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(54) **SLEEP QUALITY DATA COLLECTION AND EVALUATION**

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(57) **ABSTRACT**

A sleep quality assessment approach involves collecting data based on detected physiological or non-physiological patient conditions. At least one of detecting patient conditions and collecting data is performed using an implantable device. Sleep quality may be evaluated using the collected data by an imlantable or patient-external sleep quality processor. One approach to sleep quality evaluation involves computing one or more summary metrics based on occurrences of movement disorders or breathing disorders during sleep.

200
Sleep Quality Data System

110

Detect Physiological and Non-Physiological
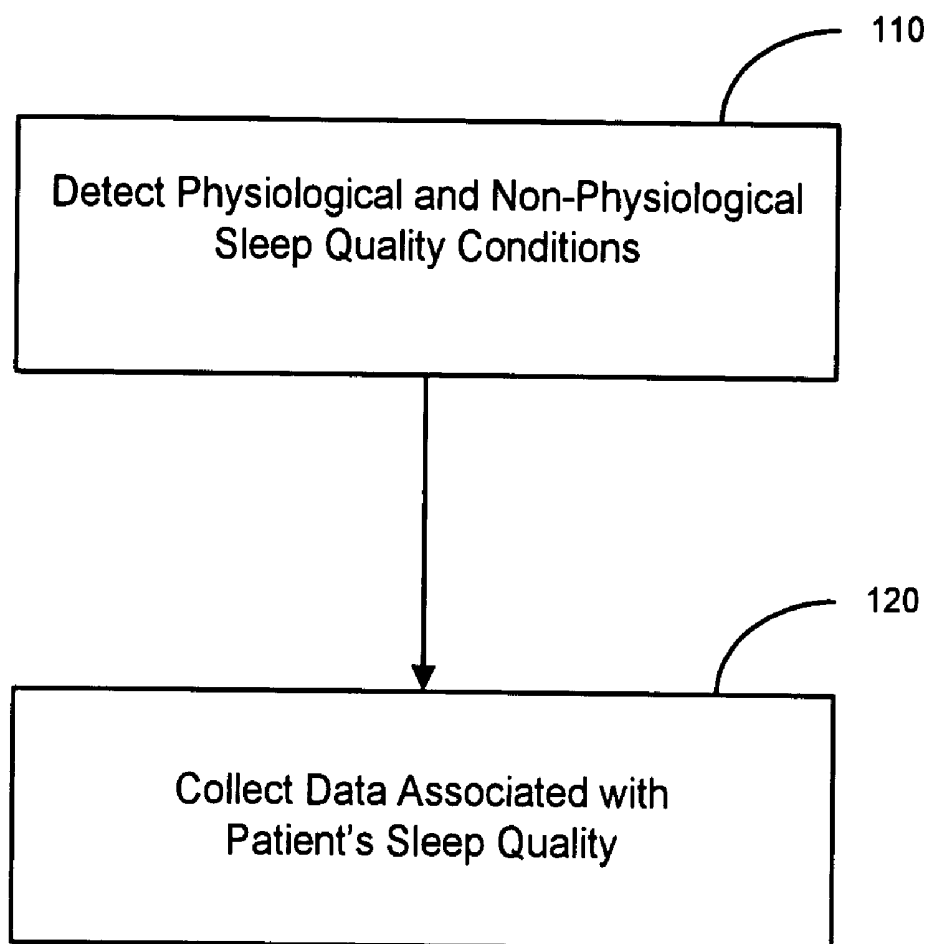Sleep Quality Conditions

120

Collect Data Associated with
Patient's Sleep Quality

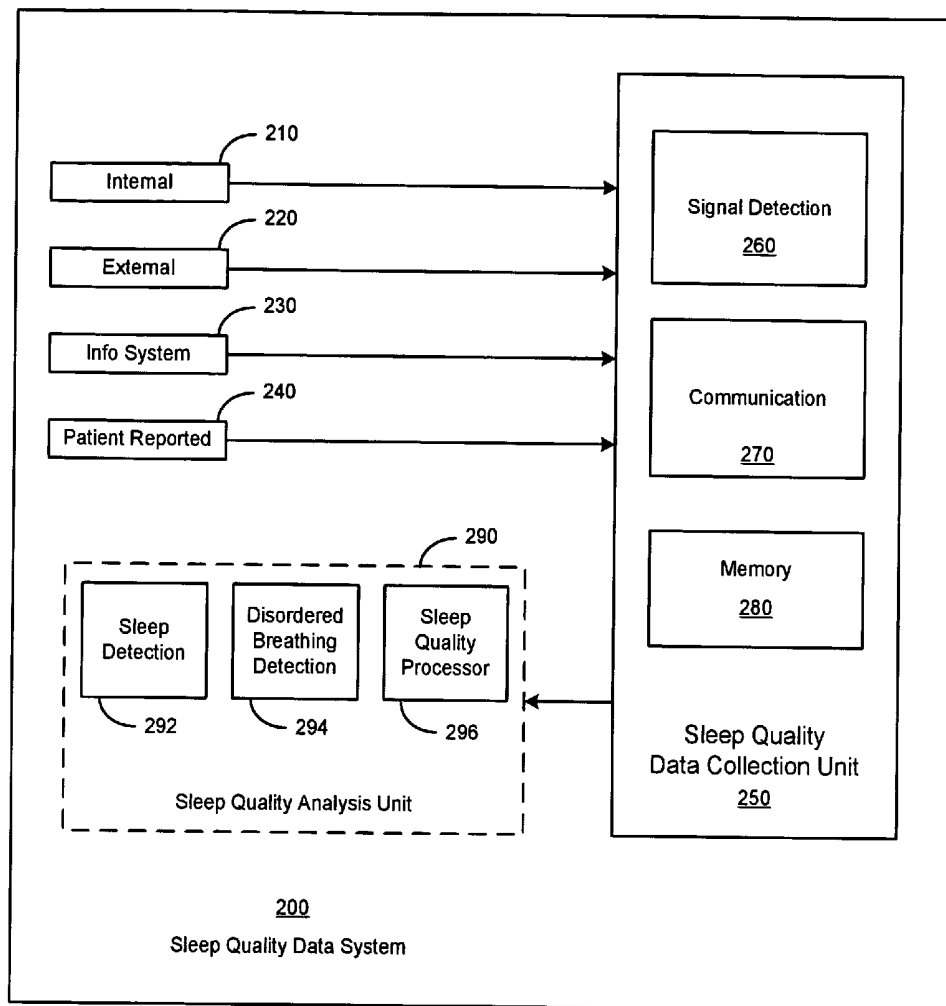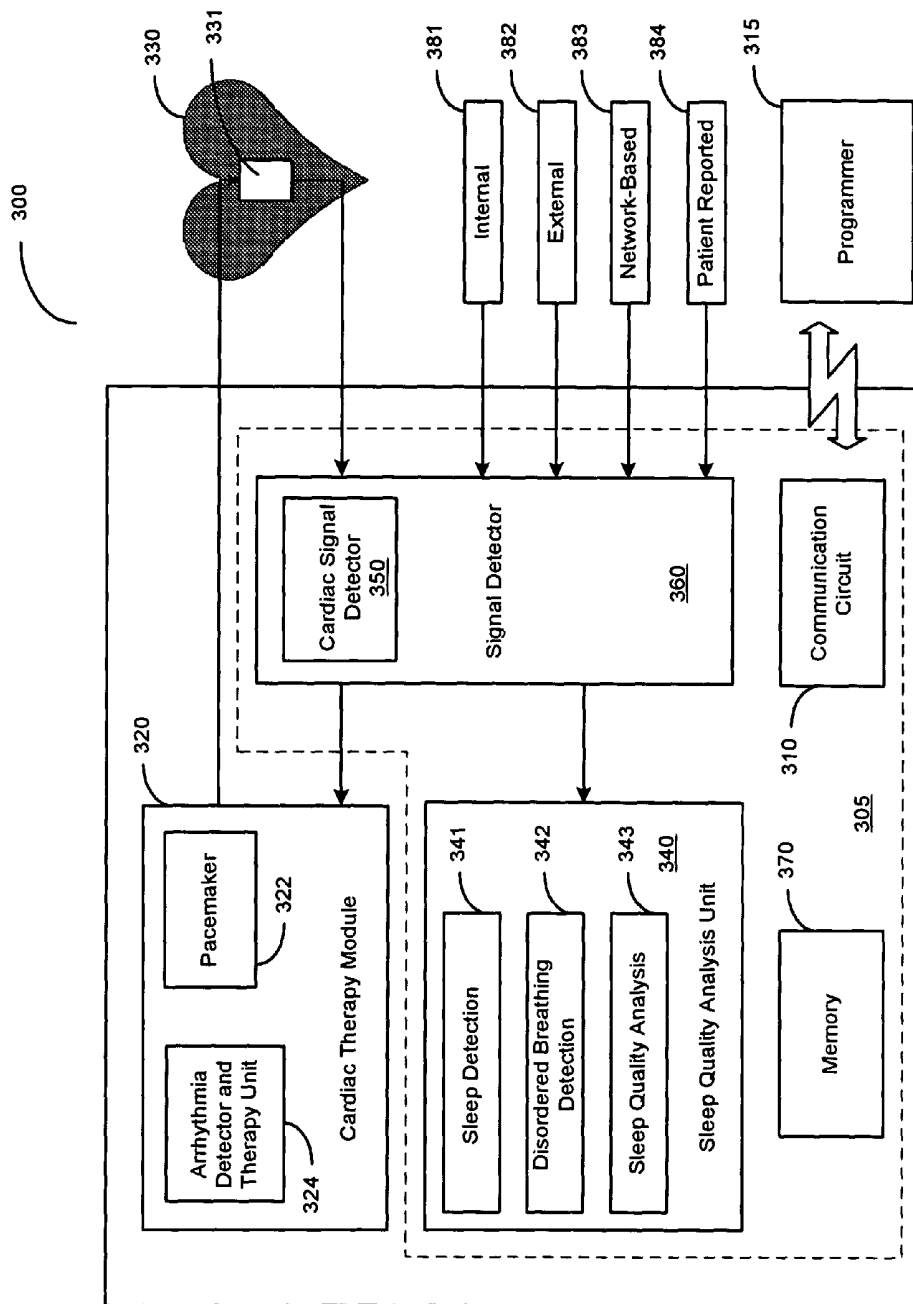Figure 1

Figure 2

Figure 3

Figure 4

505

Establish Sleep Threshold Associated
with First Sleep-Related Condition

510

Detect First Sleep-Related
Condition

520

Detect Second Sleep-Related
Condition

530

Adjust Sleep Threshold of First Sleep-
Related Condition Using Second Sleep-
Related Condition

540

No   First Condition
Consistent With Adjusted
Threshold?

Yes

550

Sleep Detected

Figure 5

Establish Preliminary Sleep Threshold for Accelerometer Signal — 610

Monitor Accelerometer Signal — 620

Monitor Minute Ventilation Signal — 625

Monitor Heart Rate — 630

Status of Minute Ventilation Signal Level? — 635

High

Low

Decrease Accelerometer Threshold — 640

Increase Accelerometer Sleep Threshold — 645

Accelerometer Less Than or Equal to Threshold? — 650

no

yes

Sleep Previously Detected? — 660

no

Sleep Previously Detected? — 665

no

yes

Sleep Termination — 670

yes

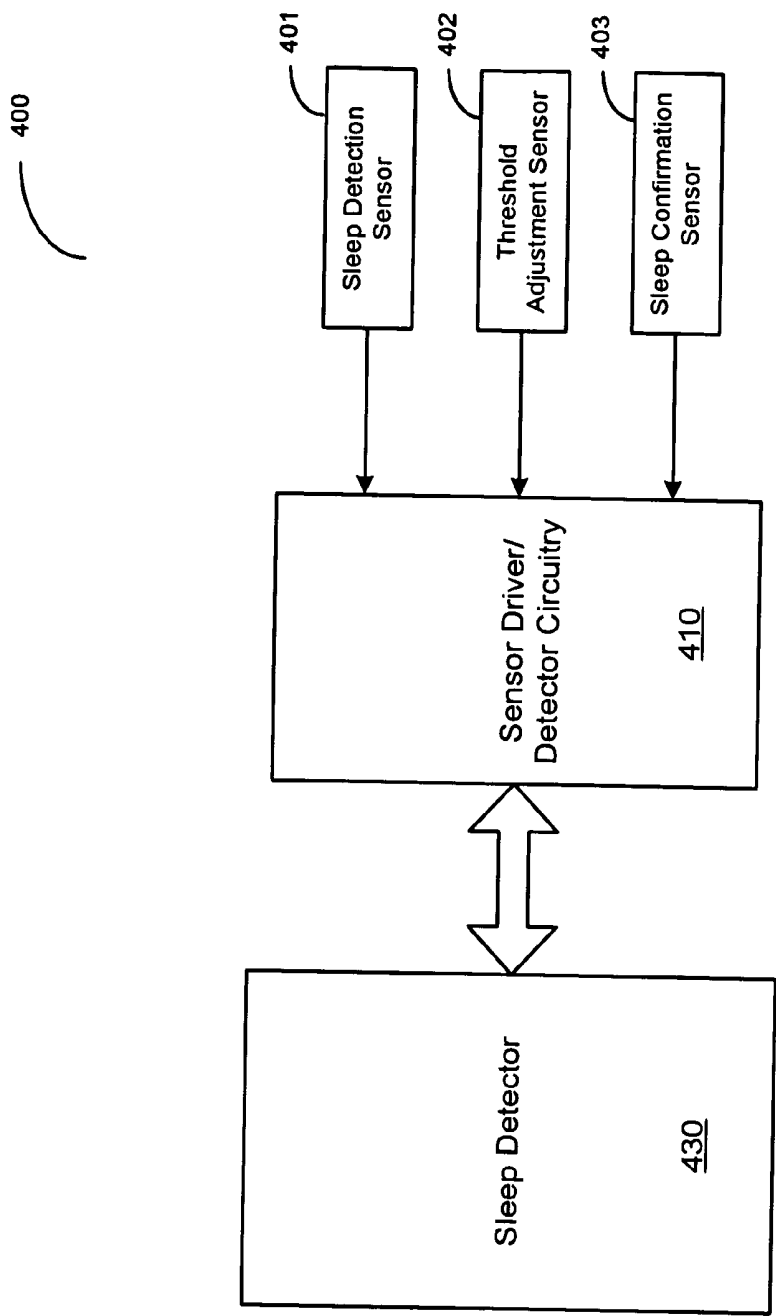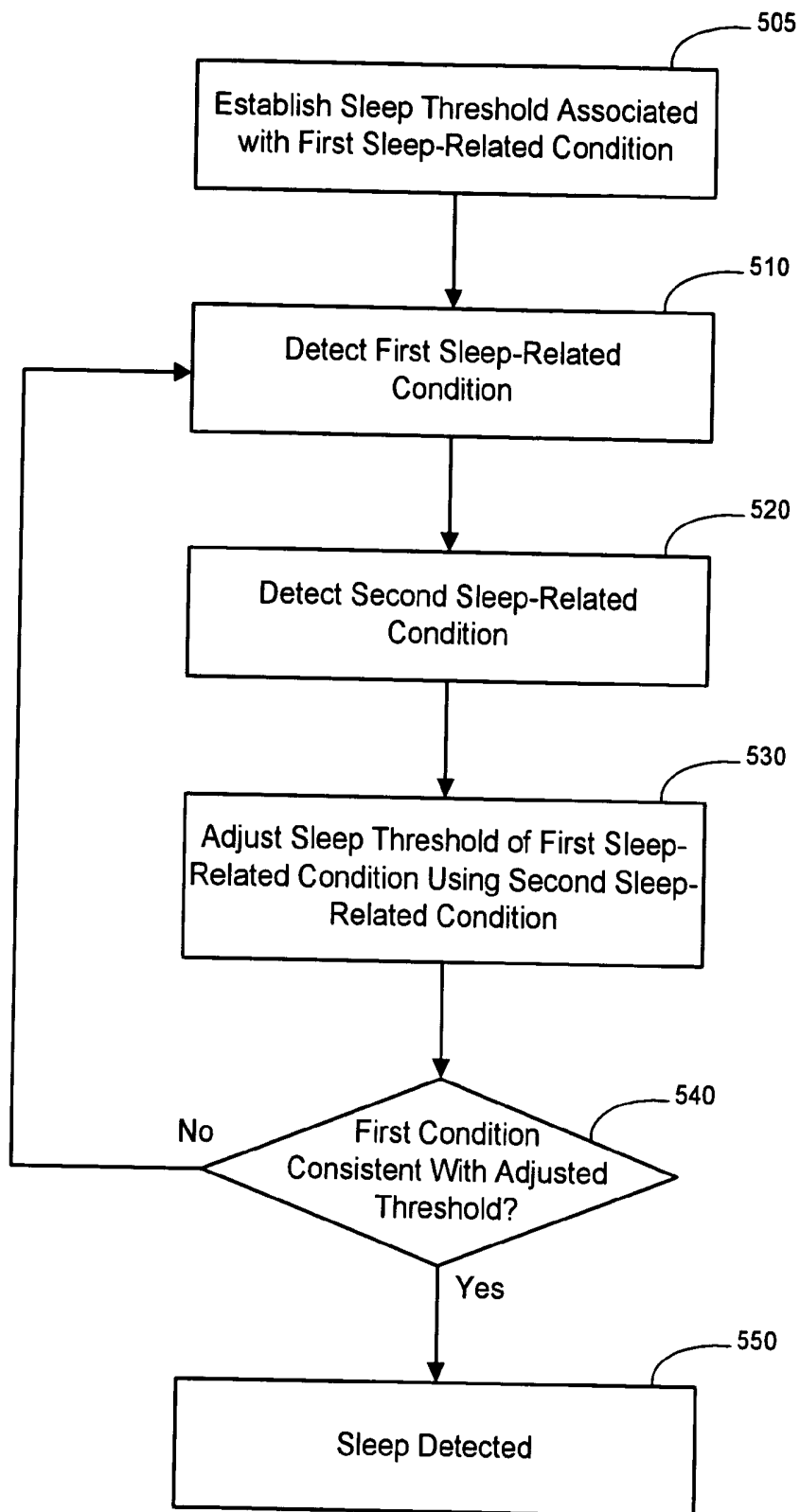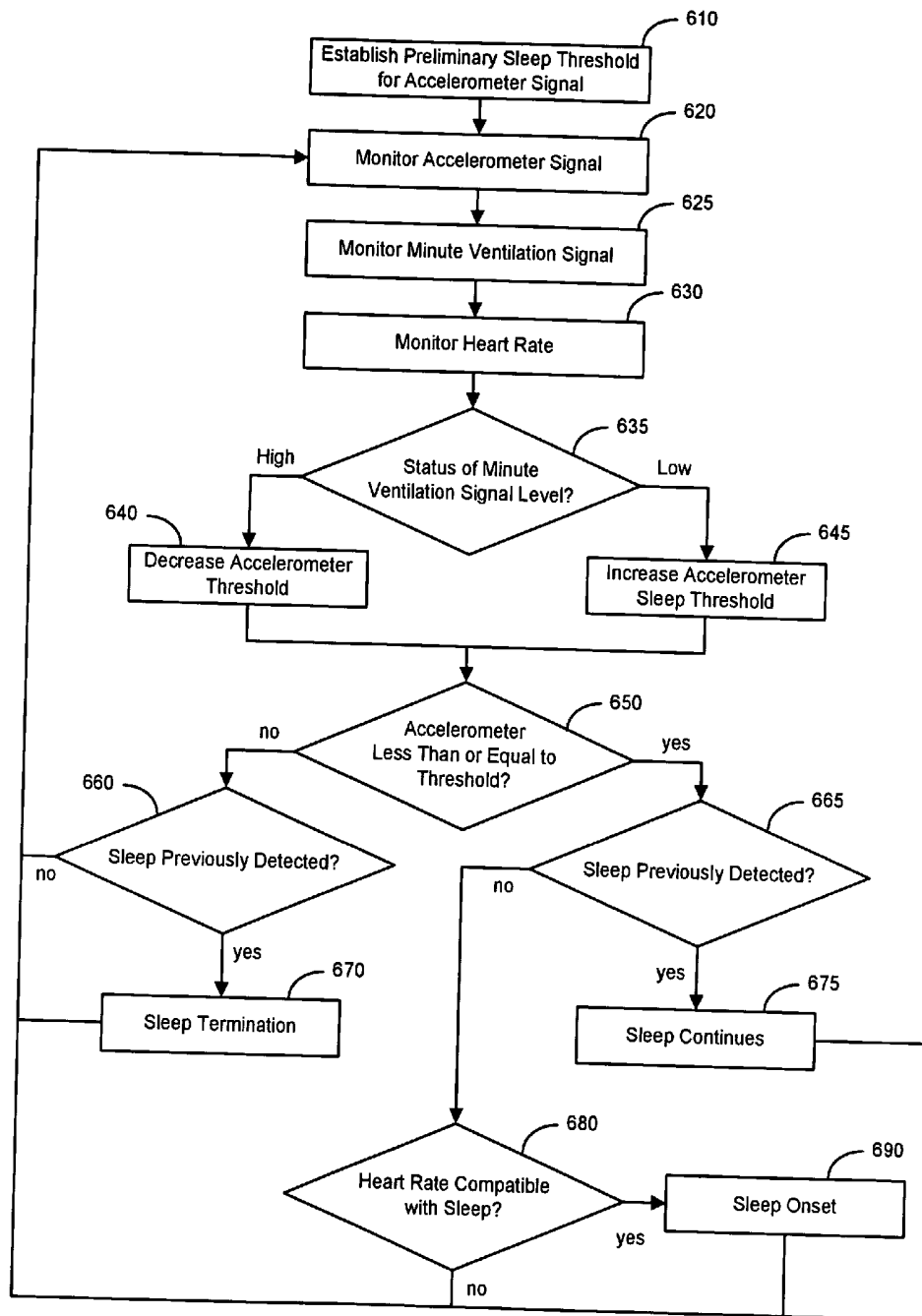Sleep Continues — 675
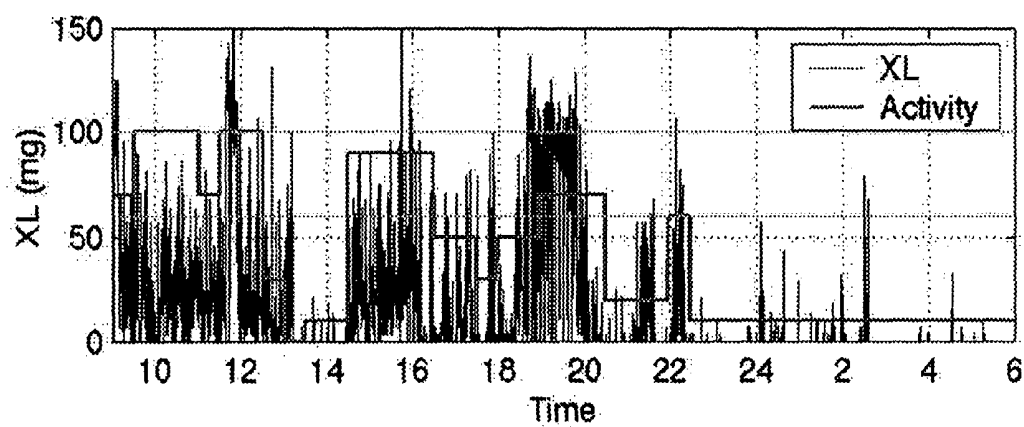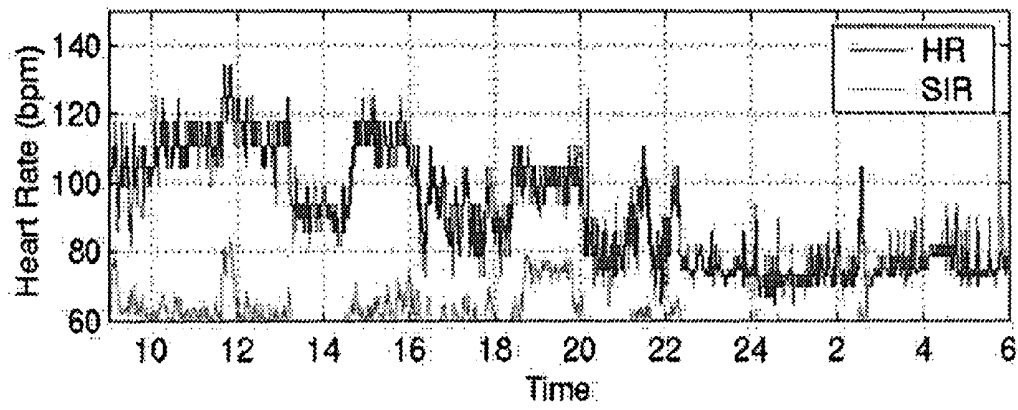
Heart Rate Compatible with Sleep? — 680
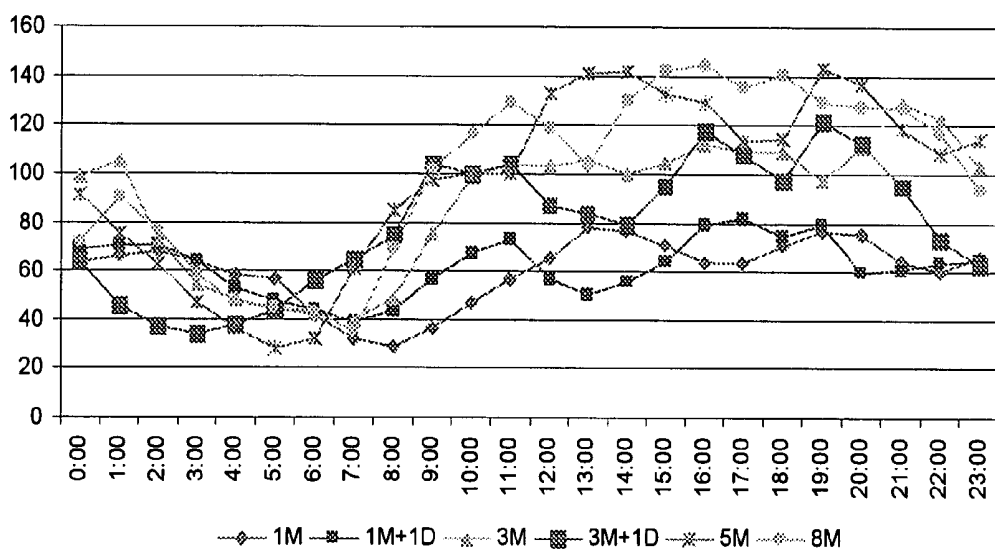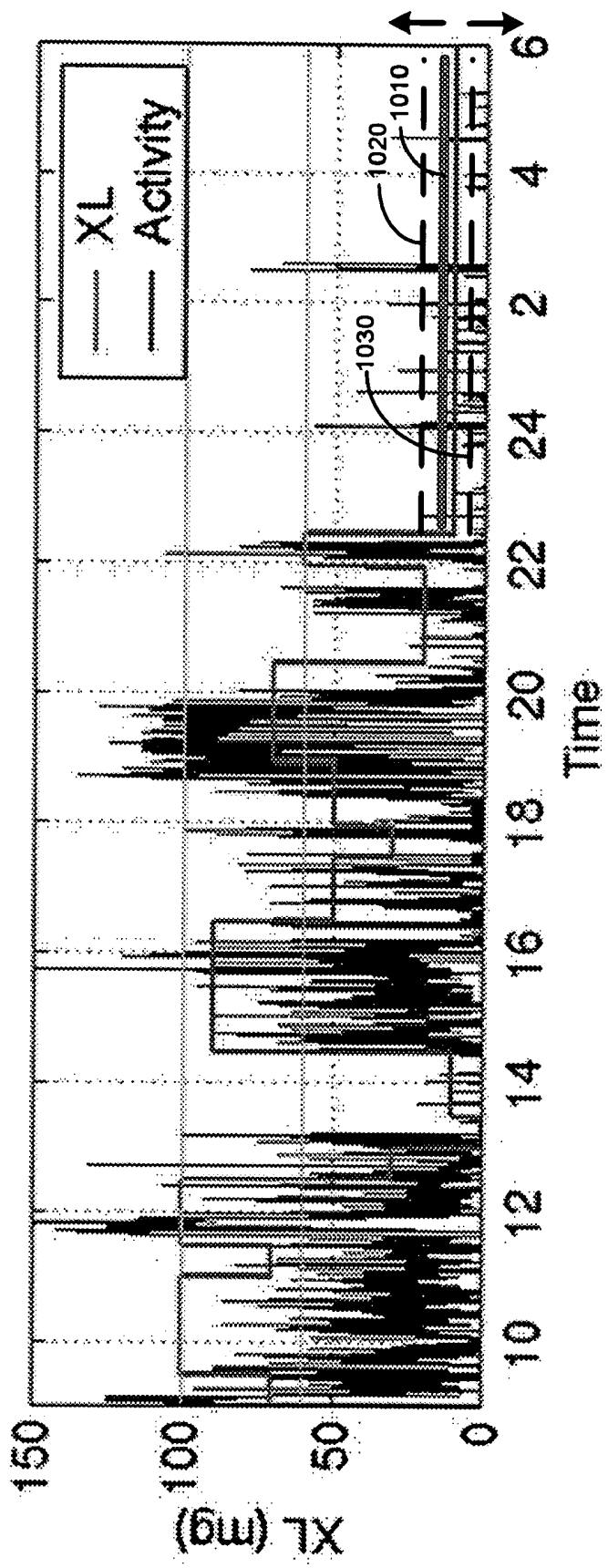
yes

Sleep Onset — 690

no

Figure 6

Figure 7

Figure 8

Figure 9

Figure 10

Figure 11

Figure 12

Figure 13

Figure 14A

Figure 14B

1501

Establish Sleep Apnea Interval,
Severe Sl ep Apnea Interval,
Hypopnea TV Threshold,
Hypopnea Inteval

1505

Sense Transthoracic
Impedance

1510

Inspiration Threshold
Reached?

no

yes

1515

Inspiration

no

1520

Max Value
Reached?

yes

1535

Expiration

1540

Expiration Threshold
Reached?

no

yes

1555

Non-breathing

no

1560

Inspiration Threshold
Reached?

no

1565

Time Out?

yes

1585

Determine Average
Tidal Volume

1570

Apnea

1575

Time Out?

no

yes

1580

Severe Apnea

1590

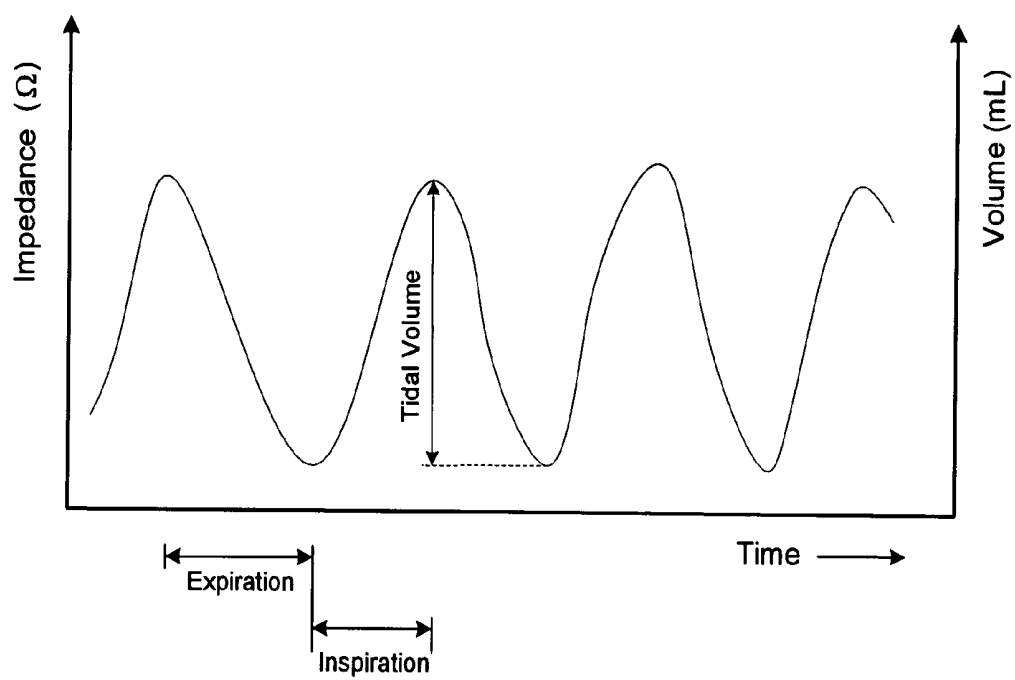Hypopnea TV
Reached?
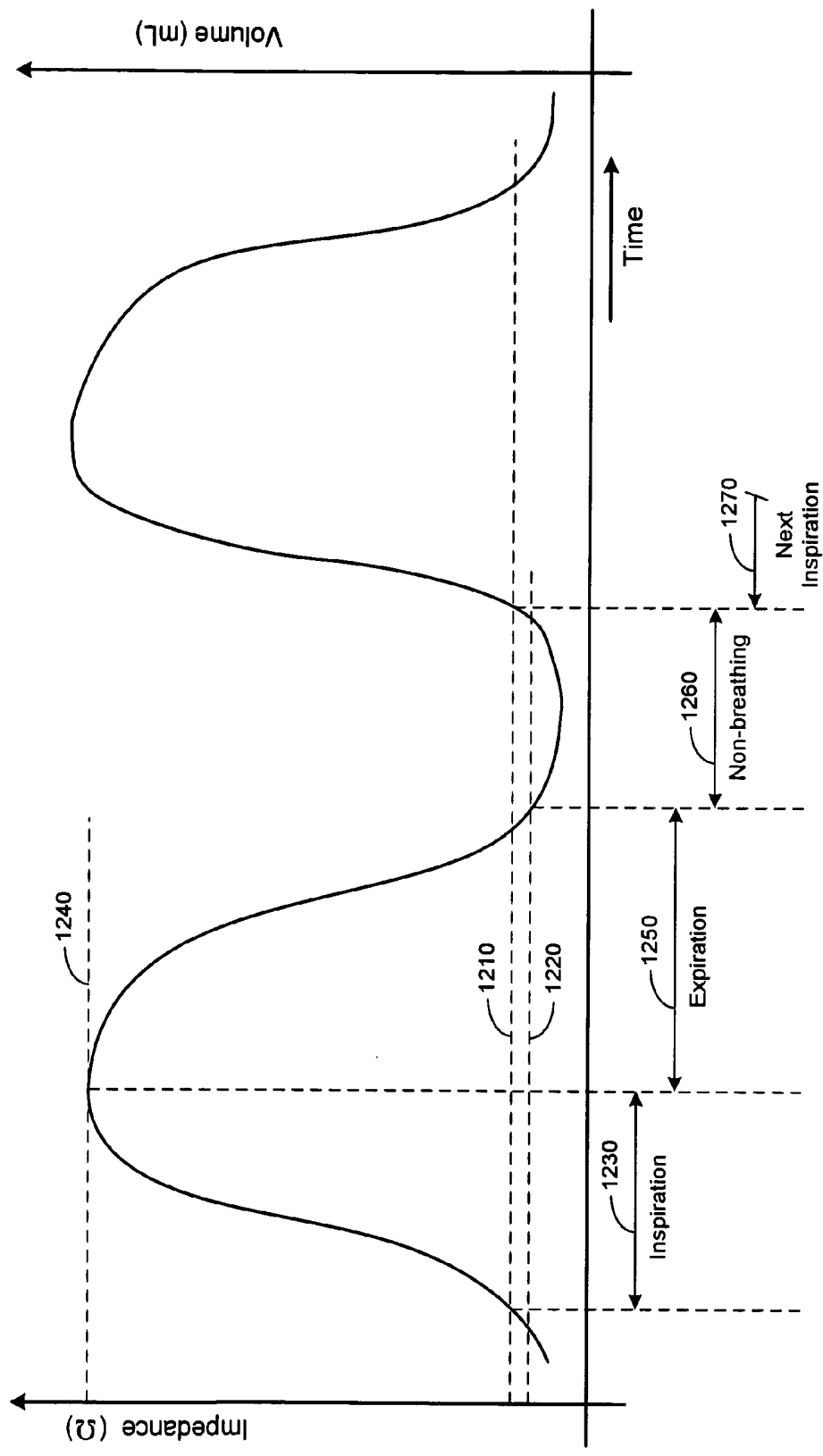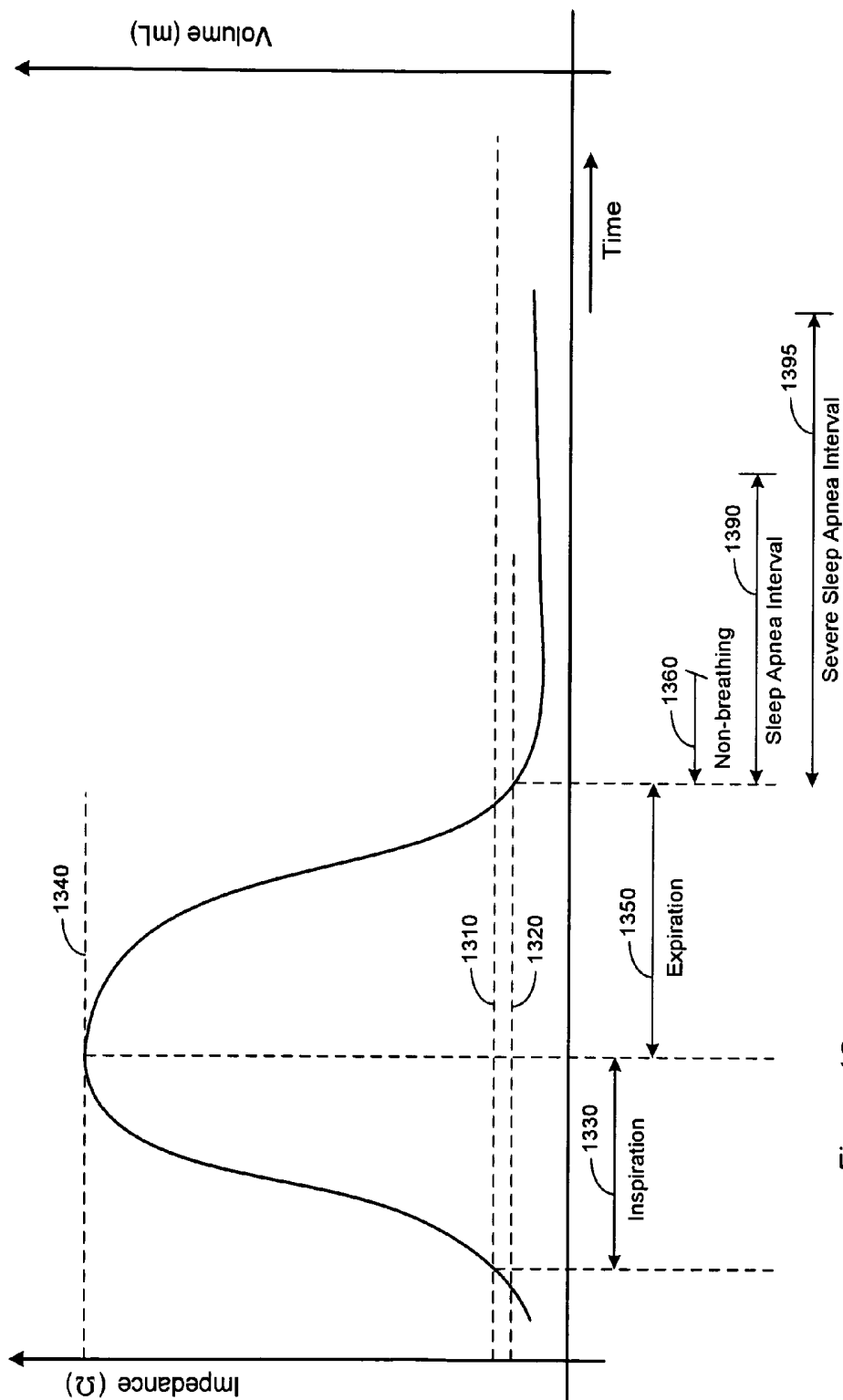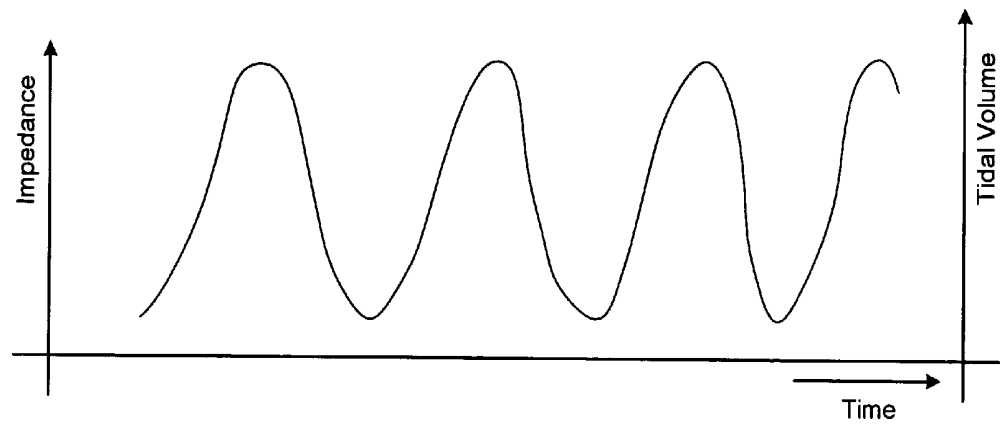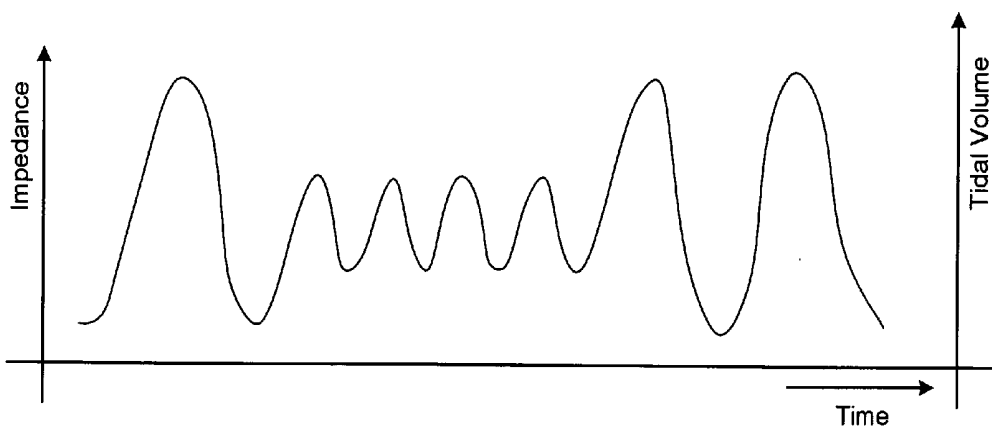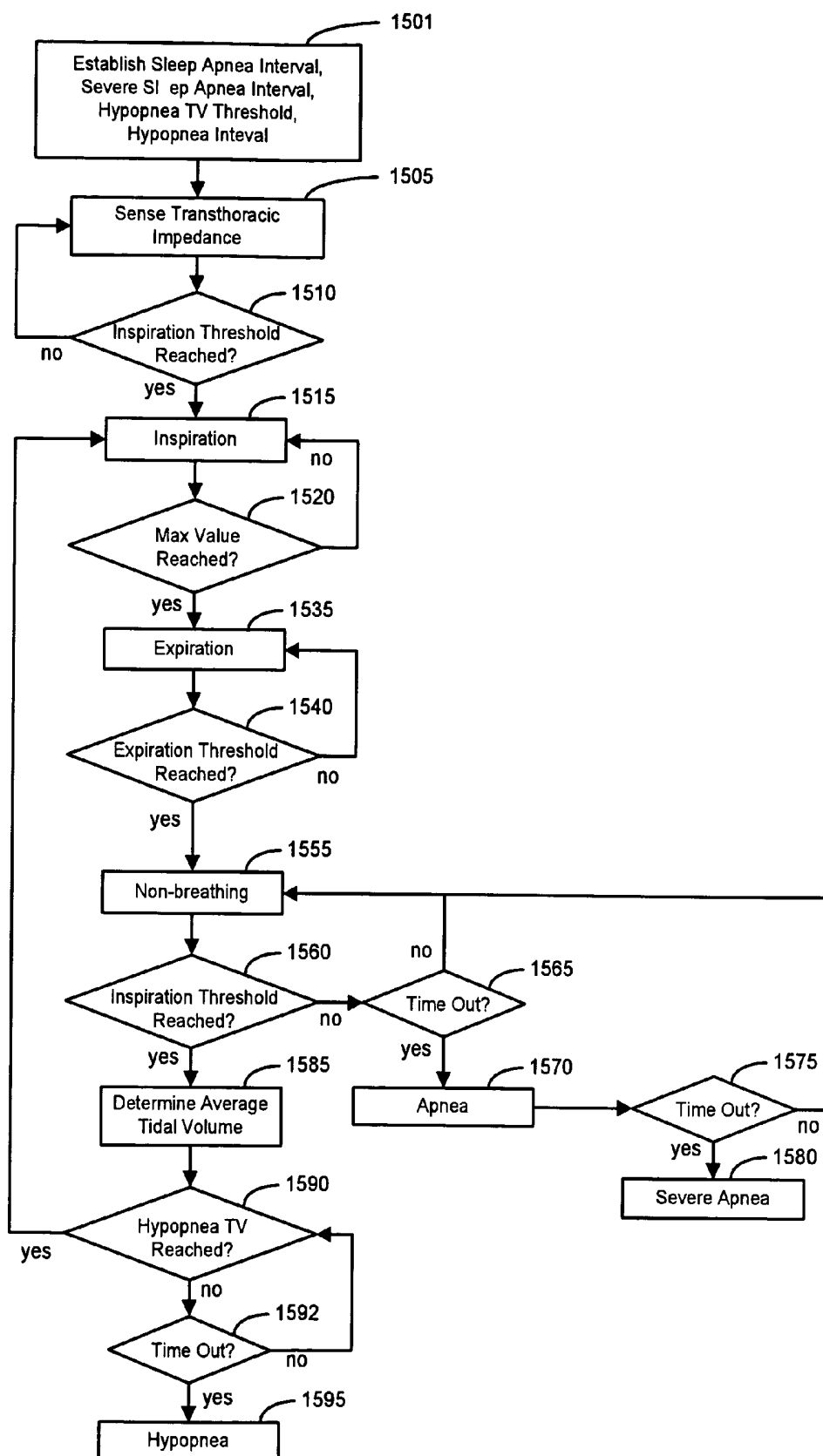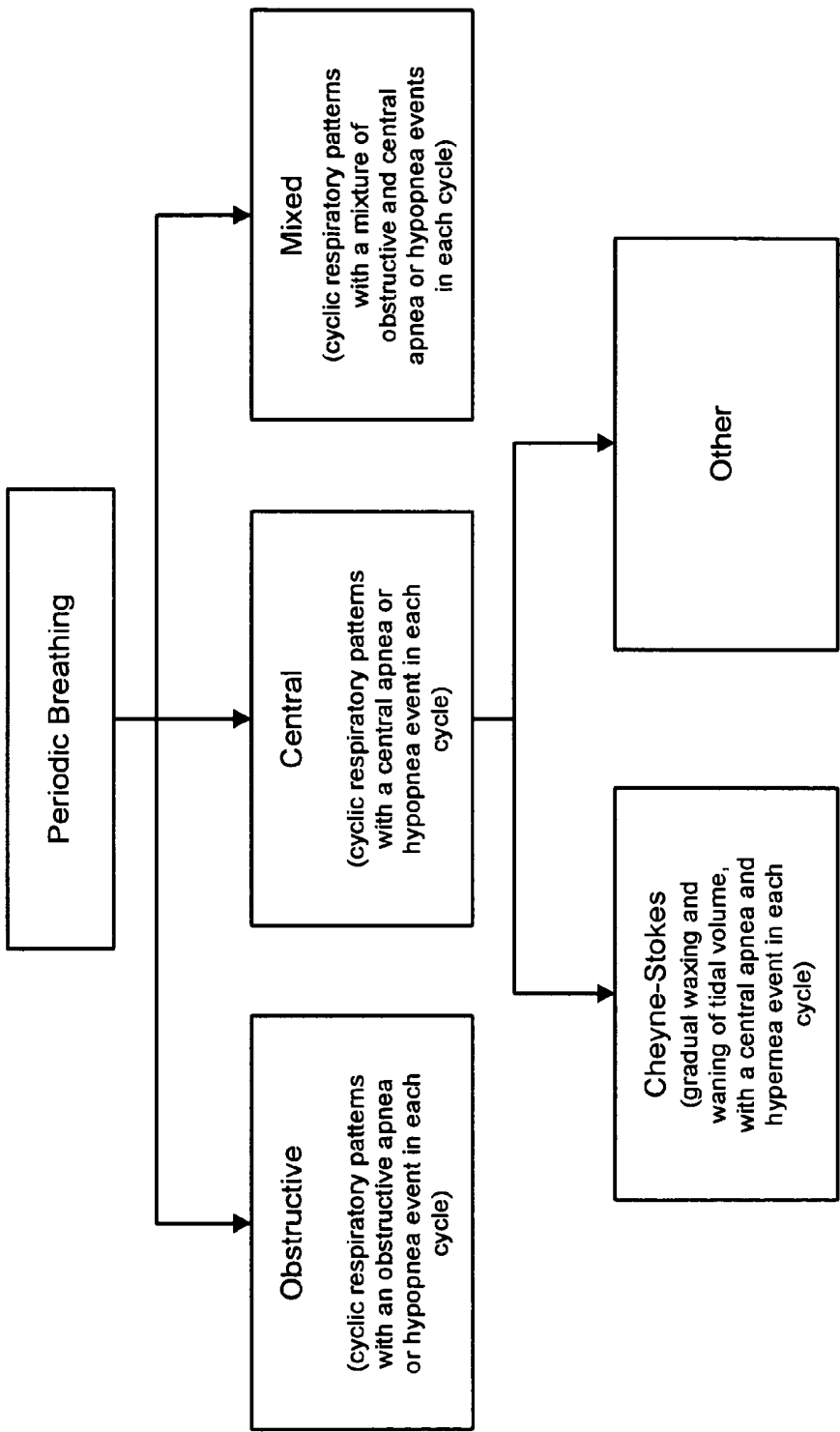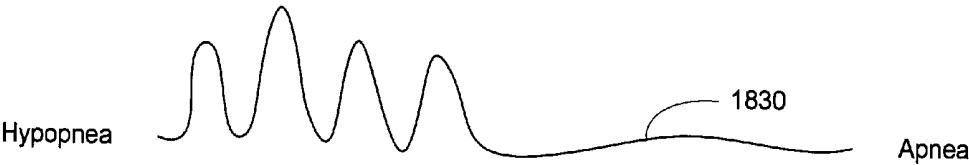
yes

no

1592

Time Out?

no

yes

1595

Hypopnea

Figure 15

Figure 16

Figure 17

Figure 18A

Figure 18B

Trigger On

Trigger Off

Apnea — 1810

Apnea

Figure 18C

Apnea — 1820

Hypopnea

Figure 18D

Hypopnea

1830

Apnea

Figure 18E

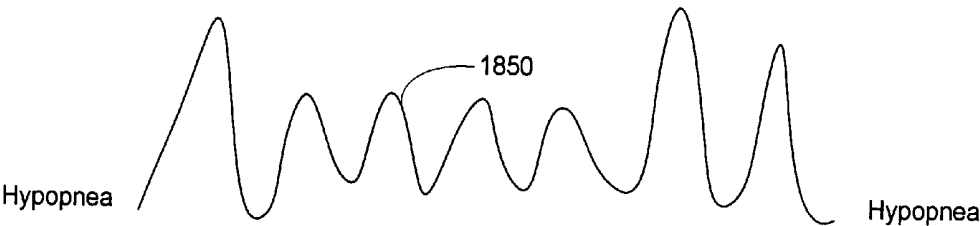Hypopnea

1850

Hypopnea

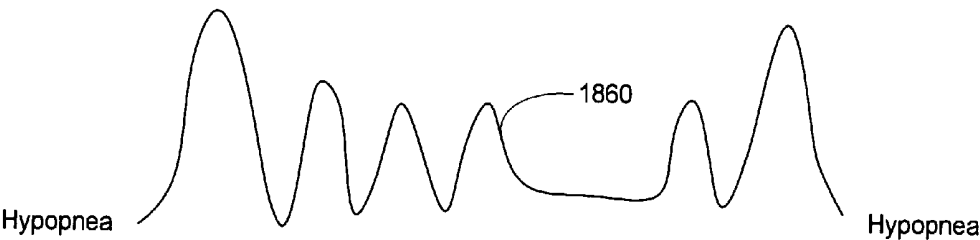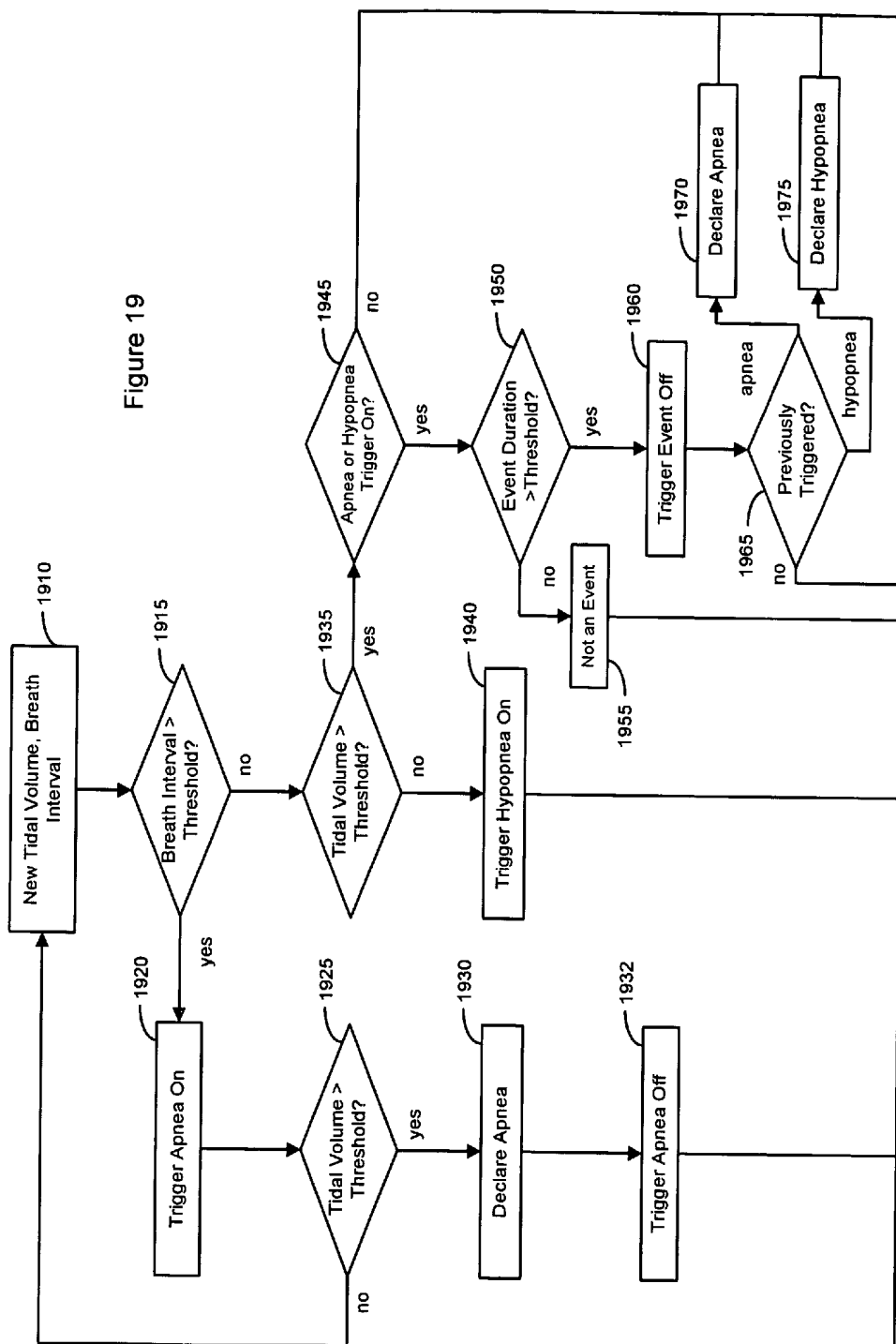Figure 18F

Hypopnea

1860

Hypopnea
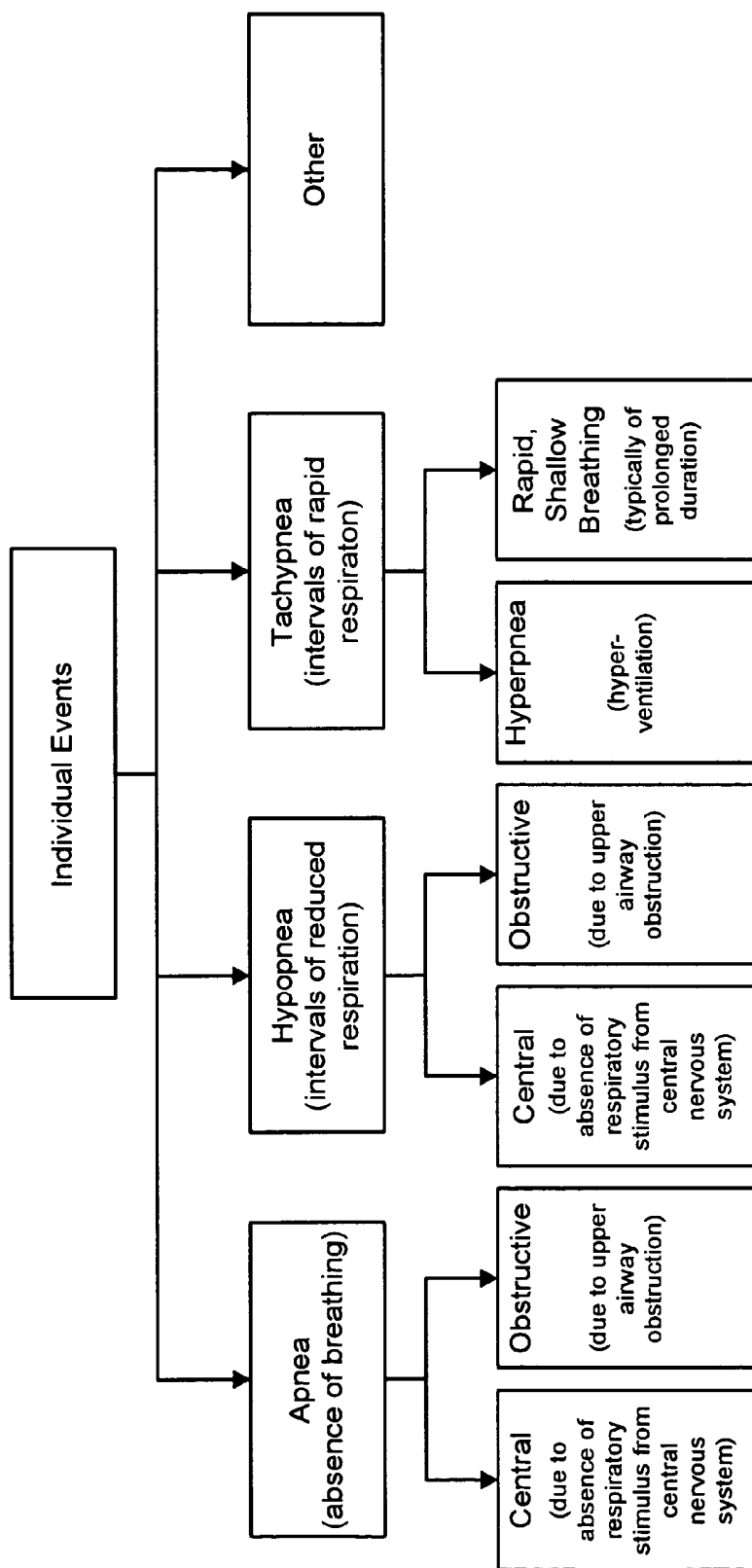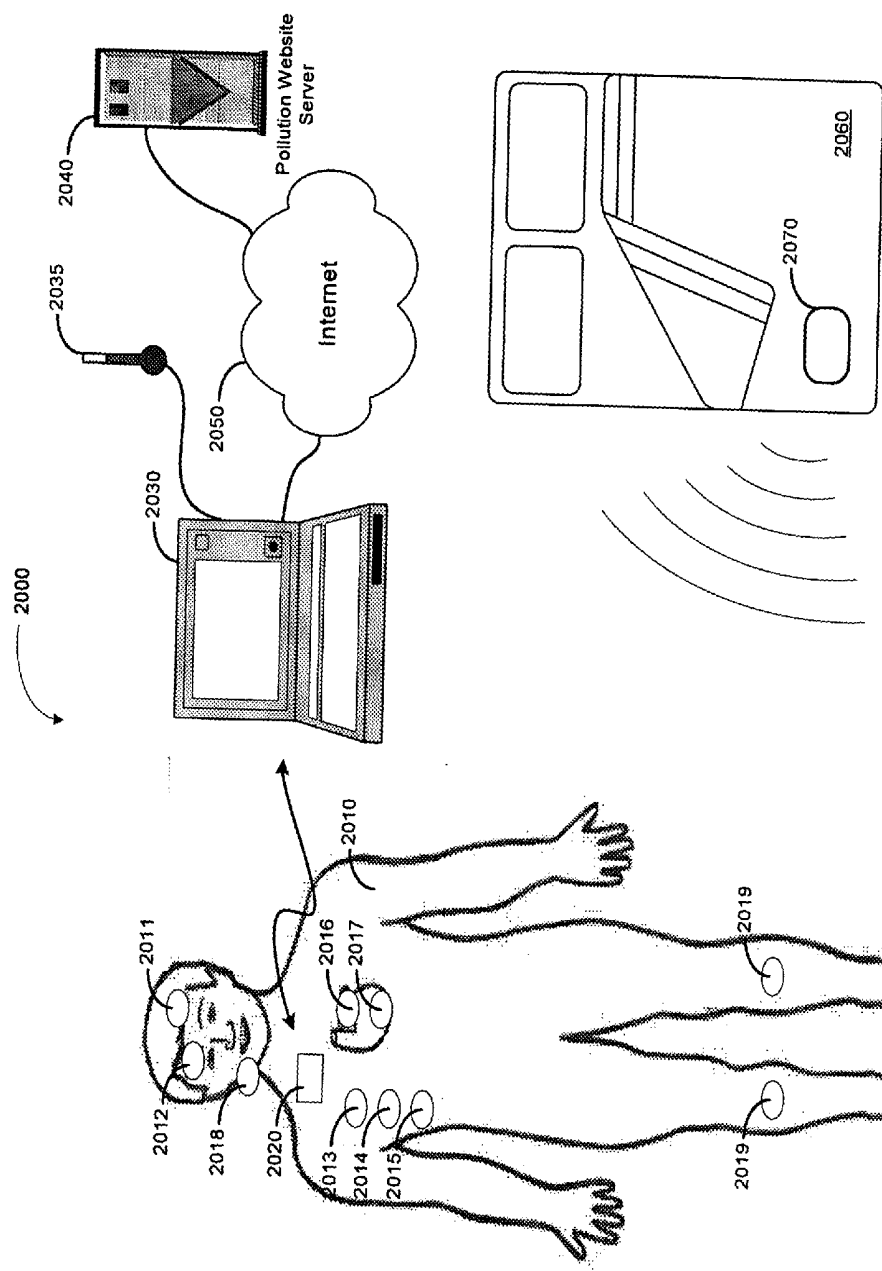
Figure 18G

Figure 19

Figure 20

SLEEP QUALITY DATA COLLECTION AND EVALUATION

FIELD OF THE INVENTION

[0001]   The present invention relates generally to collecting and evaluating information related to sleep quality.

BACKGROUND OF THE INVENTION

[0002]   Sleep is generally beneficial and restorative to a patient, exerting great influence on the quality of life. The human sleep/wake cycle generally conforms to a circadian rhythm that is regulated by a biological clock. Regular periods of sleep enable the body and mind to rejuvenate and rebuild. The body may perform various tasks during sleep, such as organizing long term memory, integrating new information, and renewing tissue and other body structures.

[0003]   Normal sleep is characterized by a general decrease in metabolic rate, body temperature, blood pressure, breathing rate, heart rate, cardiac output, sympathetic nervous activity, and other physiological functions. However, studies have shown that the brain's activity does not decrease significantly during sleep. Normally a patient alternates between rapid eye movement (REM) and non-REM (NREM) sleep in approximately 90 minute cycles throughout a sleep period. A typical eight hour sleep period may be characterized in terms of a five-step sleep cycle identifiable through EEG brain wave activity.

[0004]   Non-REM sleep includes four sleep states or stages that range from light dozing to deep sleep. Throughout NREM sleep, muscle activity is still functional, breathing is low, and brain activity is minimal. Approximately 85% of the sleep cycle is spent in NREM sleep. Stage 1 NREM sleep may be considered a transition stage between wakefulness and sleep. As sleep progresses to stage 2 NREM sleep, eye movements become less frequent and brain waves increase in amplitude and decrease in frequency. As sleep becomes progressively deeper, the patient becomes more difficult to arouse. Stage 3 sleep is characterized by 20 to 40% slow brain wave (delta) sleep as detected by an electroencephalogram (EEG). Sleep stages 3 and 4 are considered to be the most restful sleep stages.

[0005]   REM sleep is associated with more prevalent dreaming, rapid eye movements, muscle paralysis, and irregular breathing, body temperature, heart rate and blood pressure. Brain wave activity during REM sleep is similar to brain wave activity during a state of wakefulness. There are typically 4-6 REM periods per night, with increasing duration and intensity toward morning. While dreams can occur during either REM or NREM sleep, the nature of the dreams varies depending on the type of sleep. REM sleep dreams tend to be more vivid and emotionally intense than NREM sleep dreams. Furthermore, autonomic nervous system activity is dramatically altered when REM sleep is initiated.

[0006]   Lack of sleep and/or decreased sleep quality may be have a number of causal factors including, e.g., nerve or muscle disorders, respiratory disturbances, and emotional conditions, such as depression and anxiety. Chronic, long-term sleep-related disorders e.g., chronic insomnia, sleep-disordered breathing, and sleep movement disorders, including restless leg syndrome (RLS), periodic limb movement disorder (PLMD) and bruxism, may significantly affect a patient's sleep quality and quality of life.

[0007]   Movement disorders such as restless leg syndrome (RLS), and a related condition, denoted periodic limb movement disorder (PLMD), are emerging as one of the more common sleep disorders, especially among older patients. Restless leg syndrome is a disorder causing unpleasant crawling, prickling, or tingling sensations in the legs and feet and an urge to move them for relief. RLS leads to constant leg movement during the day and insomnia or fragmented sleep at night. Severe RLS is most common in elderly people, although symptoms may develop at any age. In some cases, it may be linked to other conditions such as anemia, pregnancy, or diabetes.

[0008]   Many RLS patients also have periodic limb movement disorder (PLMD), a disorder that causes repetitive jerking movements of the limbs, especially the legs. These movements occur approximately every 20 to 40 seconds and cause repeated arousals and severely fragmented sleep.

[0009]   A significant percentage of patients between 30 and 60 years experience some symptoms of disordered breathing, primarily during periods of sleep. Sleep disordered breathing is associated with excessive daytime sleepiness, systemic hypertension, increased risk of stroke, angina and myocardial infarction. Disturbed respiration can be particularly serious for patients concurrently suffering from cardiovascular deficiencies. Disordered breathing is particularly prevalent among congestive heart failure patients, and may contribute to the progression of heart failure.

[0010]   Sleep apnea is a fairly common breathing disorder characterized by periods of interrupted breathing experienced during sleep. Sleep apnea is typically classified based on its etiology. One type of sleep apnea, denoted obstructive sleep apnea, occurs when the patient's airway is obstructed by the collapse of soft tissue in the rear of the throat. Central sleep apnea is caused by a derangement of the central nervous system control of respiration. The patient ceases to breathe when control signals from the brain to the respiratory muscles are absent or interrupted. Mixed apnea is a combination of the central and obstructive apnea types. Regardless of the type of apnea, people experiencing an apnea event stop breathing for a period of time. The cessation of breathing may occur repeatedly during sleep, sometimes hundreds of times a night and occasionally for a minute or longer.

[0011]   In addition to apnea, other types of disordered respiration have been identified, including, for example, hypopnea (shallow breathing), dyspnea (labored breathing), hyperpnea (deep breathing), and tachypnea (rapid breathing).

[0012]   Combinations of the disordered respiratory events described above have also been observed. For example, Cheyne-Stokes respiration (CSR) is associated with rhythmic increases and decreases in tidal volume caused by alternating periods of hyperpnea followed by apnea and/or hypopnea. The breathing interruptions of CSR may be associated with central apnea, or may be obstructive in nature. CSR is frequently observed in patients with congestive heart failure (CHF) and is associated with an increased risk of accelerated CHF progression.

[0013]   An adequate duration and quality of sleep is required to maintain physiological homeostasis. Untreated, sleep disturbances may have a number of adverse health and

quality of life consequences ranging from high blood pressure and other cardiovascular disorders to cognitive impairment, headaches, degradation of social and work-related activities, and increased risk of automobile and other accidents.

[0014] The following commonly owned U.S. patents applications, some of which have been identified above, are hereby incorporated by reference in their respective entireties: U.S. patent application Ser. No. 10/309,770 (Docket Number GUID.064PA), filed Dec. 4, 2002, U.S. patent application Ser. No. 10/309,771 (Docket Number GUID.054PA), filed Dec. 4, 2002, U.S. patent application entitled "Prediction of Disordered Breathing," identified by Docket Number GUID.088PA and concurrently filed with this patent application, U.S. patent application entitled "Adaptive Therapy for Disordered Breathing," identified by Docket Number GUID.059PA and filed concurrently with this patent application, U.S. patent application entitled "Sleep State Classification," identified by Docket Number GUID.060PA and filed concurrently with this patent application, and U.S. patent application entitled "Therapy Triggered by Prediction of Disordered Breathing," identified by Docket Number GUID.103PA and filed concurrently with this patent application.

[0015] Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

SUMMARY OF THE INVENTION

[0016] Various embodiments of present invention involve methods and systems for collecting sleep quality data and evaluating the sleep quality of a patient.

[0017] An embodiment of the invention involves a method for collecting sleep quality data. The method includes detecting physiological and non-physiological conditions associated with the sleep quality of a patient and collecting sleep quality data based on the detected conditions. Collecting the sleep quality data is performed at least in part implantably.

[0018] Another embodiment of the invention involves a method for evaluating sleep quality. In accordance with this method, one or more metrics associated with sleep are determined. One or more metrics associated with events that disrupt sleep are determined. A composite sleep quality metric is determined using the one or more metrics associated with sleep and the one or more metrics associated with events that disrupt sleep.

[0019] In yet another embodiment of the invention, a method for evaluating sleep quality includes detecting physiological and non-physiological conditions associated with the sleep quality of a patient and collecting sleep quality data based on the detected conditions. The sleep quality of the patient is evaluated using the collected data. At least one of collecting the sleep quality data and evaluating the sleep quality of the patient is performed at least in part implantably.

[0020] Another embodiment of the invention involves a method for evaluating sleep quality. One or more conditions associated with sleep quality of a patient are detected during a period of wakefulness. Sleep quality data is collected based on the detected conditions. The patient's sleep quality is evaluated using the collected sleep quality data. At least one of collecting the data and evaluating the sleep quality is performed at least in part implantably.

[0021] A further embodiment of the invention involves a medical device including a detector system configured to detect physiological and non-physiological conditions associated with sleep quality and a data collection system for collecting sleep quality data based on the detected conditions. The data collection system includes an implantable component.

[0022] Yet another embodiment of the invention relates to a medical device configured to evaluate sleep quality. The medical device includes a detector system configured to detect physiological and non-physiological conditions associated with the sleep quality of a patient. A sleep quality processor, coupled to the detection system, is configured to determine metrics based on the detected conditions. The metrics include one or more metrics associated with sleep, one or more metrics associated with events that disrupt sleep, and at least one composite sleep quality metric based on the one or more metrics associated with sleep and the one or more metrics associated with events that disrupt sleep.

[0023] In another embodiment of the invention, a medical device for assessing sleep quality includes a detector unit configured to detect physiological and non-physiological conditions associated with sleep quality and a sleep quality data collection unit configured to collect sleep quality data based on the detected conditions. A data analysis unit coupled to the data collection unit evaluates sleep quality based on the collected sleep quality data. At least one of the data collection unit and the data analysis unit includes an implantable component.

[0024] A further embodiment of the invention involves a system for collecting sleep quality data. The system includes means for detecting physiological and non-physiological conditions associated with sleep quality and means for collecting sleep quality data based on the detected conditions. The means for collecting the sleep quality data includes an implantable component.

[0025] In yet another embodiment of the invention, a system for assessing sleep quality includes means for determining one or more metrics associated with sleep and means for determining one or more metrics associated with events that disrupt sleep. The system further includes means for determining a composite sleep quality metric as a function of the metrics associated with sleep and the metrics associated with events that disrupt sleep.

[0026] Another embodiment of the invention involves a system for evaluating sleep quality. The system includes means for detecting physiological and non-physiological conditions associated with sleep quality and means for collecting sleep quality data based on the detected conditions. The system includes means for evaluating the sleep quality of the patient based on the collected sleep quality data. At least one of the means for collecting the sleep quality data and the means for evaluating the sleep quality comprise an implantable component.

[0027] A further embodiment involves a system for evaluating the sleep quality of a patient. The system includes

means for detecting one or more patient conditions associated with sleep quality during a period of wakefulness and means for collecting sleep quality data based on the detected conditions. The system further includes means for evaluating the sleep quality of the patient using the collected sleep quality data. At least one of the means for collecting the sleep quality data and means for evaluating the sleep quality include an implantable component.

[0028] The above summary of the present invention is not intended to describe each embodiment or every implementation of the present invention. Advantages and attainments, together with a more complete understanding of the invention, will become apparent and appreciated by referring to the following detailed description and claims taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. 1 is a flow chart illustrating a method of collecting sleep quality data in accordance with embodiments of the invention;

[0030] FIG. 2 illustrates a block diagram of a sleep quality data system in accordance with embodiments of the invention;

[0031] FIG. 3 is a system block diagram illustrating a sleep quality data system incorporated within a cardiac rhythm management system in accordance with embodiments of the invention;

[0032] FIG. 4 is a block diagram of a sleep detection unit that may be used as part of a sleep quality data system according to embodiments of the invention;

[0033] FIG. 5 is a flow chart illustrating a sleep detection method according to embodiments of the invention;

[0034] FIG. 6 is a flow chart illustrating a method for detecting sleep as a part of a sleep quality data collection approach according to embodiments of the invention;

[0035] FIG. 7 is a graph of a patient's activity condition as indicated by an accelerometer signal;

[0036] FIG. 8 is a graph of a patient's heart rate;

[0037] FIG. 9 is a graph of a patient's minute ventilation (MV) condition;

[0038] FIG. 10 illustrates adjustment of a sleep threshold in accordance with embodiments of the invention;

[0039] FIG. 11 illustrates a normal respiration pattern as represented by a transthoracic impedance sensor signal;

[0040] FIG. 12 illustrates respiration intervals used for disordered breathing detection according to embodiments of the invention;

[0041] FIG. 13 illustrates detection of sleep apnea and severe sleep apnea according to embodiments of the invention;

[0042] FIGS. 14A-B are graphs of tidal volume derived from transthoracic impedance measurements according to embodiments of the invention;

[0043] FIG. 15 is a flow chart illustrating a method of apnea and hypopnea detection according to embodiments of the invention;

[0044] FIG. 16 is a graph illustrating a breathing interval according to embodiments of the invention;

[0045] FIG. 17 is a graph illustrating a hypopnea detection approach in accordance with embodiments of the invention;

[0046] FIGS. 18A-B are charts illustrating nomenclature for individual disordered breathing events and combinations of disordered breathing events, respectively;

[0047] FIGS. 18C-G are graphs illustrating disordered breathing events comprising a combination of apnea and hypopnea respiration cycles;

[0048] FIG. 19 is a flow chart of a method for detecting disordered breathing by classifying breathing patterns in accordance with embodiments of the invention; and

[0049] FIG. 20 illustrates a patient instrumented with components of a sleep quality data system according to embodiments of the invention.

[0050] While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail below. It is to be understood, however, that the intention is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

[0051] In the following description of the illustrated embodiments, references are made to the accompanying drawings which form a part hereof, and in which are shown, by way of illustration, various embodiments by which the invention may be practiced. It is to be understood that other embodiments may be utilized. Structural and functional changes may be made without departing from the scope of the present invention.

[0052] Sleep quality assessments depend upon acquiring sleep-related data, including the patient's typical sleep patterns and the physiological, environmental, contextual, emotional, and other conditions affecting the patient during sleep. Diagnosis of sleep disorders and assessment of sleep quality often involves the use of a polysomnographic sleep study at a dedicated sleep facility. However, such studies are costly, inconvenient to the patient, and may not accurately represent the patient's typical sleep behavior. In a polysomnographic sleep study, the patient is instrumented for data acquisition and observed by trained personnel. Sleep assessment in a laboratory setting presents a number of obstacles in acquiring an accurate picture of a patient's typical sleep patterns. For example, spending a night in a sleep laboratory typically causes a patient to experience a condition known as "first night syndrome," involving disrupted sleep during the first few nights in an unfamiliar location. In addition, sleeping while instrumented and observed may not result in a realistic perspective of the patient's normal sleep patterns.

[0053] Further, polysomnographic sleep studies provide an incomplete data set for the analysis of some sleep disorders, including, for example, sleep disordered breathing. A number of physiological conditions associated with

sleep disordered breathing are detectable during periods of wakefulness, e.g., decreased heart rate variability, elevated sympathetic nerve activity, norepinephrine concentration, and increased blood pressure variability. Collection of data during periods of sleep and/or during periods of wakefulness may provide a more complete picture of the patient's sleep quality.

[0054] Various aspects of sleep quality, including number and severity of arousals, sleep disordered breathing episodes, nocturnal limb movements, and cardiac, respiratory, muscle, and nervous system functioning may provide important information for diagnosis and/or therapy delivery. An initial step to sleep quality evaluation is an accurate and reliable method for discriminating between periods of sleep and periods of wakefulness. Further, acquiring data regarding the patient's sleep states or stages, including sleep onset, termination, REM, and NREM sleep states may be used in connection sleep quality assessment. For example, the most restful sleep occurs during stages 3 and 4 NREM sleep. One indicator of sleep quality is the percentage of time a patient spends in these sleep stages. Knowledge of the patient's sleep patterns may be used to diagnose sleep disorders and/or adjust patient therapy, including, e.g., cardiac or respiratory therapy. Trending disordered breathing episodes, arousal episodes, and other sleep quality aspects may be helpful in determining and maintaining appropriate therapies for patients suffering from disorders ranging from snoring to chronic heart failure.

[0055] The present invention involves methods and systems for acquiring sleep quality data using one or more implantable components. As illustrated in **FIG. 1**, methods of the invention involve detecting conditions associated with the sleep quality of the patient **110**, including physiological and non-physiological conditions. Data related to the patient's sleep quality is collected based on the detected conditions **120**. Detection of patient conditions related to sleep quality may occur during periods of wakefulness and/or during periods of sleep. Either detecting the conditions associated with sleep quality, or collecting the sleep quality data, or both, is performed using a device having a component that is at least in part implantable.

[0056] A representative set of the conditions associated with sleep quality is listed in Table 1. Patient conditions used to evaluate sleep quality may include, for example, both physiological and non-physiological (i.e., contextual) conditions. Physiological conditions associated with sleep quality may be further organized, for example, into conditions of the cardiovascular, respiratory, muscle, and nervous systems, and conditions relating to the patient's blood chemistry.

[0057] Contextual conditions may be further subdivided into environmental conditions, body-related conditions and historical/background conditions. Environmental conditions may be broadly defined to include the environmental surroundings affecting the patient, such as ambient light, temperature, humidity, air pollution, noise, and barometric pressure. Body-related conditions may include, for example, patient location, posture, and altitude. Contextual conditions relevant to sleep quality may also include historical or background conditions. For example, a patient's medical/psychological history, gender, age, weight, body mass index, neck size, drug use, and emotional state may be detected and used in connection with sleep quality evaluation and sleep disorder diagnosis. Methods and systems for detecting contextual conditions are described in commonly owned U.S. patent application, Ser. No. 10/269611, filed Oct. 11, 2002, which is incorporated herein by reference.

TABLE 1

Condition Type		Condition	Sensor type or Detection method
Physiological	Cardiovascular System	Heart rate	EGM, ECG
		Heart rate variability	
		QT interval	
		Ventricular filling pressure	Intracardiac pressure sensor
		Blood pressure	Blood pressure sensor
	Respiratory System	Snoring	Accelerometer
			Microphone
		Respiration pattern	Transthoracic impedance sensor
		(Tidal volume Minute	(AC)
		ventilation Respiratory rate)	
		Patency of upper airway	Intrathoracic impedance sensor
		Pulmonary congestion	Transthoracic impedance sensor
			(DC)
	Nervous System	Sympathetic nerve activity	Muscle sympathetic nerve
			Activity sensor
		Brain activity	EEG
	Blood Chemistry	CO2 saturation	Blood analysis
		O2 saturation	
		Blood alcohol content	
		Adrenalin	
		Brain Natriuretic Peptide (BNP)	
		C-Reactive Protein	
		Drug/Medication/Tobacco use	
	Muscle System	Muscle atonia	EMG
		Eye movement	EOG
		Patient activity	Accelerometer, MV, etc.
		Limb movements	Accelerometer
		Jaw movements	

TABLE 1-continued

Condition Type		Condition	Sensor type or Detection method
Non-physiological	Environmental	Ambient temperature	Thermometer
		Humidity	Hygrometer
		Pollution	Air quality website
		Time	Clock
		Barometric pressure	Barometer
		Ambient noise	Microphone
		Ambient light	Photodetector
	Body-related	Posture	Posture sensor
		Altitude	Altimeter
		Location	GPS, proximity sensor
		Proximity to bed	Proximity to bed sensor
	Historical/Background	Historical sleep time	Patient input, previously detected sleep onset times
		Medical history	Patient input device
		Age	
		Recent exercise	
		Weight	
		Gender	
		Body mass index	
		Neck size	
		Emotional state	
		Psychological history	
		Daytime sleepiness	
		Patient perception of sleep quality	
		Drug, alcohol, nicotine use	

[0058] Each of the conditions listed in Table 1 may serve a variety of purposes in evaluating sleep quality. For example, a subset of the conditions may be used to detect whether the patient is asleep and to track the various stages of sleep and arousal incidents. Another subset of the conditions may be used to detect disordered breathing episodes. Yet another subset may be used to detect abnormal limb movements. In one implementation, some or all of the listed conditions may be collected over a relatively long period of time and used to analyze long term sleep quality trends. Trending may be used in connection with an overall assessment of sleep quality and diagnosis and treatment of sleep-disordered breathing, movement disorders, and/or other sleep disorders.

[0059] In one implementation, sleep quality analysis may be used within the structure of an advanced patient management system. In this implementation, an advanced

patient management system having sleep quality analysis capability allows a physician to remotely and automatically monitor cardiac and respiratory functions, as well as other patient conditions, including information related to sleep quality. In one example, an implantable cardiac rhythm management system, such as a cardiac monitor, pacemaker, defibrillator, or resynchronization device, may be equipped with various telecommunications and information technologies to enable real-time data collection, diagnosis, and treatment of the patient. Systems and methods involving advanced patient management techniques are described in U.S. Pat. Nos. 6,336,903, 6,312,378, 6,270,457, and 6,398, 728 which are incorporated herein by reference in their respective entireties.

[0060] Table 2 provides examples of how some physiological and non-physiological conditions may be used in connection with sleep quality assessment.

TABLE 2

Condition Type	Condition	Examples of how condition is used in sleep quality assessment
Physiological	Heart rate	Decrease in heart rate may indicate disordered breathing episode.
		Decrease in heart rate may indicate the patient is asleep.
	Heart rate variability	May be used to determine sleep state.
		Changes in heart rate variability, detected during periods of sleep or wakefulness, may indicate that the patient suffers from sleep disordered breathing.
	QT interval	May be used to detect sleep apnea.
	Ventricular filling pressure	May be used to identify/predict pulmonary congestion associated with respiratory disturbance.
	Blood pressure	Variation in blood pressure is associated with apnea.
	Snoring	Associated with a higher incidence of obstructive sleep apnea and may be used to detect disordered breathing.
	Respiration pattern	May be used to detect disordered breathing episodes.
		May be used to determine the type of disordered breathing.
		May be used to detect sleep.

TABLE 2-continued

Condition Type	Condition	Examples of how condition is used in sleep quality assessment
	Patency of upper airway	Related to obstructive sleep apnea and may be used to detect episodes of obstructive sleep apnea.
	Pulmonary congestion	Associated with respiratory disturbances.
	Sympathetic nerve activity (SNA)	Apnea termination is associated with a spike in SNA. SNA activity may be elevated during periods of wakefulness if the patient experiences sleep disordered breathing.
	Electroencephalogram (EEG)	May be used to determine sleep stages, including REM and NREM sleep stages
	CO2 saturation	Low CO2 levels may indicate initiation of central apnea.
	O2 saturation	O2 desaturation occurs during severe apnea/hypopnea episodes.
	Blood alcohol content	Alcohol tends to increase the incidence of snoring & obstructive apnea.
	Adrenalin	End of apnea associated with a spike in blood adrenaline.
	Brain Natriuretic Peptide (BNP)	A marker of heart failure status, which is associated with Cheyne-Stokes Respiration.
	C-Reactive Protein	A measure of inflammation that may be related to apnea.
	Drug/Medication/Tobacco use	These substances may affect incidence of both central & obstructive apnea.
	Muscle atonia	Muscle atonia may be used in connection with detection of REM and non-REM sleep.
	Eye movement	Eye movement may be used in connection with detection of REM and non-REM sleep.
	Activity	May be used to detect sleep and patient well being.
	Limb movements	May be used to detect abnormal limb movements during sleep.
Non-physiological	Ambient Temperature	Ambient temperature may predispose the patient to episodes of disordered breathing during sleep.
	Humidity	Humidity may predispose the patient to episodes of disordered breathing during sleep.
	Pollution	Pollution may predispose the patient to episodes of disordered breathing during sleep.
	Posture	Posture may be used to determine if the patient is asleep. Posture may predispose the patient to disordered breathing.
	Time	Used to establish historical sleep time.
	Ambient noise level	Noise level may affect sleep quality.
	Location	Patient location may used to determine if the patient is in bed as a part of sleep detection.
	Altitude	Altitude may predispose the patient to episodes of disordered breathing and may affect sleep quality.
	Barometric Pressure	Barometric pressure may predispose the patient to episodes of disordered breathing.
	Proximity to bed	May be used to determine if patient is in bed.
	Historical sleep time	May be used in connection with sleep detection.
	Medical history	History of medical disorders, e.g., CHF, that are associated with disordered breathing such as Cheyne-Stokes respiration.
	Age	Age is associated with increased risk of disordered breathing, RLS and other sleep disruptive disorders.
	Weight	Associated with sleep disordered breathing, e.g., obstructive
	Gender	sleep apnea.
	Obesity	
	Neck size	
	Patient reported drug, alcohol, nicotine use	Patient drug, alcohol and nicotine use may affect sleep quality.
	Psychological history	Psychological factors, e.g., clinical depression may be associated with insomnia.
	Emotional state	Emotional state, e.g., stress, anxiety, euphoria, may affect sleep quality.
	Daytime sleepiness	May be used to evaluate sleep quality.
	Patient perceptions of sleep quality	

[0061] FIG. 2 illustrates a block diagram of a sleep quality data system **200** configured in accordance with embodiments of the invention. In this implementation, the sleep quality data system **200** may use signals acquired from a variety of sources to collect data relevant to sleep quality. The collected data may be stored in the memory **280** of a data collection unit **250** and/or transmitted to a sleep quality analysis unit **290** for further processing. It is contemplated that at least one, some, or all components of the system **200** are implanted in the patient.

[0062] The sleep quality data system **200** may use patient-internal sensors **210** implanted within the body of the patient to detect physiological conditions relevant to sleep quality.

The conditions detected using patient-internal sensors **210** may include, for example, heart rate, respiratory pattern, and patient activity.

[0063] The system **200** may also use patient-external sensors **220** to detect physiological or non-physiological patient conditions. In one example configuration, whether the patient is snoring may be useful in evaluating sleep quality. Snoring data may be detected using an external microphone and transferred to the sleep quality data collection unit **250**. In another configuration, ambient temperature and humidity may be factors related to the patient's sleep quality. The ambient temperature and humidity of the patient's room may be sensed using sensors located near patient. Signals from the temperature and humidity sensors may be transmitted to the data collection unit **250**. Limb and/or jaw movements may be sensed using patient-external accelerometers and/or other sensors placed in appropriate locations on or near the patient and transmitted to the data collection unit **250**.

[0064] Information relevant to sleep quality may also be reported **240** by the patient. According to embodiments of the invention, the patient's self-described conditions, including medication use, tobacco use, perceptions of sleep quality, and/or psychological or emotional state, for example, may be relevant to sleep quality assessment. The patient may enter information about these conditions through an appropriate interface device, such as a medical device programmer, coupled to the sleep quality data collection unit **250**.

[0065] Some information related to sleep quality may be accessible through information systems **230**, including network-based systems. For example, information about the patient's present cardiac, respiratory, or other therapy may be downloaded from an external device via a wireless or wired network. In another example, information about conditions affecting the patient, such as local air quality data, may be accessed through an internet-connected website.

[0066] The patient-internal sensors **210**, patient-external sensors **220**, patient-reported input devices **240**, and information systems **230**, may be coupled to the data collection unit **250** in a variety of ways. In one example, one or more of the sensors **210, 220**, patient-reported input devices **240**, and information systems **230** have wireless communication capabilities, such as a wireless Bluetooth communications link, or other proprietary communications protocol. In this implementation, the devices having wireless communication capabilities may remotely transmit signals to the data collection unit **250**. In this application, the data collection unit **250** may be configured as an implantable or patient-external device. In other implementations, one or more of the patient-internal sensors **210**, patient-external sensors **220**, patient-reported input devices **240**, and information systems **230** may be coupled to the data collection unit **250** through leads or other wired connections.

[0067] The implantable or patient-external data collection unit **250** includes detection circuitry **260** for processing signals from the sensors **210, 220**, patient-reported input devices **240**, and information systems **230**. The detection circuitry **260** may include, for example, amplifiers, filters, A/D converters, signal processors and/or sensor driver circuitry configured to provide sensor signals used in the evaluation of sleep quality. The data collection unit **250** may

further include wireless communication circuitry **270** for receiving and transmitting signals to wirelessly connected components.

[0068] In one embodiment, the sleep quality data system **200** collects data from the sensors **210, 220**, input devices **240**, and information systems **230**, and stores the collected data in memory **280** prior to further processing or transmission. In another embodiment, the sleep quality data system **200** may transmit the collected data to a separate device (not shown) for storage, analysis, or display.

[0069] In a further embodiment, the sleep quality data system **200** may evaluate or further process the collected sleep quality data. For this purpose, the sleep quality data system **200** may optionally include a sleep quality analysis unit **290**. In one configuration, the data collection unit **250** and the sleep quality analysis unit **290** are arranged in separate devices. In such a configuration, the data collection unit **250** transfers the collected sleep quality data to the sleep quality analysis unit **290** through a wireless or wired connection. In another configuration, the sleep quality analysis unit **290** and the data collection unit **250** are arranged within the same device which may be a patient-external device or a fully or partially implantable device.

[0070] The sleep quality analysis unit **290** may include one or more subsystems useful in sleep quality assessment. The subsystems may include, for example a sleep detector **292** used to detect sleep onset, sleep offset, and arousal, for example. The sleep detector may also detect sleep stages, including the various stages of NREM and REM sleep. The sleep quality analysis unit **290** may include circuitry to detect various sleep-related disorders. For example, the sleep quality analysis unit **290** may include circuitry **294** for detecting disordered breathing and circuitry **295** for detecting abnormal nocturnal movements. Further, the sleep quality analysis unit **290** may include a processor for evaluating sleep quality **296**, for example, by calculating one or more metrics quantifying the patient's sleep quality.

[0071] **FIG. 3** illustrates a sleep quality data system **305** incorporated within a cardiac rhythm management system (CRM) **300**. The CRM **300** may include, for example, a cardiac therapy module **320** including a pacemaker **322** and an arrhythmia detector/therapy unit **324**. The cardiac therapy module **320** is coupled to a lead system having electrodes **331** implantable within the patient's body. The implanted electrodes **331** are arranged to receive signals from the heart **330** and deliver stimulation therapy to the heart **330**. Cardiac signals sensed using the implanted electrodes **331** are received by a cardiac signal detector **350** coupled to the cardiac therapy module **320**.

[0072] The cardiac therapy module **320** analyzes the cardiac signals to determine an appropriate therapy to treat arrhythmia conditions affecting the heart **330**. The cardiac therapy may include pacing therapy controlled by the pacemaker **322** to treat cardiac rhythms that are too slow. The pacemaker **322** controls the delivery of periodic low energy pacing pulses to ensure that the periodic contractions of the heart are maintained at a hemodynamically sufficient rate.

[0073] The cardiac therapy may also include therapy to terminate tachyarrhythmia, wherein the heart rate is too fast. The arrhythmia detector/therapy unit **324** analyzes cardiac signals received from the cardiac signal detector **350** to

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recognize tachyarrhythmias including atrial or ventricular tachycardia or fibrillation. The arrhythmia detector/therapy unit **324** recognizes cardiac signals indicative of tachyarrhythmia and delivers high energy stimulations to the heart **330** through the implanted electrodes **331** to terminate the arrhythmias.

[0074] Various input devices, including implantable sensors **381**, patient-external sensors **382**, patient input devices **384**, and information systems **383** may be coupled to the CRM **300**. These devices **381, 382, 383, 384** may be used to provide information about physiological and/or non-physiological conditions affecting the patient relevant to sleep quality, such as the representative set of patient conditions listed in Table 1 above.

[0075] The CRM **300** includes signal detection circuitry **360** for receiving and processing signals from the various sensors and input devices **381, 382, 384, 383**. As previously discussed, the signal detection circuitry **360** may include signal processing circuitry configured to amplify, digitize, or otherwise process signals representing the sensed sleep quality conditions. In the illustrated implementation, the patient input devices **384**, patient-external sensors **382**, and information systems **383** are wirelessly coupled to the CRM **300**. The patient-internal sensors **381** may be coupled to the CRM **300** through leads, through a wireless link, or integrated within or on the housing of the CRM **300** (e.g., integral accelerometer).

[0076] In one embodiment, the sleep quality data system **305** incorporated within the CRM **300** collects data from cardiac electrodes **331**, patient-internal sensors **381**, patient-external sensors **382**, patient input devices **384**, and information systems **383** and stores the collected data in memory. The sleep quality data system may transmit the collected data to a separate device, such as the CRM programmer **315** or other device, periodically as required or desired.

[0077] In another embodiment, the CRM sleep quality data system **305** may perform further processing and/or evaluation of the sleep quality data. For this purpose, the CRM sleep quality data system **305** may include a sleep quality analysis unit **340** coupled to the signal detector **360**. The sleep quality analysis unit **340** may include one or more components for evaluating the patient's sleep quality. For example, the sleep quality analysis unit **340** may include sleep detection circuitry **341**, disordered breathing detection circuitry **342**, abnormal nocturnal movement detection circuitry **344**, and a sleep quality processor **343**, as previously described in connection with **FIG. 2**.

[0078] The cardiac therapy module **320**, signal detector **360**, and sleep quality analysis unit **340** operate in cooperation with a memory unit **370**. The memory unit **370** may store parameters associated with cardiac therapy in addition to diagnostic or other data related to cardiac functioning and sleep quality. A communication unit **310** located within the CRM **300** may be used to transmit programming information and collected data from the CRM **300** to an external device such as a programmer **315**.

[0079] Sleep quality assessment involves a reliable method for discriminating between a state of sleep and a state of wakefulness. One method of detecting sleep involves comparing one or more detected physiological conditions to thresholds indicative of sleep. When the

detected conditions are consistent with thresholds indicating sleep, then sleep onset is declared. For example, decreased patient activity is a condition associated with sleep. When the patient's activity falls below a predetermined threshold, the system declares the onset of sleep. When the patient's activity rises above the threshold, the system declares the end of sleep. In a similar manner, a number of patient conditions, such as heart rate, respiration rate, brain wave activity, etc., may be compared individually or collectively compared to thresholds or other indices to detect sleep.

[0080] An enhanced method of sleep detection is described in commonly owned U.S. patent application, Ser. No. 10/309,771, filed Dec. 4, 2002, which is incorporated herein by reference. The method involves adjusting a sleep threshold associated with a first patient condition using a second patient condition. The first patient condition is compared to the adjusted threshold to determine if the patient is asleep or awake.

[0081] **FIG. 4** is a block diagram of a sleep detection unit **400** that may be used as part of a sleep quality data system according to embodiments of the invention. The sleep detection unit **400** uses a number of sensors **401, 402, 403** to sense sleep-related patient conditions. A representative set of sleep-related conditions include, for example, patient activity, patient location, posture, heart rate, QT interval, eye movement, respiration rate, transthoracic impedance, tidal volume, minute ventilation, brain activity, muscle tone, body temperature, time of day, and blood oxygen level.

[0082] According to embodiments of the invention, a first sleep-related condition detected using a sleep detection sensor **401** is compared to a sleep threshold for detecting the onset and termination of sleep. A second sleep-related condition, detected using a threshold adjustment sensor **402**, is used to adjust the sleep threshold. Although the example described herein involves one sleep detection sensor **401** and one threshold adjustment sensor **402**, any number of thresholds or other indices corresponding to a number of sleep detection sensors may be used. Furthermore, conditions detected using any number of adjustment sensors may be used to adjust the thresholds or indices of a plurality of sleep detection signals. Additional sleep-related signals derived from one or more confirmation sensors **403** may optionally be used to confirm the onset or termination of the sleep condition.

[0083] Signals derived from the sensors **401, 402, 403** are received by a sensor driver/detection circuitry **410** that may include, for example, amplifiers, signal processing circuitry, and/or A/D conversion circuitry for processing each sensor signal. The sensor driver/detection system **410** may further include sensor drive circuitry required to activate the sensors **401, 402, 403**.

[0084] The sensor signal detection system **410** is coupled to a sleep detector **430**. The sleep detector **430** is configured to compare the level of a first sleep-related condition detected using the sleep detection sensor **401** to a sleep threshold adjusted by a second sleep-related condition detected using the threshold adjustment sensor **402**. A determination of sleep onset or sleep termination may be made by the sleep detector **430** based on the comparison. The onset or termination of sleep may optionally be confirmed using patient conditions derived using a sleep confirmation sensor **403**.

[0085] **FIG. 5** is a flow chart illustrating a method of detecting sleep used in a sleep quality data system configured according to principles of the invention. A sleep threshold associated with a first sleep-related patient condition is established **505**. The sleep threshold may be determined from clinical data of a sleep threshold acquired using a group of subjects, for example. The sleep threshold may also be determined using historical data taken from the particular patient for whom the sleep condition is to be detected.

[0086] First and second sleep-related conditions are detected **510, 520**. The first and the second sleep-related conditions may be detected using sensors implanted in the patient, attached externally to the patient or located remote from the patient, for example, as previously described in connection with **FIG. 3**. The first and the second sleep-related conditions may include any condition associated with sleep and are not limited to the representative sleep-related conditions listed above.

[0087] The sleep threshold established for the first sleep-related condition is adjusted using the second sleep-related condition **530**. For example, if the second sleep-related condition indicates a high level of activity that is incompatible with a sleep state, the sleep threshold of the first sleep-related condition may be adjusted downward to require sensing a decreased level of the first sleep-related condition before a sleep condition is detected.

[0088] If the first sleep-related condition is consistent with sleep according to the adjusted sleep threshold **540**, sleep is detected **550**. If the first sleep-related condition is not consistent with sleep using the adjusted sleep threshold, the first and the second sleep-related conditions continue to be detected **510, 520** and the threshold adjusted **530** until sleep is detected **550**.

[0089] The flow chart of **FIG. 6** illustrates a method for detecting sleep using accelerometer and MV signals according to embodiments of the invention. In the method illustrated in **FIG. 6**, an accelerometer and a minute ventilation sensor are used to detect patient activity and patient respiration conditions, respectively. A preliminary sleep threshold is determined **610** with respect to the patient activity condition sensed by the accelerometer. The preliminary sleep threshold may be determined from clinical data derived from a group of subjects or from historical data taken from the patient over a period of time.

[0090] The activity condition of the patient is monitored **620** using an accelerometer that may be incorporated in an implantable cardiac rhythm management system as described in connection with **FIG. 3**. Alternatively, the accelerometer may be attached externally to the patient. The patient's MV condition is monitored **625**, for example, using a transthoracic impedance sensor. A transthoracic impedance sensor may be implemented as a component of an implantable CRM device.

[0091] In this embodiment, the patient's activity represents the sleep detection condition and is compared to the sleep threshold. The patient's MV is used as the threshold adjustment condition to adjust the sleep threshold. In addition, in this example, the patient's heart rate is monitored **630** and used to provide a sleep confirmation condition.

[0092] The sleep threshold adjustment is accomplished using the patient's MV condition to adjust the activity sleep

threshold. If the patient's MV condition is low relative to an expected MV level associated with sleep, the activity sleep threshold is increased. Similarly, if the patient's MV level is high relative to an expected MV level associated with sleep, the activity sleep threshold is decreased. Thus, when the patient's MV level is high, less activity is required to make the determination that the patient is sleeping. Conversely when the patient's MV level is relatively low, a higher activity level may result in detection of sleep. The use of two sleep-related conditions to determine the patient's sleep state enhances the accuracy of sleep detection over previous methods.

[0093] Various signal processing techniques may be employed to process the raw sensor signals. For example, a moving average of a plurality of samples of the sensor signals may be calculated. Furthermore, the sensor signals may be amplified, filtered, digitized or otherwise processed.

[0094] If the MV level is high **635** relative to an expected MV level associated with sleep, the activity sleep threshold is decreased **640**. If the MV level is low **635** relative to an expected MV level associated with sleep, the activity sleep threshold is increased **645**.

[0095] If the patient's activity level is less than or equal to the adjusted sleep threshold **650**, and if the patient is currently in a sleep state **665**, then the patient's heart rate is checked **680** to confirm that the patient is asleep. If the patient's heart rate is compatible with sleep **680**, then sleep onset is determined **690**. If the patient's heart rate is incompatible with sleep, then the patient's sleep-related conditions continue to be monitored.

[0096] If the patient's activity level is less than or equal to the adjusted sleep threshold **650** and if the patient is currently in a sleep state **665**, then a continuing sleep state is determined and the patient's sleep-related conditions continue to be monitored for sleep termination to occur.

[0097] If the patient's activity level is greater than the adjusted sleep threshold **650** and the patient is not currently in a sleep state **660**, then the patient's sleep-related conditions continue to be monitored until sleep onset is detected **690**. If the activity level is greater than the adjusted sleep threshold **650** and the patient is currently in a sleep state **660**, then sleep termination is detected **670**.

[0098] The graphs of **FIGS. 7-10** illustrate the adjustment of the activity sleep threshold. The relationship between patient activity and the accelerometer and MV signals is trended over a period of time to determine relative signal levels associated with sleep. The graph of **FIG. 7** illustrates the patient's activity as indicated by an accelerometer. The patient's heart rate for the same period is shown in the graph of **FIG. 8**. The accelerometer signal indicates a period of sleep associated with a relatively low level of activity beginning slightly before 23:00 and continuing through 6:00. The patient's heart rate appropriately tracks the activity level indicated by the accelerometer indicating a similar period of decreased heart rate corresponding to sleep. The signal level of the accelerometer during known periods of sleep may be used to establish a threshold for sleep detection.

[0099] **FIG. 9** is a graph of the patient's minute ventilation signal over time. Historical data of minute ventilation is graphed over an 8 month period. The minute ventilation data

may be used to determine the minute ventilation signal level associated with sleep. In this example, a composite minute ventilation graph using the historical data presents a roughly sinusoidal shape with the relatively low minute ventilation levels occurring during the period approximately from hours 21:00 through 8:00. The decreased minute ventilation level is associated with periods of sleep. The minute ventilation level associated with sleep is used to implement sleep threshold adjustment.

[0100] FIG. 10 illustrates adjustment of the activity sleep threshold using the MV data. The initial sleep threshold 1010 is established using the baseline activity data acquired as discussed above. If the patient's MV level is low relative to an expected MV level associated with sleep, the activity sleep threshold is increased 1020. If the patient's MV level is high relative to an expected MV level associated with sleep, the activity sleep threshold is decreased 1030. When the patient's MV level is high, less activity detected by the accelerometer is required to make the determination that the patient is sleeping. However, if the patient's MV level is relatively low, a higher activity level may result in detection of sleep. The use of two sleep-related signals to establish and adjust a sleep threshold enhances the accuracy of sleep detection over previous methods.

[0101] Additional sleep-related conditions may be sensed and used to improve the sleep detection method described above. For example, a posture sensor may be used to detect the posture of the patient and used to confirm sleep. If the posture sensor signal indicates an upright posture, then the posture sensor signal may be used to override a determination of sleep using the sleep detection and threshold adjustment conditions. Other conditions may also be used in connection with sleep determination or confirmation, including the representative set of sleep-related conditions indicated above. In another example, a proximity to bed sensor may be used alone or in combination with a posture sensor to detect that the patient is in bed and is lying down.

[0102] A sleep detection system may detect sleep onset, termination, arousals as well as the sleep stages, including REM and non-REM sleep. REM sleep may be discriminated from NREM sleep, for example, by examining one or more signals indicative of REM, e.g., muscle atonia, rapid eye movements, or EEG signals. Methods and systems for detecting REM sleep that are particularly useful for patients with implantable devices are discussed in commonly owned U.S. patent application identified under Docket Number GUID.060PA, and entitled "Sleep State Classification," concurrently filed with the present application, and incorporated herein by reference. Various conditions indicative of sleep state may be detected using sensors, e.g., electroencephalogram (EEG), electrooculogram (EOG), or electromyogram (EMG) sensors, coupled through wired or wireless connections to the sleep detection circuitry. The sleep detection circuitry may analyze the various patient conditions sensed by the sensors to track the patient's sleep through various sleep states, including REM and NREM stages.

[0103] Returning to FIG. 3, the sleep quality data system 300 may also employ disordered breathing detection circuitry 342 to detect episodes of disordered breathing. Disordered breathing may be detected in numerous ways using one or more of the patient conditions listed in Table 1. Methods and systems for detecting disordered breathing are

described in commonly owned U.S. patent application, Ser. No. 10/309,770, filed Dec. 4, 2002, which is incorporated herein by reference. According to this approach, disordered breathing may be detected by examining characteristics of the patient's respiration patterns to determine if the respiration patterns are consistent with disordered breathing.

[0104] FIG. 11 illustrates a normal respiration pattern as represented by a transthoracic impedance sensor signal. The transthoracic impedance increases during respiratory inspiration and decreases during respiratory expiration. During NREM sleep, a normal respiration pattern includes regular, rhythmic inspiration—expiration cycles without substantial interruptions.

[0105] In one embodiment, detection of disordered breathing, including, for example, sleep apnea and hypopnea, involves defining and examining a number of respiratory cycle intervals. FIG. 12 illustrates respiration intervals used for disordered breathing detection according to an embodiment of the invention. A respiration cycle is divided into an inspiration period corresponding to the patient inhaling, an expiration period, corresponding to the patient exhaling, and a non-breathing period occurring between inhaling and exhaling. Respiration intervals are established using inspiration 1210 and expiration 1220 thresholds. The inspiration threshold 1210 marks the beginning of an inspiration period 1230 and is determined by the transthoracic impedance signal rising above the inspiration threshold 1210. The inspiration period 1230 ends when the transthoracic impedance signal is maximum 1240. A maximum transthoracic impedance signal 1240 corresponds to both the end of the inspiration interval 1230 and the beginning of the expiration interval 1250. The expiration interval 1250 continues until the transthoracic impedance falls below an expiration threshold 1220. A non-breathing interval 1260 starts from the end of the expiration period 1250 and continues until the beginning of the next inspiration period 1270.

[0106] Detection of sleep apnea and severe sleep apnea according to embodiments of the invention is illustrated in FIG. 13. The patient's respiration signals are monitored and the respiration cycles are defined according to inspiration 1330, expiration 1350, and non-breathing 1360 intervals as described in connection with FIG. 12. A condition of sleep apnea is detected when a non-breathing period 1360 exceeds a first predetermined interval 1390, denoted the sleep apnea interval. A condition of severe sleep apnea is detected when the non-breathing period 1360 exceeds a second predetermined interval 1395, denoted the severe sleep apnea interval. For example, sleep apnea may be detected when the non-breathing interval exceeds about 10 seconds, and severe sleep apnea may be detected when the non-breathing interval exceeds about 20 seconds.

[0107] Hypopnea is a condition of disordered breathing characterized by abnormally shallow breathing. FIGS. 14A-B are graphs of respiration patterns derived from transthoracic impedance measurements. The graphs compare the tidal volume of a normal breathing cycle to the tidal volume of a hypopnea episode. FIG. 14A illustrates normal respiration tidal volume and rate. As shown in FIG. 14B, hypopnea involves a period of abnormally shallow respiration.

[0108] According to an embodiment of the invention, hypopnea is detected by comparing a patient's respiratory

tidal volume to a hypopnea tidal volume threshold. The tidal volume for each respiration cycle may be derived from transthoracic impedance measurements. The hypopnea tidal volume threshold may be established using clinical results providing a representative tidal volume and duration for hypopnea events. In one configuration, hypopnea is detected when an average of the patient's respiratory tidal volume taken over a selected time interval falls below the hypopnea tidal volume threshold.

[0109] FIG. 15 is a flow chart illustrating a method of apnea and/or hypopnea detection according to embodiments of the invention. Various parameters are established **1501** before analyzing the patient's respiration for disordered breathing episodes, including, for example, inspiration and expiration thresholds, sleep apnea interval, severe sleep apnea interval, and hypopnea tidal volume threshold.

[0110] The patient's transthoracic impedance is detected **1505**. If the transthoracic impedance exceeds **1510** the inspiration threshold, the beginning of an inspiration interval is detected **1515**. If the transthoracic impedance remains below **1510** the inspiration threshold, then the impedance signal is checked **1505** periodically until inspiration **1515** occurs.

[0111] During the inspiration interval, the patient's transthoracic impedance is monitored until a maximum value of the transthoracic impedance is detected **1520**. Detection of the maximum value signals an end of the inspiration period and a beginning of an expiration period **1535**.

[0112] The expiration interval is characterized by decreasing transthoracic impedance. When the transthoracic impedance falls below **1540** the expiration threshold, a non-breathing interval is detected **1555**.

[0113] If the transthoracic impedance does not exceed **1560** the inspiration threshold within a first predetermined interval **1565**, denoted the sleep apnea interval, then a condition of sleep apnea is detected **1570**. Severe sleep apnea is detected **1580** if the non-breathing period extends beyond a second predetermined interval **1575**, denoted the severe sleep apnea interval.

[0114] When the transthoracic impedance exceeds **1560** the inspiration threshold, the tidal volume from the peak-to-peak transthoracic impedance is calculated **1585**. The peak-to-peak transthoracic impedance provides a value proportional to the tidal volume of the respiration cycle. This value is compared **1590** to a hypopnea tidal volume threshold. If the peak-to-peak transthoracic impedance is consistent with **1590** the hypopnea tidal volume threshold for a predetermined time **1592**, then a hypopnea cycle is detected **1595**.

[0115] Additional sensors, such as motion sensors and/or posture sensors, may be used to confirm or verify the detection of a sleep apnea or hypopnea episode. The additional sensors may be employed to prevent false or missed detections of sleep apnea or hypopnea due to posture and/or motion related artifacts.

[0116] Another embodiment of the invention involves classifying respiration patterns as disordered breathing episodes based on the breath intervals and/or tidal volumes of one or more respiration cycles within the respiration patterns. According to this embodiment, the duration and tidal

volumes associated with a respiration pattern are compared to duration and tidal volume thresholds. The respiration pattern may be determined to represent a disordered breathing episode based on the comparison.

[0117] According to this embodiment, a breath interval **1630** is established for each respiration cycle. A breath interval represents the interval of time between successive breaths, as illustrated in **FIG. 16**. A breath interval **1630** may be defined in a variety of ways, for example, as the interval of time between successive maxima **1610**, **1620** of the impedance signal waveform.

[0118] Detection of disordered breathing, in accordance with methods of the invention, involves the establishment of a duration threshold and a tidal volume threshold. If a breath interval exceeds the duration threshold, an apnea event is detected. Detection of sleep apnea, in accordance with this embodiment, is illustrated in the graph of **FIG. 16**. Apnea represents a period of non-breathing. A breath interval **1630** exceeding a duration threshold **1640** comprises an apnea episode.

[0119] Hypopnea may be detected using a duration threshold and a tidal volume threshold. A hypopnea event represents a period of shallow breathing greater than the duration threshold. Each respiration cycle in a hypopnea event is characterized by a tidal volume less than the tidal volume threshold. Further, the decreased tidal volume cycles persist longer than the duration threshold.

[0120] A hypopnea detection approach, in accordance with embodiments of the invention, is illustrated in **FIG. 17**. Shallow breathing is detected when the tidal volume of one or more breaths is below a tidal volume threshold **1710**. If the shallow breathing continues for an interval greater than a duration threshold **1720**, then the breathing pattern represented by the sequence of shallow respiration cycles, is classified as a hypopnea event.

[0121] **FIGS. 18A and 18B** provide charts illustrating classification of individual disordered breathing events and combination of periodic breathing events, respectively. As illustrated in **FIG. 18A**, individual disordered breathing events may be grouped into apnea, hypopnea, tachypnea and other disordered breathing events. Apnea events are characterized by an absence of breathing. Intervals of reduced respiration are classified as hypopnea events. Tachypnea events include intervals of rapid respiration characterized by an elevated respiration rate.

[0122] As illustrated in **FIG. 18A**, apnea and hypopnea events may be further subdivided as either central events, e.g., caused either by central nervous system dysfunction, or obstructive events, e.g., caused by upper airway obstruction. A tachypnea event may be further classified as a hyperpnea event, represented by rapid deep breathing (hyperventilation). A tachypnea event may alternatively be classified as rapid shallow breathing, typically of prolonged duration.

[0123] **FIG. 18B** illustrates classification of periodic disordered breathing events. Periodic breathing may be classified as obstructive, central or mixed. Obstructive periodic breathing is characterized by cyclic respiratory patterns with an obstructive apnea or hypopnea event in each cycle. In central periodic breathing, the cyclic respiratory patterns include a central apnea or hypopnea event in each cycle. Periodic breathing may also be of mixed origin. In this case,

cyclic respiratory patterns have a mixture of obstructive and central apnea events in each cycle. Cheyne-Stokes respiration is a particular type of periodic breathing characterized by a gradual waxing and waning of tidal volume and having a central apnea and hyperpnea event in each cycle. Other manifestations of periodic breathing are also possible.

[0124] As illustrated in FIGS. 18C-G, a respiration pattern detected as a disordered breathing episode may include only an apnea respiration cycle 1810 (FIG. 18C), only hypopnea respiration cycles 1850 (FIG. 18F), or a mixture of hypopnea and apnea respiration cycles 1820 (FIG. 18D), 1830 (FIG. 18E), 1860 (FIG. 18G). A disordered breathing event 1820 may begin with an apnea respiration cycle and end with one or more hypopnea cycles. In another pattern, the disordered breathing event 1830 may begin with hypopnea cycles and end with an apnea cycle. In yet another pattern, a disordered breathing event 1860 may begin and end with hypopnea cycles with an apnea cycle in between the hypopnea cycles. Analysis of the characteristic respiration patterns associated with various types of disordered breathing may be used to detect, classify and evaluate disordered breathing episodes.

[0125] FIG. 19 is a flow chart of a method for detecting disordered breathing by classifying breathing patterns using breath intervals in conjunction with tidal volume and duration thresholds as previously described above. In this example, a duration threshold and a tidal volume threshold are established for determining both apnea and hypopnea breath intervals. An apnea episode is detected if the breath interval exceeds the duration threshold. A hypopnea episode is detected if the tidal volume of successive breaths remains less than the tidal volume threshold for a period in excess of the duration threshold. Mixed apnea/hypopnea episodes may also occur. In these cases, the period of disordered breathing is characterized by shallow breaths or non-breathing intervals. During the mixed apnea/hypopnea episodes, the tidal volume of each breath remains less than the tidal volume threshold for a period exceeding the duration threshold.

[0126] The patient's respiration cycles are determined, for example, using transthoracic impedance signals. Each breath 1910 is characterized by a breath interval, i.e., the interval of time between two impedance signal maxima and a tidal volume (TV). If a breath interval exceeds 1915 the duration threshold, then the respiration pattern is consistent with an apnea event, and an apnea event trigger is turned on 1920. If the tidal volume of the breath interval exceeds 1925 the tidal volume threshold, then the breathing pattern is characterized by two respiration cycles of normal volume separated by a non-breathing interval. This pattern represents a purely apneic disordered breathing event, and apnea is detected 1930. Because the final breath of the breath interval was normal, the apnea event trigger is turned off 1932, signaling the end of the disordered breathing episode. However, if the tidal volume of the breath interval does not exceed 1925 the tidal volume threshold, the disordered breathing period is continuing and the next breath is checked 1910.

[0127] If the breath interval does not exceed 1915 the duration threshold, then the tidal volume of the breath is checked 1935. If the tidal volume does not exceed 1935 the tidal volume threshold, the breathing pattern is consistent

with a hypopnea cycle and a hypopnea event trigger is set on 1940. If the tidal volume exceeds the tidal volume threshold, then the breath is normal.

[0128] If a period of disordered breathing is in progress, detection of a normal breath signals the end of the disordered breathing. If disordered breathing was previously detected 1945, and if the disordered breathing event duration has not exceeded 1950 the duration threshold, and the current breath is normal, then no disordered breathing event is detected 1955. If disordered breathing was previously detected 1945, and if the disordered breathing event duration has extended for a period of time exceeding 1950 the duration threshold, and the current breath is normal, then the disordered breathing trigger is turned off 1960. In this situation, the duration of the disordered breathing episode was of sufficient duration to be classified as a disordered breathing episode. If an apnea event was previously triggered 1965, then an apnea event is declared 1970. If a hypopnea was previously triggered 1965, then a hypopnea event is declared 1975.

[0129] As previously discussed in connection with FIG. 3, a sleep quality analysis unit 340 may incorporate an abnormal nocturnal movement detector 344 to evaluate the movements of a patient during the night to detect nocturnal movement disorders such as RLS, PLMD, and/or bruxism. The patient may be instrumented with accelerometers located on the limbs or jaw, for example, to sense patient movement. Excessive movement, or movements having a characteristic pattern, e.g., periodic limb or jaw movements, may be classified as abnormal nocturnal movements. For example, bruxism is a sleep disorder wherein the patient grinds his teeth during sleep. An accelerometer attached to the patient's jaw may be used to sense movement of the jaw. Signals from the jaw accelerometer may be transferred to the abnormal movement detector for evaluation to determine if the movements are excessive or unusually periodic, indicating bruxism. In a similar application, accelerometers attached to the patient's limbs may generate signals used by the abnormal movement detector 344 to detect and classify disorders such as RLS and PLMD.

[0130] FIG. 20 illustrates a patient 2010 instrumented with a sleep quality data system 2000 according to embodiments of the invention. The sleep quality data system collects sleep quality data from the patient using a number of sensors 2011-2019. In one configuration, the collected data is analyzed by a sleep quality analysis unit that may be an integrated component of an implantable sleep quality data collection and analysis unit 2020. In another configuration, the collected data may be downloaded to a patient-external device 2030 for storage, analysis, or display.

[0131] In the implementation illustrated in FIG. 20, the sleep quality data system 2000 includes an implantable sleep quality data collection and analysis unit 2020 coupled to a number of sensors 2011-2019. In this example, the sensors include an EGM sensor 2016 for detecting heart rate and heart rate variability conditions. A transthoracic impedance sensor 2017 is used to detect the respiration conditions of the patient, including, for example, minute ventilation, respiration rate, and tidal volume. An activity detector, e.g., accelerometer, 2015 may be used to detect patient activity conditions. The sleep quality data system detects patient conditions including the patient's posture and location using a posture sensor 2014 and a proximity to bed sensor 2013,

respectively. The sleep quality data system senses the patient's brain activity using EEG sensors **2011** and the patient's eye movements using EOG sensors **2012**. Jaw and limb movements are sensed using accelerometers attached to the patient's jaw **2018** and legs **2019**.

[0132] In this application, the sleep quality data collection and analysis unit **2020** is configured to track the patient's heart rate, heart rate variability, minute ventilation, respiration rate, tidal volume, posture, proximity to bed, brain activity, eye movements, jaw movements and leg movements. At periodic intervals, the system samples signals from the sensors and stores data regarding the detected conditions in memory circuitry within the sleep quality data collection and analysis unit **2020**. The sleep quality data collection and analysis unit **2020** may additionally access an external input unit **2030** to detect patient reported conditions, for example, recent tobacco and medication use by the patient. Further, the sleep quality data collection and analysis unit **2020** may monitor conditions using one or more external sensors. In the illustrated example, a thermometer **2035** is coupled through the external programmer **2030** and a pollution website **2040** is accessible to the sleep quality data collection and analysis unit **2020** through the internet **2050**.

[0133] The sleep quality data collection and analysis unit **2020** may operate to acquire data during periods of both sleep and wakefulness. It may be beneficial, for example, to track changes in particular conditions measured during periods of wakefulness that are associated with sleep disordered breathing. For example, some patients who suffer from sleep apnea experience changes in heart rate variability, blood pressure variability, and/or sympathetic nerve activity during periods of wakefulness. Detection and analysis of the physiological changes attributable to sleep disorders and measurable during the time the patient is awake provides a more complete picture of sleep quality.

[0134] In another example, the patient's sleep quality may be evaluated by determining the patient's activity level while the patient is awake. The activity level of the patient during the day may provide important information regarding the patient's sleep quality. For example, if the patient is very inactive during periods of wakefulness, this may indicate that the patient's sleep is of inadequate quality or duration. Such information may also be used in connection with assessing the efficacy of a particular sleep disorder therapy and/or adjusting the patient's sleep disorder therapy. Methods and systems for determining the patient's activity level and generally assessing the well-being of a patient are described in commonly owned U.S. Pat. No. 6,021,351 which is incorporated herein by reference.

[0135] The analysis unit **2020** may calculate one or more sleep quality metrics quantifying the patient's sleep quality. A representative set of the sleep quality metrics include, for example, sleep efficiency, sleep fragmentation, number of arousals per hour, denoted the arousal index (AI).

[0136] The analysis unit **2020** may also compute one or more metrics quantifying the patient's disordered breathing, such as the apnea hypopnea index (AHI) providing the number of apneas and hypopneas per hour, and the percent time in periodic breathing (% PB).

[0137] Further, metrics associated with sleep movement disorders may also be determined by the analysis unit **2020**.

Such metrics may include, for example, a general sleep movement disorder index (MDI) representing the number of abnormal movements arising from movement disorders such as restless leg syndrome, periodic limb movement disorder and bruxism per hour. In addition, specific indices may be calculated for each type of movement disorder, e.g., a bruxism index (BI) characterizing the number of jaw movements per hour, a RLS index (RLSI) characterizing the number of restless leg syndrome episodes per hour, and a PLM index (PLMI) characterizing the number of periodic limb movements experienced by the patient per hour.

[0138] In addition, percentage of sleep time during which the patient experiences movement disorders (% MD) may be calculated. Specific metrics relating to the percentage of time during which the patient experiences bruxism (% B), restless leg syndrome (% RLS), and periodic leg movement disorder (% PLMD) may also be determined.

[0139] Further, sleep summary metrics may be computed, either directly from the collected patient condition data, or by combining the above-listed sleep quality and sleep disorder metrics. In one embodiment, a composite sleep disordered respiration metric (SDRM) may be computed by combining the apnea hypopnea index AHI and the arousal index AI. The composite sleep disordered respiration metric (SDRM) may be computed as a linear combination of the AHI and AI as follows:

$$SDRM = c_1 * AHI + c_2 * AI \qquad [1]$$

[0140] where c_1 and c_2 are constants chosen to balance the relative contributions of respiratory and arousal effects on sleep disturbance. The AHI may be monitored by performing disordered breathing detection based on transthoracic impedance measurements as previously described. The AI may be estimated, for example, by monitoring the patient activity, minute ventilation, and posture sensors for body motion indicating sleep termination or arousal. A more sensitive measure of arousal may be made using EEG signals. In this implementation, the constant c_2 may be adjusted to reflect the increased sensitivity to arousal.

[0141] In another embodiment, an undisturbed respiration sleep time (URST) or undisturbed respiration sleep efficiency (URSE) may be computed based on the amount of time the patient spends asleep in bed without respiratory disturbance.

[0142] The URST or URSE metrics may be determined using three parameters: total time in bed (TIB), total time asleep (TA), and combined sleep time duration in disturbed respiration (STDR). Time in bed may be determined by a combination of posture sensing and sensing the proximity of the patient to bed. The posture condition of the patient may determined, for example, using an implantable multiaxis accelerometer sensor.

[0143] The patient's total time in bed (TIB) may be determined using a proximity to bed sensor. The proximity to bed sensor may use a receiver in the sleep quality data collection and analysis unit **2020** for receiving signals transmitted from a beacon **2070** located at the patient's bed **2060**. If the proximity to bed receiver detects a signal of sufficient strength from the proximity to bed beacon **2070**, then the receiver detects that the patient is in bed **2060**.

[0144] Total time asleep (TA) may be determined using the sleep detection method described in more detail above.

The total sleep time in disturbed respiration (STDR) may be determined, for example, based on detection of sleep and disordered breathing using the sleep and disordered breathing detection methods described above.

[0145] The patient's undisturbed respiration sleep time (URST) is calculated as:

$$URST = TA - STDR \quad [2]$$

[0146] where TA=total time asleep and STDR=sleep time in disturbed breathing.

[0147] The undisturbed respiration sleep efficiency (USE) in percent is calculated

$$URSE = 100 * URST / TIB \quad [3]$$

[0148] where URST=undisturbed respiration sleep time and TIB=total time in bed.

[0149] Similar metrics may be calculated for movement disorders generally, or for specific movement disorders, e.g., RLS, PLMD, or bruxism. For example, the composite RLS, PLMD, and bruxism metrics, RLSM, PLMDM, and BM, respectively, may be calculated using equations similar in form to equation 1 above:

$$RLSM = c_1 * RLSI + c_2 * AI \quad [4]$$

[0150] where RLSI=number of restless leg movement syndrome episodes per hour, AI=number of arousals per hour, and c_1 and c_2 are constants chosen to balance the relative contributions of abnormal movement and arousal effects on sleep disturbance.

$$PLMDM = c_1 * PLMDI + c_2 * AI \quad [5]$$

[0151] where PLMDI=number of periodic leg movement syndrome episodes per hour, AI=number of arousals per hour, and c_1 and c_2 are constants chosen to balance the relative contributions of abnormal movement and arousal effects on sleep disturbance.

$$BM = c_1 * BMI + c_2 * AI \quad [6]$$

[0152] where BMI=number of bruxism movement episodes per hour, AI=number of arousals per hour, and c_1 and c_2 are constants chosen to balance the relative contributions of abnormal movement and arousal effects on sleep disturbance.

[0153] The patient's undisturbed movement sleep time (UMST) and undisturbed movement sleep efficiency (UMSE) may be calculated for each movement related disorder separately or in combination using equations similar in form to equations 2 and 3, above.

[0154] In addition, a composite sleep disorder index SDI quantifying the combined effect of both respiratory and movement disorders may be computed by combining the apnea hypopnea index (AHI), the movement disorder index (MDI), and the arousal index (AI).

[0155] A sleep disturbance index (SDI) may be computed as a linear combination of the AHI, and the combined disorder index DI_c. The combined disorder index may include both abnormal breathing and movement components. For example, the sleep disturbance index SDI is characterizable by the equation:

$$SDI = c_4 * DI_c + c_3 * AI, \quad [7]$$

[0156] where DI_c is a combined disorder index of the form:

$$DI_c = c_{41} * DI_1 + c_{42} * DI_2 \quad [7a]$$

[0157] In equation 7, c_4 and c_3 are constants chosen to balance the relative contributions of the combined disorder and arousal effects, respectively. The disorder index, DI_c, may be used to characterize the effects of one or more sleep disorders, including, e.g., disorders associated with disturbed respiration and/or abnormal movements. The combined disorder index may represent only one disorder index, or may be a linear combination of two or more sleep disorder indices, e.g., the apnea/hypopnea index (AHI) and the abnormal movement disorder index (MDI). The constants C_{41} and c_{42} may be used as weighting factors associated with particular disorder indices.

[0158] The patient's undisturbed sleep time (UST) may be calculated:

$$UST = TA - STSD \quad [8]$$

[0159] where TA=total time asleep and STSD=sleep time spent in sleep disorders.

[0160] The undisturbed sleep efficiency (USE) in percent may be calculated:

$$USE = 100 * UST / TIB \quad [9]$$

[0161] where UST=undisturbed sleep time and TIB=total time in bed.

[0162] Sleep quality metrics, such as those described above, or other metrics, may be acquired and analyzed using the sleep quality data collection and analysis unit 2020. Sleep quality metrics, in addition to raw or processed data based on physiological and non-physiological conditions may determined periodically, e.g., daily, and stored or transmitted to another device. Such data can be presented to the patient's health care professional on a real-time basis, or as a long-term, e.g., month long or year long, trend of daily measurements.

[0163] The health care professional may access the data during clinic visits via programmer interrogation of the implanted device, through occasional or periodic transtelephonic device interrogations, or through an automatic or "on-demand" basis in the context of an advanced patient management system. The health care professionals may use the sleep quality indicator trends alone or in conjunction with other device-gathered or clinical data to diagnose disorders and/or adjust the patient's device or medical therapy as needed to improve the patient's quality of sleep.

[0164] The present invention provides diagnostic, monitoring, and evaluation capabilities relating to sleep quality and may be particularly valuable in the context of an advanced patient management system. Undiagnosed sleep disorders can lead to increased morbidity and mortality, such as those arising from various respiratory and cardiovascular consequences. Routine monitoring of patient sleep quality may lead to improved diagnosis and treatment of these syndromes and their associated co-morbidities. The invention may provide less obtrusive sleep quality monitoring, particularly and is suited for patients having an implanted device. The present invention serves to improve diagnosis of sleep disorders by reducing the inconveniences, unnatural sleep environment issues, and expenses associated with sleep clinic polysomnogram studies.

[0165] The following commonly owned U.S. patents applications, some of which have been identified above, are hereby incorporated by reference in their respective entireties: U.S. patent application Ser. No. 10/309,770 (Docket Number GUID.064PA), filed Dec. 4, 2002, U.S. patent application Ser. No. 10/309,771 (Docket Number GUID.054PA), filed Dec. 4, 2002, U.S. patent application entitled "Prediction of Disordered Breathing," identified by Docket Number GUID.088PA and concurrently filed with this patent application, U.S. patent application entitled "Adaptive Therapy for Disordered Breathing," identified by Docket Number GUID.059PA and filed concurrently with this patent application, U.S. patent application entitled "Prediction of Disordered Breathing," identified by Docket Number GUID.088PA and filed concurrently with this patent application, and U.S. patent application entitled "Therapy Triggered by Prediction of Disordered Breathing," identified by Docket Number GUID.103PA and filed concurrently with this patent application.

[0166] Various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

What is claimed is:

1. A method for collecting sleep quality data, comprising:

detecting physiological and non-physiological conditions associated with sleep quality of a patient; and

collecting sleep quality data based on the detected conditions, wherein collecting the sleep quality data is performed at least in part implantably.

2. The method of claim 1, wherein detecting the conditions comprises detecting a cardiovascular system condition.

3. The method of claim 1, wherein detecting the conditions comprises detecting a respiratory system condition.

4. The method of claim 1, wherein detecting the conditions comprises detecting a muscle system condition.

5. The method of claim 1, wherein detecting the conditions comprises detecting a blood chemistry condition.

6. The method of claim 1, wherein detecting the conditions comprises detecting a nervous system condition.

7. The method of claim 1, wherein detecting the conditions comprises detecting an environmental condition.

8. The method of claim 1, wherein detecting the conditions comprises detecting a contextual condition.

9. The method of claim 1, wherein collecting the sleep quality data comprises collecting data associated with sleep stages.

10. The method of claim 1, wherein collecting the sleep quality data comprises collecting data associated with sleep disruption.

11. The method of claim 1, wherein collecting the sleep quality data comprises collecting data associated with disordered breathing.

12. The method of claim 1, wherein collecting the sleep quality data comprises collecting data associated with a movement disorder.

13. The method of claim 1, further comprising storing the collected sleep quality data.

14. The method of claim 1, further comprising transmitting the collected sleep quality data.

15. A method for assessing sleep quality, comprising:

determining one or more metrics associated with sleep;

determining one or more metrics associated with events that disrupt sleep; and

determining a composite sleep quality metric as a function of the one or more metrics associated with sleep and the one or more metrics associated with events that disrupt sleep.

16. The method of claim 15, wherein at least one of determining the one or more metrics associated with sleep, determining the one or more metrics associated with events that disrupt sleep, and determining the composite sleep quality metric is performed at least in part implantably.

17. The method of claim 15, wherein determining the one or more metrics associated with sleep comprises determining a metric characterizing arousals.

18. The method of claim 15, wherein determining the one or more metrics associated with sleep comprises determining a metric characterizing total time asleep.

19. The method of claim 15, wherein determining the one or more metrics associated with sleep comprises determining a metric characterizing time in bed.

20. The method of claim 15, wherein determining the one or more metrics associated with events that disrupt sleep comprises determining one or more metrics associated with a sleep disorder.

21. The method of claim 15, wherein determining the one or more metrics associated with events that disrupt sleep comprises determining one or more metrics associated with a movement disorder.

22. The method of claim 15, wherein determining the one or more metrics associated with events that disrupt sleep comprises determining one or more metrics associated with disordered breathing.

23. The method of claim 15, wherein determining the one or more metrics associated with events that disrupt sleep comprises determining a metric characterizing sleep time spent in one or more sleep disorders.

24. The method of claim 15, wherein determining the composite sleep quality metric comprises determining a sleep disturbance index.

25. The method of claim 24, wherein determining the sleep disturbance index comprises calculating a metric as a function of a combination of one or more sleep disorder indices and an arousal index.

26. The method of claim 24, wherein determining the sleep disturbance index comprises calculating a metric as a function of a combination of a movement disorder index and an arousal index.

27. The method of claim 24, wherein determining the sleep disturbance metric comprises calculating a metric as a function of a combination of a disordered breathing index and an arousal index.

28. The method of claim 24, wherein the sleep disturbance index is characterizable using the equation:

$$SDI = c_1 \cdot DI + c_2 \cdot AI$$

where DI is associated with a sleep disorder index, AI is associated with an arousal index, and c_1 and c_2 are constants.

29. The method of claim 15, wherein determining the composite sleep quality metric comprises determining an undisturbed sleep time metric.

30. The method of claim 29, wherein the undisturbed sleep time metric, UST, is characterizable using the equation:

$$UST = TA - STSD,$$

where TA is associated with total time asleep and STSD is associated with sleep time spent in sleep disorders.

31. The method of claim 15, wherein determining the composite sleep quality metric comprises determining an undisturbed sleep efficiency metric.

32. The method of claim 31, wherein the undisturbed sleep efficiency metric, USE, is characterizable using the equation:

$$USE = 100*(TA - STSD)/TIB,$$

where TA is associated with total time asleep, STSD is associated with sleep time in sleep disorders, and TIB is associated with time in bed.

33. The method of claim 15, further comprising trending at least one of the one or more metrics associated with sleep, the one or more metrics associated with events that disrupt sleep, and the composite sleep quality metric over time.

34. The method of claim 15, further comprising using at least one of the one or more metrics associated with sleep, the one or more metrics associated with events that disrupt sleep, and the composite sleep quality metric for advanced patient management.

35. A method for assessing sleep quality of a patient, comprising:

detecting physiological and non-physiological conditions associated with the sleep quality of the patient;

collecting sleep quality data based on the detected conditions; and

evaluating the sleep quality of the patient using the collected data, wherein at least one of collecting the sleep quality data and evaluating the sleep quality is performed at least in part implantably.

36. The method of claim 35, wherein both collecting the sleep quality data and evaluating the sleep quality are performed at least in part implantably.

37. The method of claim 35, wherein evaluating the sleep quality comprises determining one or more sleep stages.

38. The method of claim 35, wherein evaluating the sleep quality comprises detecting events associated with sleep disruption.

39. The method of claim 38, wherein detecting the events associated with sleep disruption comprises detecting disordered breathing.

40. The method of claim 38, wherein detecting the events associated with sleep disruption comprises detecting movement disorders.

41. The method of claim 35, wherein evaluating the sleep quality comprises determining one or more metrics associated with sleep quality.

42. The method of claim 35, wherein evaluating the sleep quality comprises trending one or more metrics associated with sleep quality over time.

43. The method of claim 35, wherein evaluating the sleep quality comprises determining one or more metrics associated with disordered breathing.

44. The method of claim 35, wherein evaluating the sleep quality comprises determining one or more metric associated with movement disorders.

45. The method of claim 35, wherein evaluating the sleep quality comprises determining one or more composite metrics based on metrics associated with sleep and metrics associated with events that disrupt sleep.

46. The method of claim 35, further comprising transmitting at least one of the sleep quality data and the sleep quality evaluation to a separate device.

47. A method for evaluating sleep quality, comprising:

detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness;

collecting sleep quality data based on the detected one or more conditions; and

evaluating the sleep quality of the patient using the collected sleep quality data, wherein at least one of collecting the sleep quality data and evaluating the sleep quality is performed at least in part implantably.

48. The method of claim 47, wherein detecting the one or more conditions comprises detecting a physiological condition.

49. The method of claim 47, wherein detecting the one or more conditions comprises detecting a non-physiological condition.

50. The method of claim 47, wherein detecting the one or more conditions comprises detecting a nervous system condition.

51. The method of claim 47, wherein detecting the one or more conditions comprises detecting a cardiovascular system condition.

52. The method of claim 47, wherein

detecting the one or more conditions comprises detecting patient activity; and

collecting the sleep quality data comprises collecting data associated with the patient activity during the period of wakefulness.

53. The method of claim 47, further comprising storing the collected sleep quality data.

54. The method of claim 47, further comprising transmitting the collected sleep quality data.

55. The method of claim 47, wherein evaluating the sleep quality comprises determining one or more sleep quality metrics.

56. The method of claim 47, further comprising transmitting at least one of the sleep quality data and the sleep quality evaluation to a separate device.

57. A medical device, comprising:

a detector system configured to detect physiological and non-physiological conditions associated with sleep quality of a patient; and

a data collection system coupled to the detector system and configured to collect sleep quality data based on the detected conditions, wherein the data collection system includes an implantable component.

58. The device of claim 57, wherein the detector system comprises a patient-internal component.

59. The device of claim 57, wherein the detector system comprises a patient-external component.

60. The device of claim 57, wherein the detector system comprises a patient input device.

61. The device of claim 57, wherein the detector system comprises a wirelessly coupled device.

62. The device of claim 57, wherein the detector system comprises a network accessible device.

63. The device of claim 57, wherein the data collection system is configured to collect data associated with sleep stages.

64. The device of claim 57, wherein the data collection system is configured to collect data associated with events that disrupt sleep.

65. The device of claim 57, wherein the data collection system is configured to collect data associated with disordered breathing.

66. The device of claim 57, wherein the data collection system is configured to collect data associated with a movement disorder.

67. The device of claim 57, further comprising a memory unit configured to store the collected data.

68. The device of claim 57, further comprising a communication unit configured to transmit the collected data.

69. The device of claim 68, wherein the communication unit is configured to transmit the collected data over a wireless link.

70. The device of claim 68, wherein the communication unit is configured to transmit the collected data to a remote device.

71. The device of claim 57, wherein the device is configured to be implemented as a component of an advanced patient management system.

72. A sleep quality evaluation device, comprising:

a detector system configured to detect physiological and non-physiological conditions affecting sleep quality of a patient; and

a sleep quality processor coupled to the detector system and configured to determine one or more metrics associated with sleep and one or more metrics associated with events that disrupt sleep, the sleep quality processor further configured to generate at least one composite sleep quality metric based on the one or more metrics associated with sleep and the one or more metrics associated with events that disrupt sleep.

73. The device of claim 72, wherein at least one of the detector system and the sleep quality processor includes an implantable component.

74. The device of claim 72, wherein both the detector system and the sleep quality processor include an implantable component.

75. The device of claim 72, wherein the one or more metrics associated with events that disrupt sleep characterize a sleep disorder.

76. The device of claim 72, wherein the one more metrics associated with sleep characterize arousals.

77. The device of claim 72, wherein the at least one composite metric characterizes undisturbed sleep time.

78. The device of claim 72, wherein the sleep quality processor is configured to trend over time at least one of the one or more metrics associated with sleep, the one or more metrics associated with events that disrupt sleep, and the at least one composite sleep quality metric.

79. The device of claim 72, wherein the device is configured to be used as a component of an advanced patient management system.

80. A medical device for evaluating sleep quality, comprising:

a detector system configured to detect physiological and non-physiological conditions associated with sleep quality of a patient;

a data collection system coupled to the detector system and configured to collect sleep quality data based on the detected conditions; and

a data analysis system coupled to the data collection system and configured to evaluate the sleep quality using the collected sleep quality data, wherein at least one of the the data collection system and the data analysis system include an implantable component.

81. The device of claim 80, wherein both of the the data collection system and the data analysis system include an implantable component.

82. The device of claim 80, wherein the data analysis system is configured to detect sleep stages.

83. The device of claim 80, wherein the data analysis system is configured to detect one or more sleep disorders.

84. The device of claim 83, wherein the one or more sleep disorders comprise disordered breathing.

85. The device of claim 83, wherein the one or more sleep disorders comprise a movement disorder.

86. The device of claim 80, wherein the data analysis system is configured to determine one or more metrics associated with sleep quality.

87. The device of claim 80, wherein the data analysis system is configured to trend the sleep quality data over time.

88. The device of claim 80, further comprising a communication system configured to transmit at least one of the collected sleep quality data and the sleep quality evaluation to a separate device.

89. The device of claim 80, wherein the device is configured to be used as a component in an advanced patient management system.

90. A system for collecting sleep quality data, comprising:

means for detecting physiological and non-physiological conditions associated with sleep quality of a patient; and

means for collecting sleep quality data based on the detected conditions, wherein the means for collecting includes an implantable component.

91. The system of claim 90, further comprising means for storing the collected sleep quality data.

92. The system of claim 90, further comprising means for transmitting the collected sleep quality data.

93. A system for assessing sleep quality, comprising:

means for determining one or more metrics associated with sleep;

means for determining one or more metrics associated with events that disrupt sleep; and

means for determining a composite sleep quality metric as a function of the one or more metrics associated with sleep and the one or more metrics associated with events that disrupt sleep.

94. The system of claim 93, further comprising means for trending at least one of the one or more metrics associated

with sleep, the one or more metrics associated with events that disrupt sleep, and the composite sleep quality metric over time.

95. A system for assessing sleep quality of a patient, comprising:

means for detecting physiological and non-physiological conditions associated with the sleep quality of the patient;

means for collecting sleep quality data associated with the sleep quality of the patient based on the detected conditions; and

means for evaluating the sleep quality of the patient using the collected data, wherein at least one of the means for collecting and the means for evaluating include an implantable component.

96. A sleep quality evaluation system, comprising:

means for detecting one or more conditions associated with the sleep quality of a patient during a period of wakefulness;

means for collecting sleep quality data based on the one or more conditions; and

means for evaluating the sleep quality of the patient using the collected sleep quality data, wherein at least one of the means for collecting the data and the means for evaluating the sleep quality comprises an implantable component.

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摘要(译)

睡眠质量评估方法涉及基于检测到的生理或非生理患者状况收集数据。使用可植入设备执行检测患者状况和收集数据中的至少一个。可以通过可植入或患者外部睡眠质量处理器使用所收集的数据来评估睡眠质量。睡眠质量评估的一种方法涉及基于睡眠期间运动障碍或呼吸障碍的发生来计算一个或多个概要度量。

Internal — 210

External — 220

Info System — 230

Patient Reported — 240

Signal Detection
260

Communication
270

Memory
280

Sleep Quality
Data Collection Unit
250

290

Sleep Detection
292

Disordered Breathing Detection
294

Sleep Quality Processor
296

Sleep Quality Analysis Unit

200
Sleep Quality Data System