
ETCO2 (MMHG)
TRANSFORM-
ATION FUNC.
OUTPUT *10
50
45
40
35
30
25
20
15
10
5
0
370
375
380
385
390
395
400
Time (min)
EtCO2
f

FIG. 6

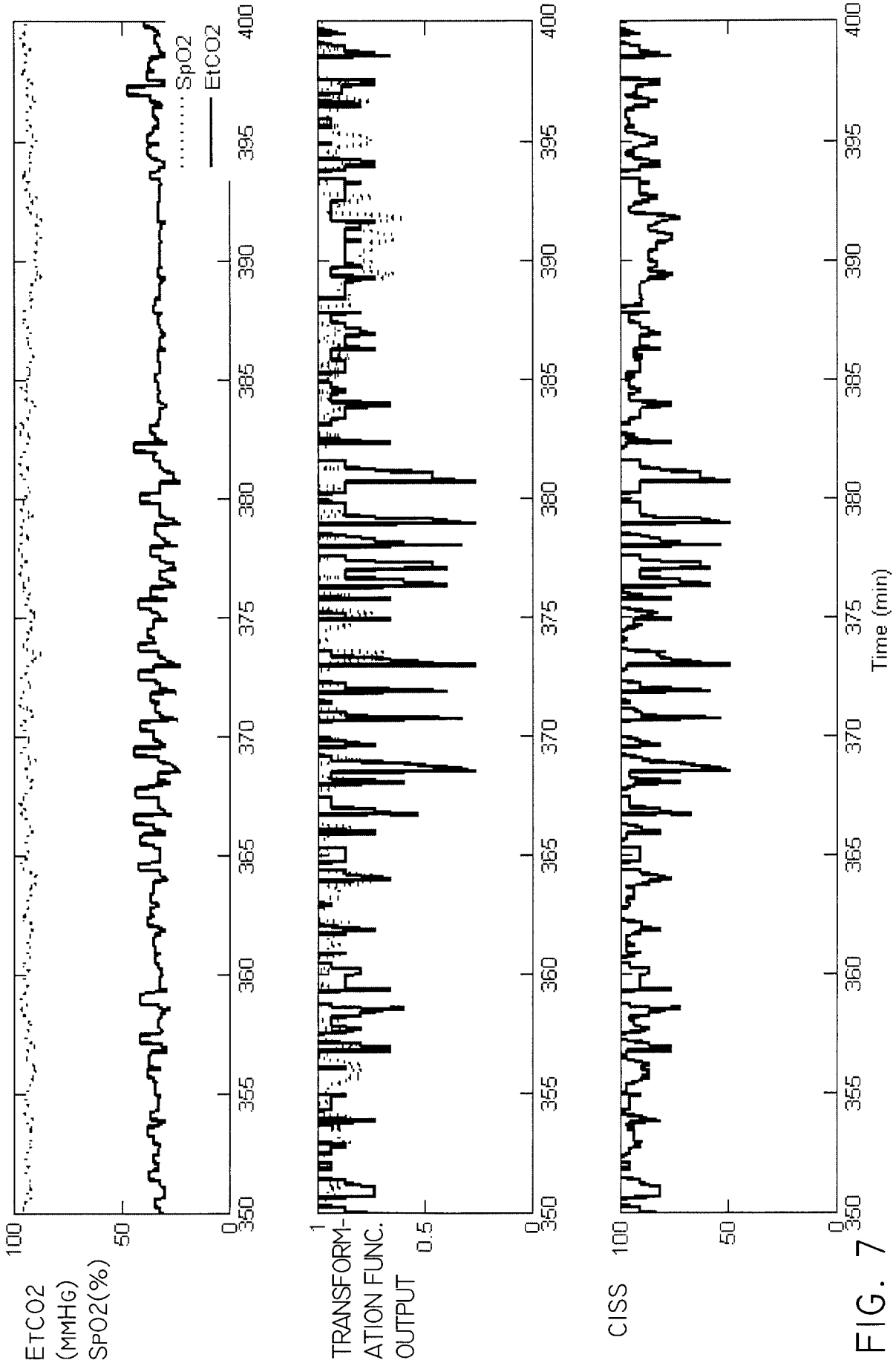
ETCO2 (MMHG) SPO2(%)
100
50
0
SpO2
EtCO2
TRANSFORM-ATION FUNC. OUTPUT
1
0.5
0
CISS
100
50
0
350
355
360
365
370
375
380
385
390
395
400
Time (min)

FIG. 7

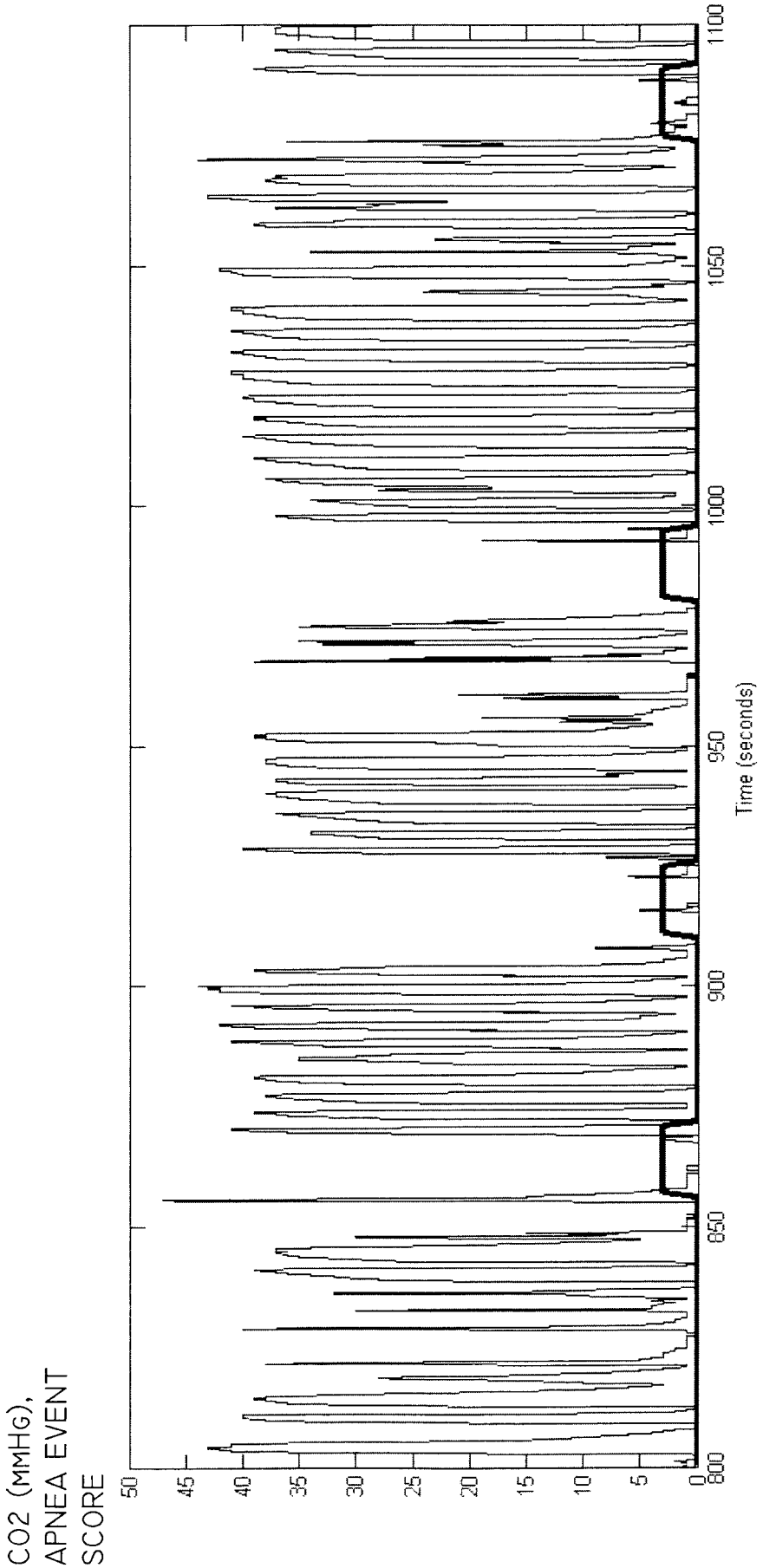
CO2 (mmHg),
APNEA EVENT
SCORE
50
45
40
35
30
25
20
15
10
5
0
800
850
900
950
1000
1050
1100
Time (seconds)

FIG. 8

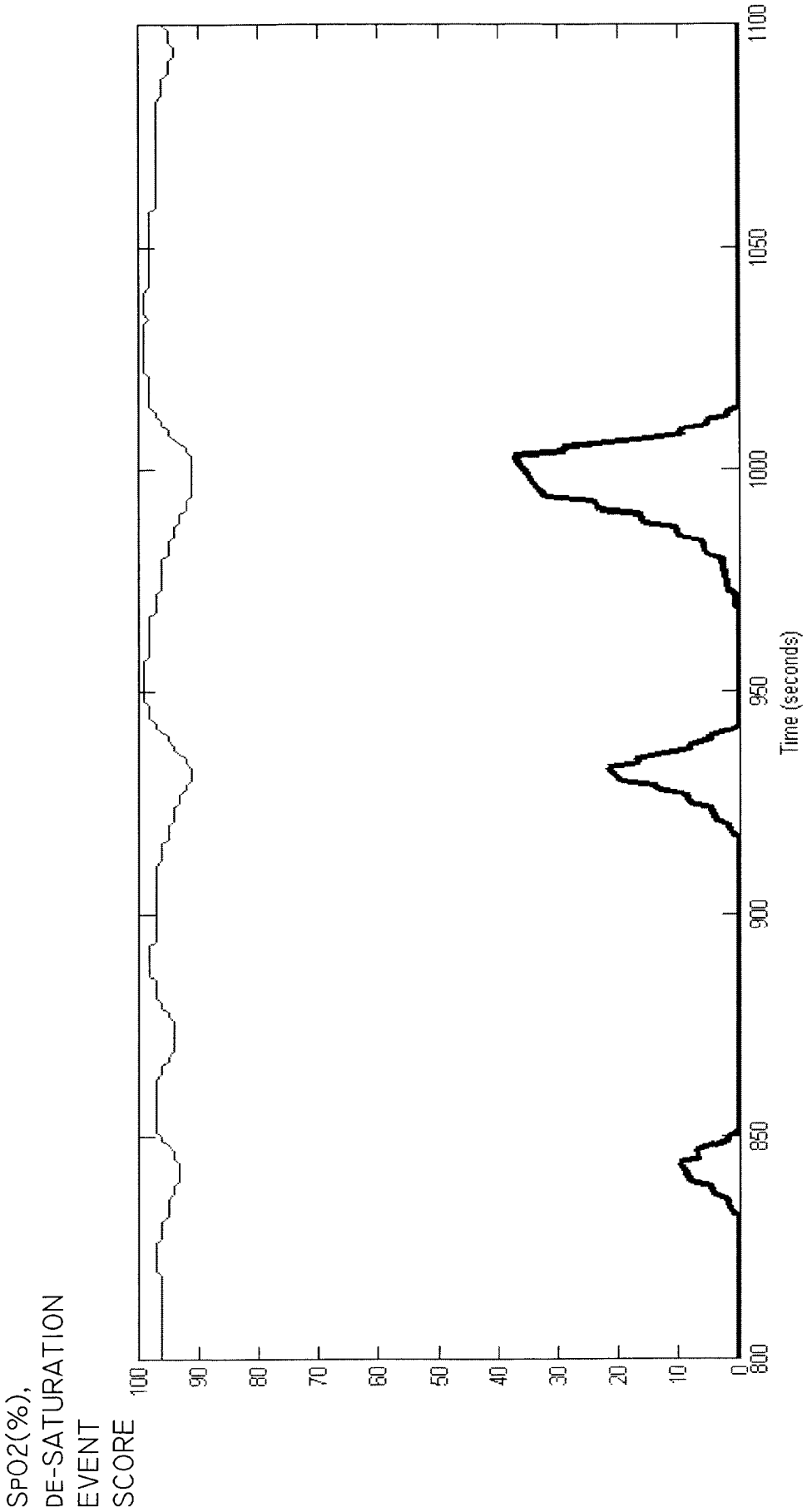
SPO2(%),
DE-SATURATION
EVENT
SCORE
100
90
80
70
60
50
40
30
20
10
0
800
850
900
950
1000
1050
1100
Time (seconds)

FIG. 9

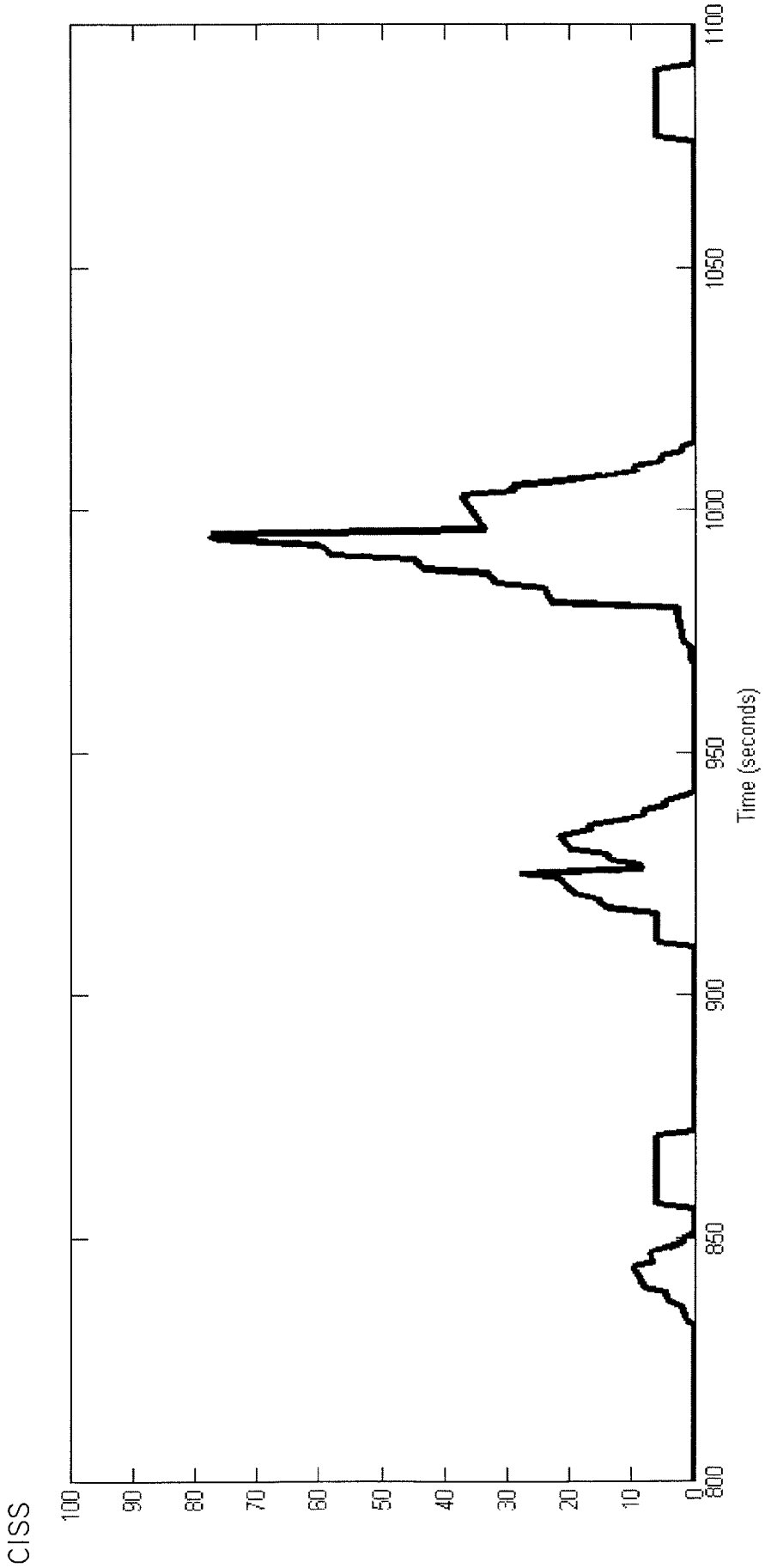
CISS
100
90
80
70
60
50
40
30
20
10
0
800
850
900
950
1000
1050
1100
Time (seconds)

FIG. 10

专利名称(译)	睡眠障碍分析的方法和系统		
公开(公告)号	EP2584966A2	公开(公告)日	2013-05-01
申请号	EP2011797728	申请日	2011-06-23
申请(专利权)人(译)	ORIDION MEDICAL 1987年LTD.		
当前申请(专利权)人(译)	ORIDION MEDICAL 1987年LTD.		
[标]发明人	COLMAN JOSHUA LEWIS LAIN DAVID RONEN MICHAL		
发明人	COLMAN, JOSHUA LEWIS LAIN, DAVID RONEN, MICHAL		
IPC分类号	A61B5/08 A61B5/00		
CPC分类号	A61B5/0205 A61B5/0836 A61B5/113 A61B5/14551 A61B5/4806 A61B5/4818 A61B5/7264 G16H50/20 A61B5/0476		
优先权	61/357558 2010-06-23 US		
其他公开文献	EP2584966A4		
外部链接	Espacenet		

摘要(译)

一种用于自动睡眠测试分析的系统，该系统包括：脉冲血氧计，用于连续监测患者的氧饱和度值;用于连续监测患者的呼出二氧化碳（CO 2）值的二氧化碳图;计算单元，被配置为基于氧饱和度值和呼出的CO 2值的顺序分析来计算连续的综合睡眠分数，其中连续的综合睡眠分数指示患者在至少一部分期间的呼吸相关的睡眠质量。睡眠测试。