US 20050215847A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0215847 A1

Heruth et al. (43) Pub. Date: Sep. 29, 2005

(54) COLLECTING SLEEP QUALITY INFORMATION VIA A MEDICAL DEVICE

(76) Inventors: **Kenneth T. Heruth**, Edina, MN (US); **Keith A. Miesel**, St. Paul, MN (US)

Correspondence Address:
SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125 (US)

(21) Appl. No.: **11/081,811**

(22) Filed: **Mar. 16, 2005**

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/826,925, filed on Apr. 15, 2004.

(60) Provisional application No. 60/553,783, filed on Mar. 16, 2004.

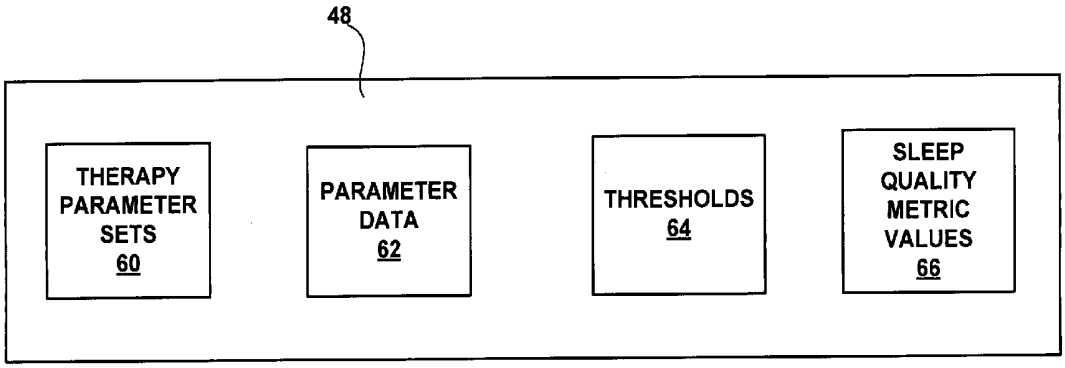
Publication Classification

(51) **Int. Cl.**[7] **A61M 21/00**; A61B 5/00; A61B 5/04

(52) **U.S. Cl.** **600/26**; 600/544; 600/549; 600/509

(57) **ABSTRACT**

At least one of a medical device, such as an implantable medical device, a monitor, and a computing device determines values for one or more metrics that indicate the quality of a patient's sleep. Sleep efficiency, sleep latency, and time spent in deeper sleep states are example sleep quality metrics for which values may be determined. In some embodiments, determined sleep quality metric values are associated with a current therapy parameter set. In some embodiments, a programming device presents sleep quality information to a user based on determined sleep quality metric values values. A clinician, for example, may use the sleep quality information presented by the programming device to evaluate the effectiveness of therapy delivered to the patient by the medical device, to adjust the therapy delivered by the medical device, or to prescribe a therapy not delivered by the medical device in order to improve the quality of the patient's sleep.



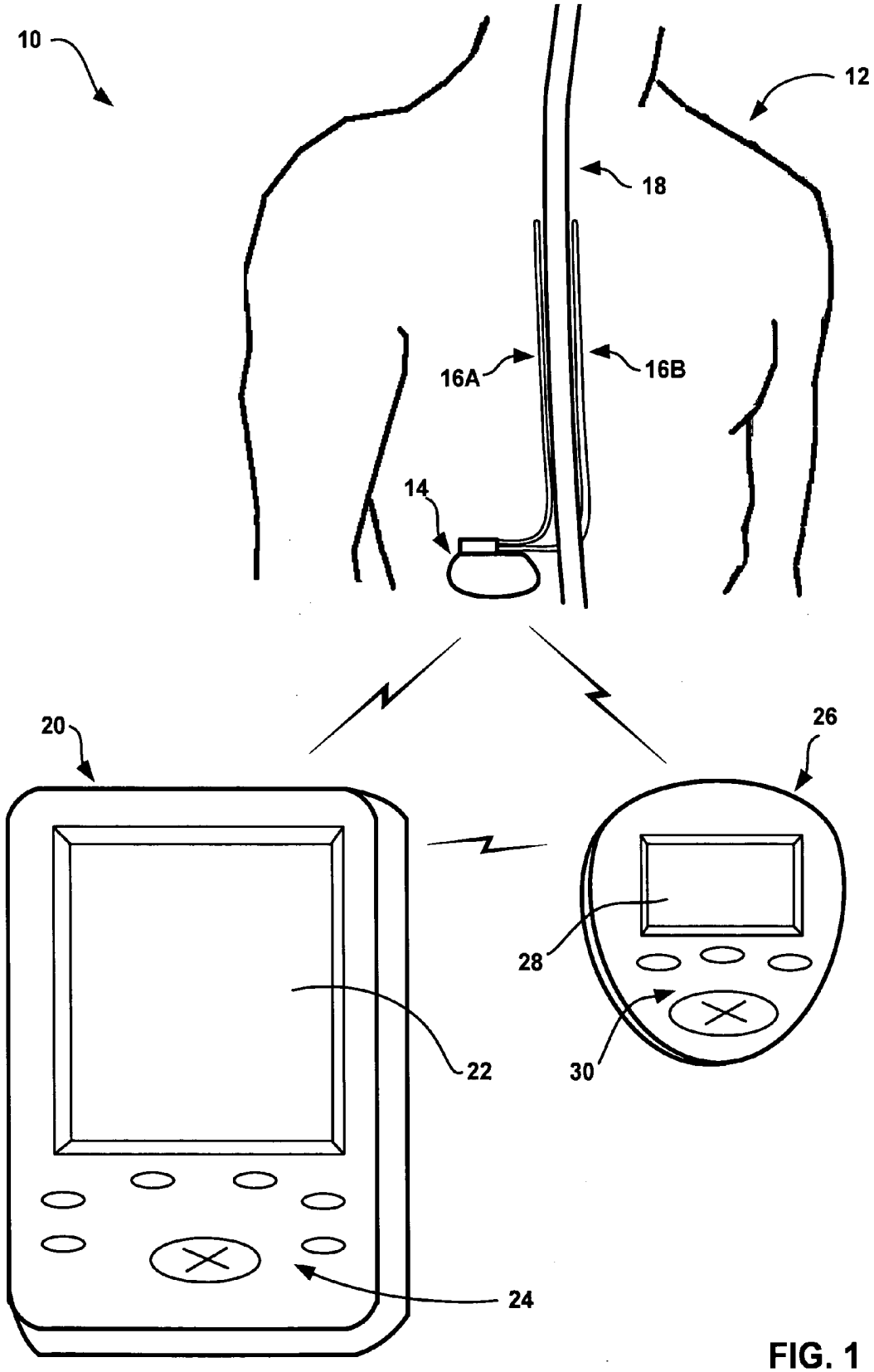


FIG. 1

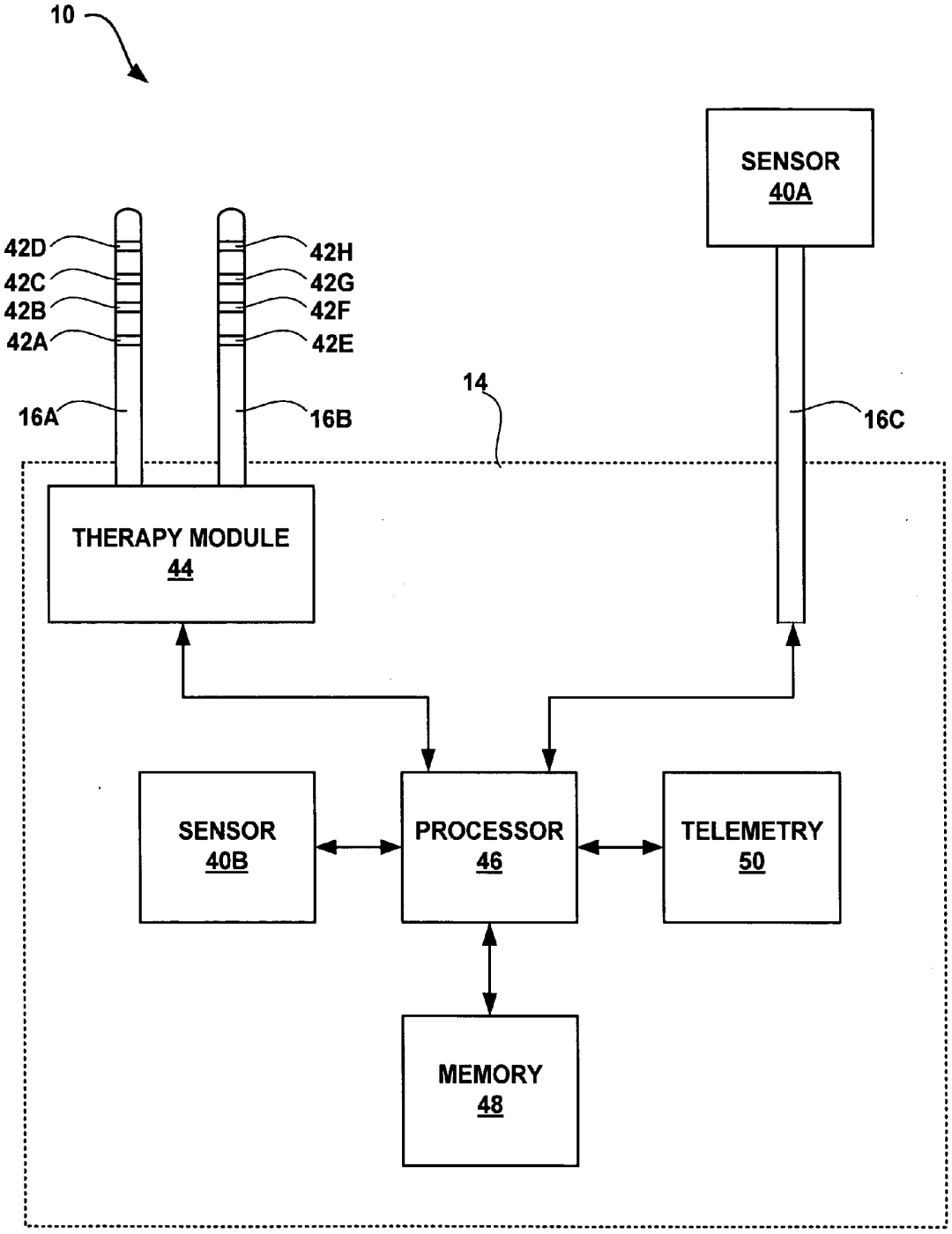

10
SENSOR
40A
42D
42C
42B
42A
42H
42G
42F
42E
14
16A
16B
16C
THERAPY MODULE
44
SENSOR
40B
PROCESSOR
46
TELEMETRY
50
MEMORY
48

FIG. 2

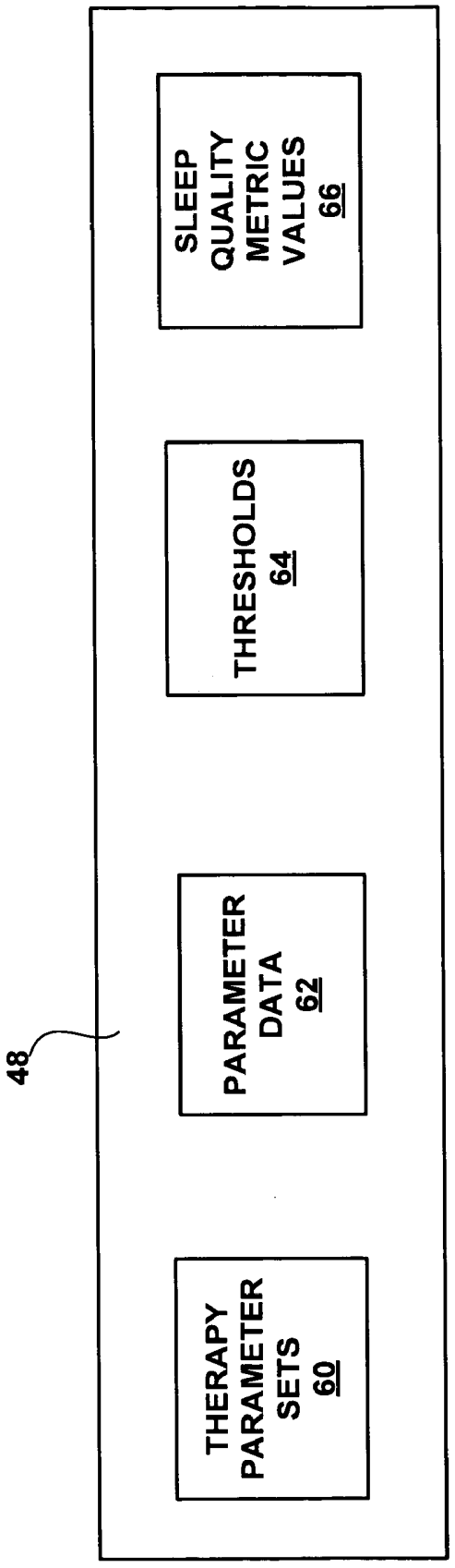

48
THERAPY PARAMETER SETS 60
PARAMETER DATA 62
THRESHOLDS 64
SLEEP QUALITY METRIC VALUES 66

FIG. 3

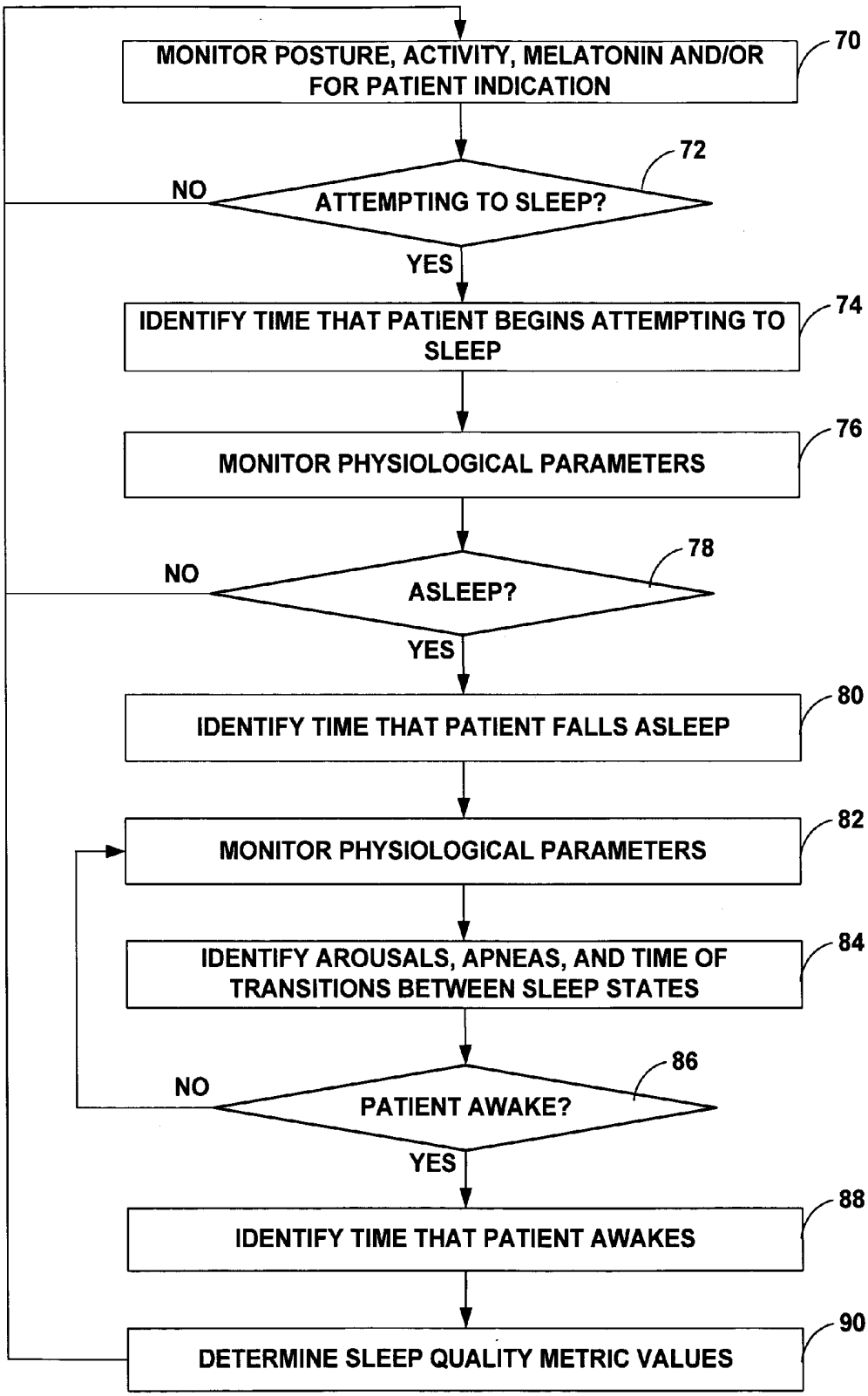

MONITOR POSTURE, ACTIVITY, MELATONIN AND/OR FOR PATIENT INDICATION
70
ATTEMPTING TO SLEEP?
72
NO
YES
IDENTIFY TIME THAT PATIENT BEGINS ATTEMPTING TO SLEEP
74
MONITOR PHYSIOLOGICAL PARAMETERS
76
ASLEEP?
78
NO
YES
IDENTIFY TIME THAT PATIENT FALLS ASLEEP
80
MONITOR PHYSIOLOGICAL PARAMETERS
82
IDENTIFY AROUSALS, APNEAS, AND TIME OF TRANSITIONS BETWEEN SLEEP STATES
84
PATIENT AWAKE?
86
NO
YES
IDENTIFY TIME THAT PATIENT AWAKES
88
DETERMINE SLEEP QUALITY METRIC VALUES
90

FIG. 4

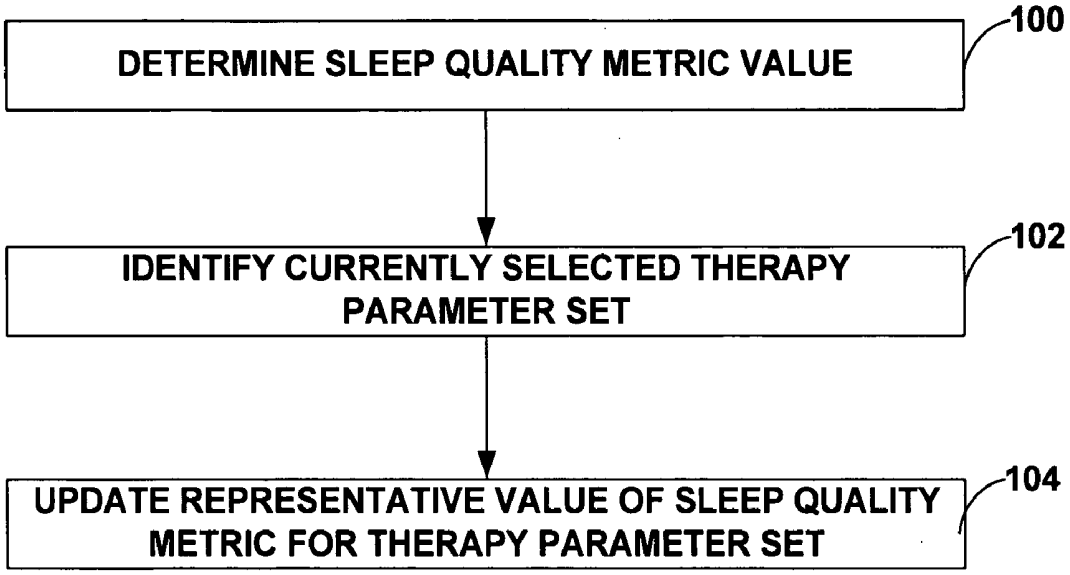

DETERMINE SLEEP QUALITY METRIC VALUE
100
IDENTIFY CURRENTLY SELECTED THERAPY PARAMETER SET
102
UPDATE REPRESENTATIVE VALUE OF SLEEP QUALITY METRIC FOR THERAPY PARAMETER SET
104

FIG. 5

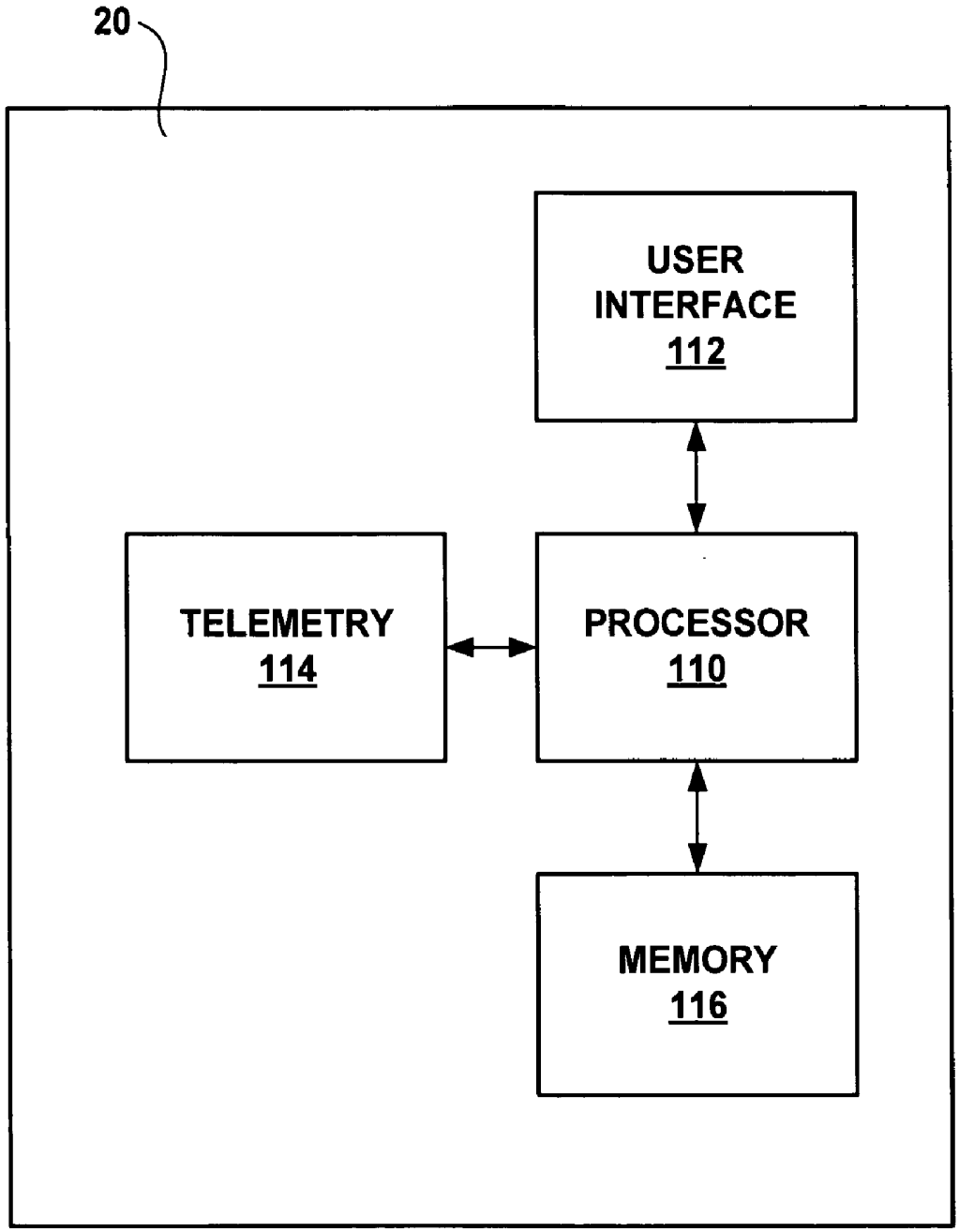

20
USER INTERFACE 112
TELEMETRY 114
PROCESSOR 110
MEMORY 116

FIG. 6

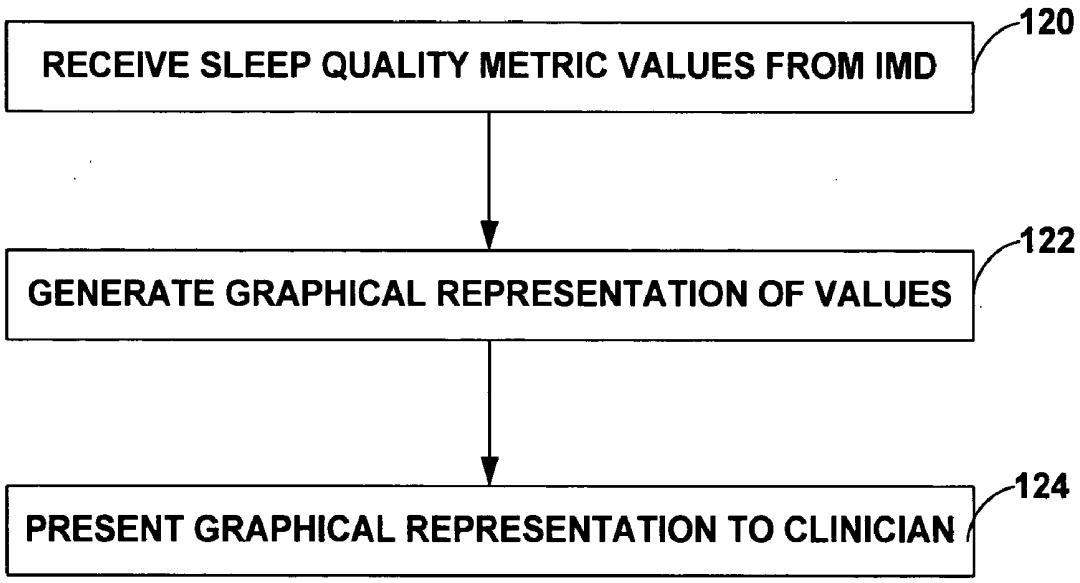

RECEIVE SLEEP QUALITY METRIC VALUES FROM IMD
120
GENERATE GRAPHICAL REPRESENTATION OF VALUES
122
PRESENT GRAPHICAL REPRESENTATION TO CLINICIAN
124

FIG. 7

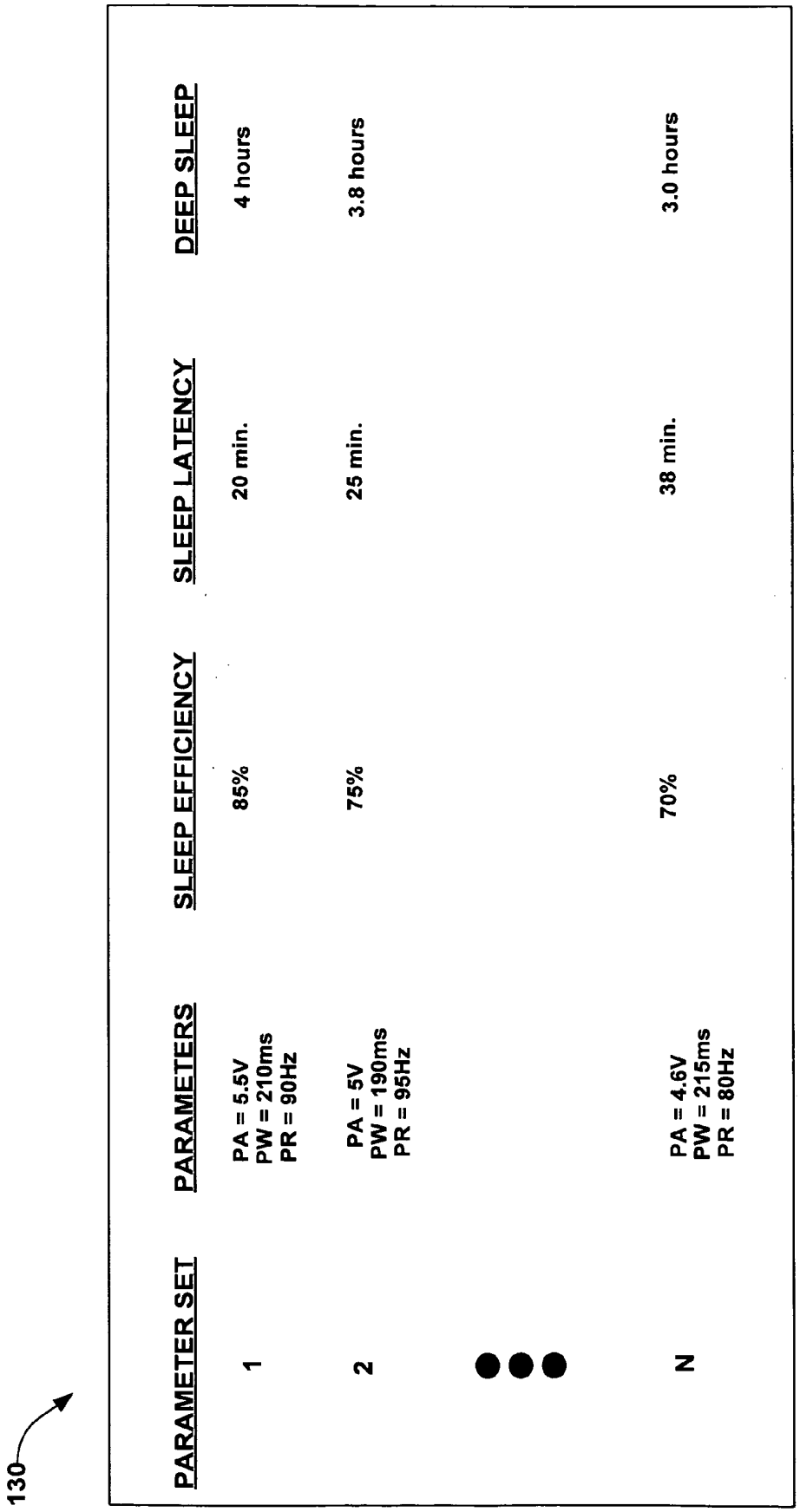

130
PARAMETER SET
PARAMETERS
SLEEP EFFICIENCY
SLEEP LATENCY
DEEP SLEEP
1
PA = 5.5V
PW = 210ms
PR = 90Hz
85%
20 min.
4 hours
2
PA = 5V
PW = 190ms
PR = 95Hz
75%
25 min.
3.8 hours
N
PA = 4.6V
PW = 215ms
PR = 80Hz
70%
38 min.
3.0 hours

FIG. 8

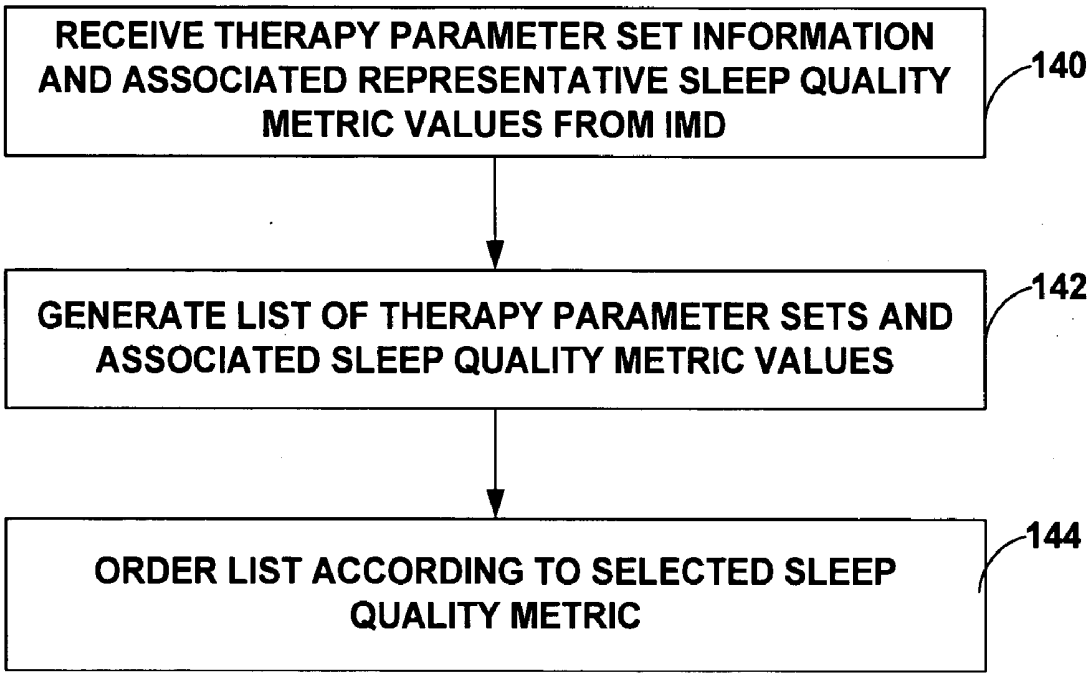

RECEIVE THERAPY PARAMETER SET INFORMATION AND ASSOCIATED REPRESENTATIVE SLEEP QUALITY METRIC VALUES FROM IMD
140
GENERATE LIST OF THERAPY PARAMETER SETS AND ASSOCIATED SLEEP QUALITY METRIC VALUES
142
ORDER LIST ACCORDING TO SELECTED SLEEP QUALITY METRIC
144

FIG. 9

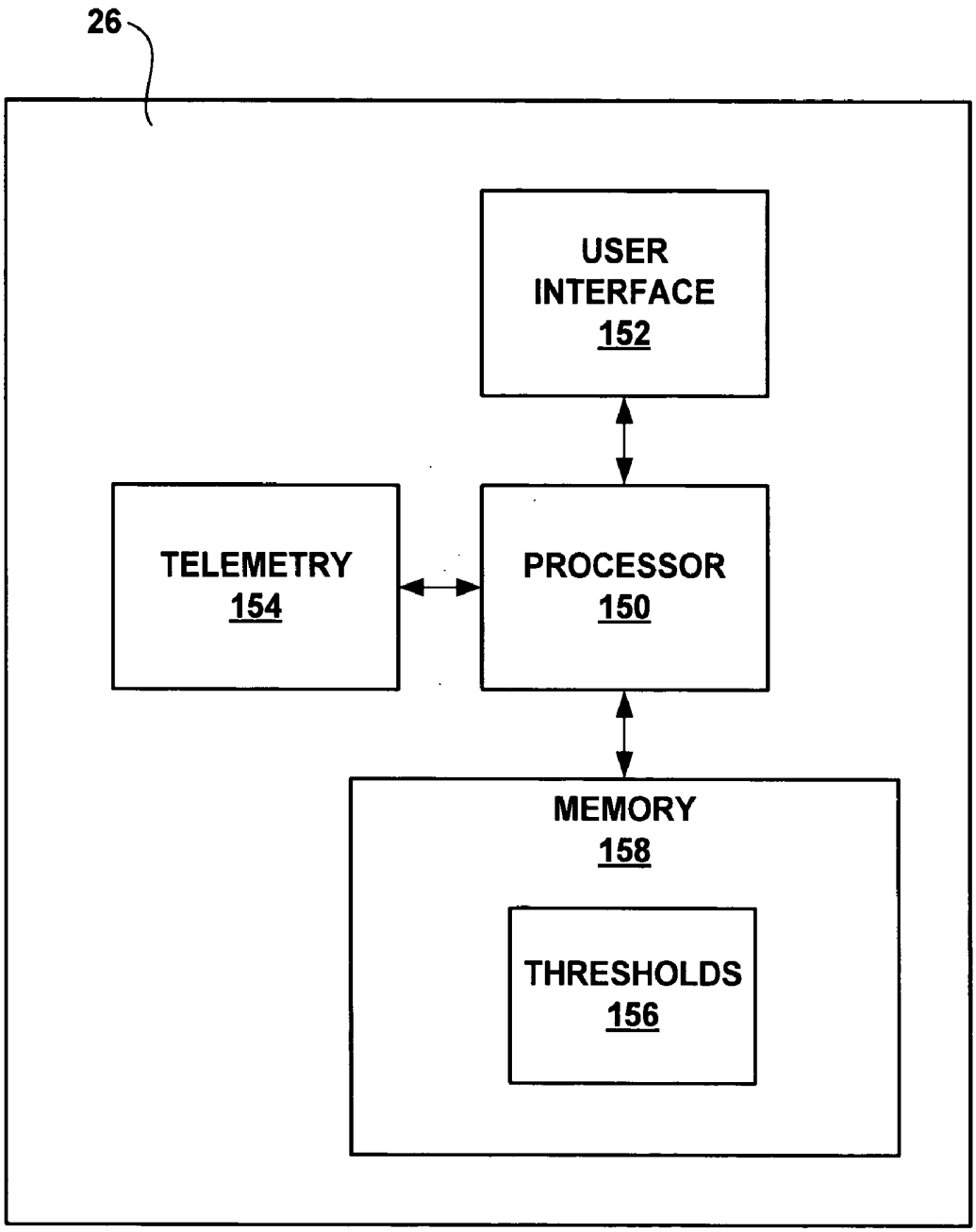

26
USER INTERFACE 152
TELEMETRY 154
PROCESSOR 150
MEMORY 158
THRESHOLDS 156

FIG. 10

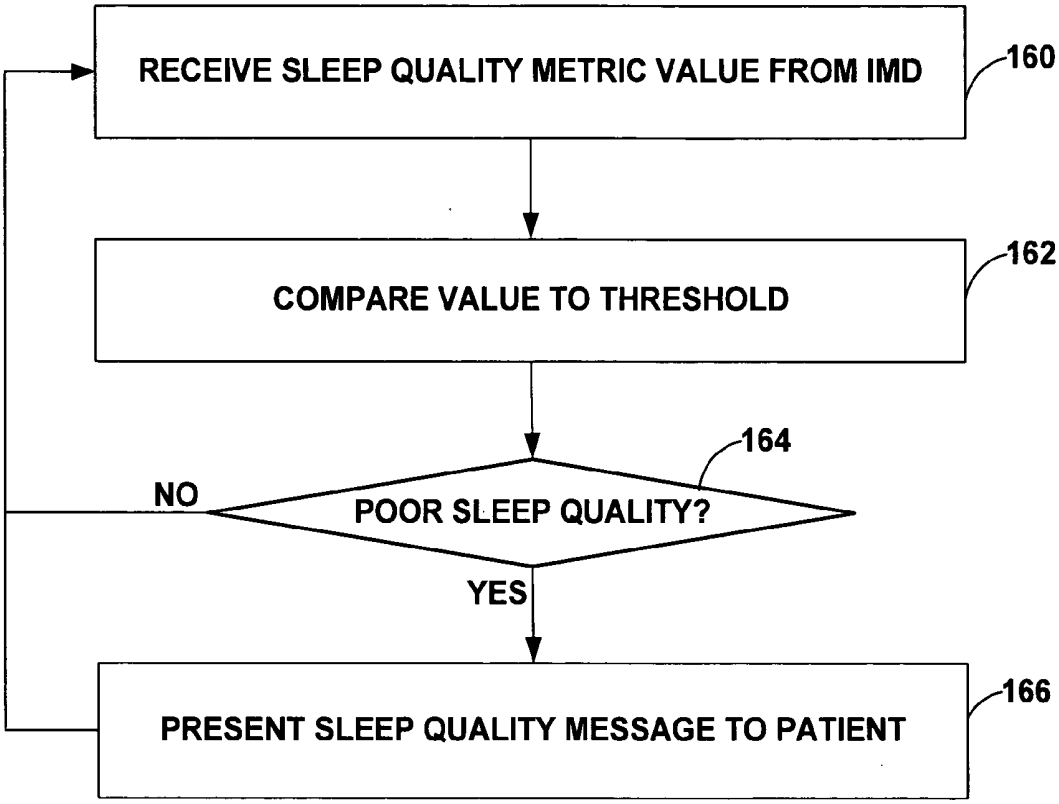

RECEIVE SLEEP QUALITY METRIC VALUE FROM IMD
160
COMPARE VALUE TO THRESHOLD
162
164
POOR SLEEP QUALITY?
NO
YES
PRESENT SLEEP QUALITY MESSAGE TO PATIENT
166

FIG. 11

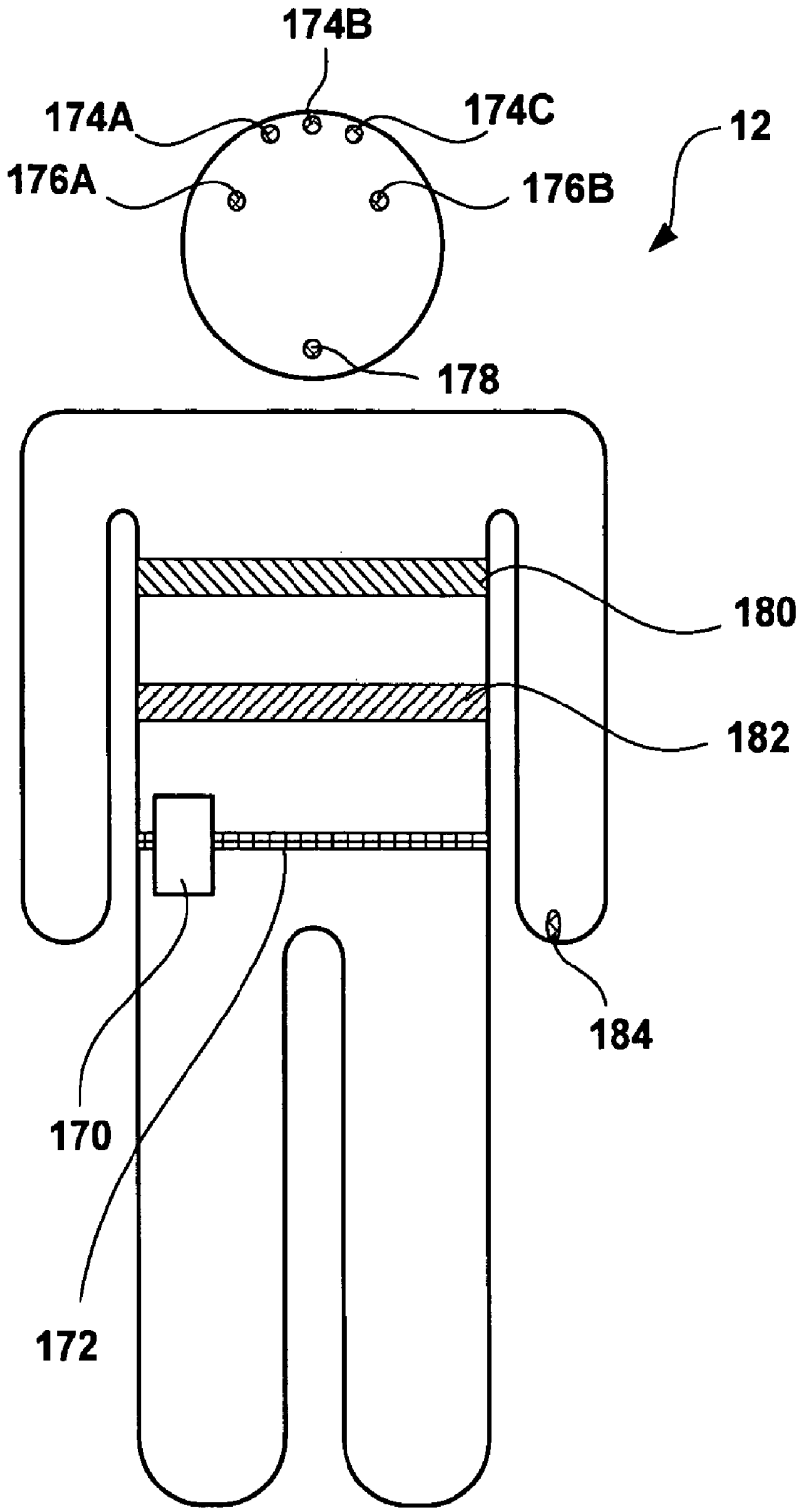


FIG. 12

COLLECTING SLEEP QUALITY INFORMATION VIA A MEDICAL DEVICE

[0001] This application is a continuation-in-part of U.S. application Ser. No. 10/826,925, filed Apr. 15, 2004, which claims the benefit of U.S. Provisional Application No. 60/553,783, filed Mar. 16, 2004. The entire content of both applications is incorporated herein by reference.

TECHNICAL FIELD

[0002] The invention relates to medical devices and, more particularly, to medical devices that monitor physiological parameters.

BACKGROUND

[0003] In some cases, an ailment that a patient has may affect the quality of the patient's sleep. For example, chronic pain may cause a patient to have difficulty falling asleep, and may disturb the patient's sleep, e.g., cause the patient to wake. Further, chronic pain may cause the patient to have difficulty achieving deeper sleep states, such as one or more of the nonrapid eye movement (NREM) sleep states. Other ailments that may negatively affect patient sleep quality include movement disorders, psychological disorders, sleep apnea, congestive heart failure, gastrointestinal disorders and incontinence. In some cases, these ailments are treated via an implantable medical device (IMD), such as an implantable stimulator or drug delivery device.

[0004] Further, in some cases, poor sleep quality may increase the symptoms experienced by a patient due to an ailment. For example, poor sleep quality has been linked to increased pain symptoms in chronic pain patients. The link between poor sleep quality and increased symptoms is not limited to ailments that negatively impact sleep quality, such as those listed above. Nonetheless, the condition of a patient with such an ailment may progressively worsen when symptoms disturb sleep quality, which in turn increases the frequency and/or intensity of symptoms.

SUMMARY

[0005] In general, the invention is directed to techniques for collecting information that relates to the quality of patient sleep via a medical device, such as an implantable medical device (IMD). In particular, values for one or more metrics that indicate the quality of the patient's sleep are determined based on physiological parameters monitored by a medical device. In some embodiments, sleep quality information is presented to a user based on the sleep quality metric values. A clinician, for example, may use the presented sleep quality information to evaluate the effectiveness of therapy delivered to the patient by the medical device, to adjust the therapy delivered by the medical device, or to prescribe a therapy not delivered by the medical device in order to improve the quality of the patient's sleep.

[0006] The medical device that delivers the therapy or a separate monitoring device monitors one or more physiological parameters of the patient. Example physiological parameters that the medical device may monitor include activity level, posture, heart rate, electrocardiogram (ECG) morphology, respiration rate, respiratory volume, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity and tone, core temperature, subcutaneous temperature, arterial blood flow, melatonin level within one or more bodily fluids, brain electrical activity, eye motion, and galvanic skin response. In order to monitor one or more of these parameters, the medical device or monitoring device may include, or be coupled to one or more sensors, each of which generates a signal as a function of one or more of these physiological parameters.

[0007] The medical device or monitoring device may determine a value of one or more sleep quality metrics based on the one or more monitored physiological parameters, and/or the variability of one or more of the monitored physiological parameters. In other embodiments, one or both of the medical device or monitoring device records values of the one or more physiological parameters, and provides the physiological parameter values to a programming device, such as a clinician programming device or a patient programming device, or another computing device. In such embodiments, the programming or other computing device determines values of one or more sleep quality metrics based on the physiological parameter values received from the medical device and/or the variability of one or more of the physiological parameters. The medical device or monitoring device may provide the recorded physiological parameter values to the programming or other computing device in real time, or may provide physiological parameter values recorded over a period of time to the programming or other computing device when interrogated.

[0008] Sleep efficiency and sleep latency are example sleep quality metrics for which a medical device or programming device may determine values. Sleep efficiency may be measured as the percentage of time while the patient is attempting to sleep that the patient is actually asleep. Sleep latency may be measured as the amount of time between a first time when the patient begins attempting to fall asleep and a second time when the patient falls asleep, and thereby indicates how long a patient requires to fall asleep.

[0009] The time when the patient begins attempting to fall asleep may be determined in a variety of ways. For example, the patient may provide an indication that he or she is trying to fall asleep, e.g., via a patient programming device. In other embodiments, the medical device or monitoring may monitor the activity level of the patient, and the time when the patient is attempting to fall asleep may be identified by determining whether the patient has remained inactive for a threshold period of time, and identifying the time at which the patient became inactive. In still other embodiments, the medical device or monitoring device may monitor patient posture, and the medical device or a programming device may identify the time when the patient is recumbent, e.g., lying down, as the time when the patient is attempting to fall asleep. In these embodiments, the medical device or monitoring device may also monitor patient activity, and either the medical device, monitoring device, programming device, or other computing device may confirm that the patient is attempting to sleep based on the patient's activity level.

[0010] As another example, the medical device or monitoring device may determine the time at which the patient begins attempting to fall asleep based on the level of

melatonin within one or more bodily fluids, such as the patient's blood, cerebrospinal fluid (CSF), or interstitial fluid. The medical device or monitoring device may also determine a melatonin level based on metabolites of melatonin located in the saliva or urine of the patient. Melatonin is a hormone secreted by the pineal gland into the bloodstream and the CSF as a function of exposure of the optic nerve to light, which synchronizes the patient's circadian rhythm. In particular, increased levels of melatonin during evening hours may cause physiological changes in the patient, which, in turn, may cause the patient to attempt to fall asleep. The medical device or monitoring device may, for example, detect an increase in the level of melatonin, and estimate the time that the patient will attempt to fall asleep based on the detection.

[0011] The time at which the patient has fallen asleep may be determined based on the activity level of the patient and/or one or more of the other physiological parameters that may be monitored by the medical device as indicated above. For example, a discernable change, e.g., a decrease, in one or more physiological parameters, or the variability of one or more physiological parameters, may indicate that the patient has fallen asleep. In some embodiments, a sleep probability metric value may be determined based on a value of a physiological parameter monitored by the medical device. In such embodiments, the sleep probability metric value may be compared to a threshold to identify when the patient has fallen asleep. In some embodiments, a plurality of sleep probability metric values are determined based on a value of each of a plurality of physiological parameters, the sleep probability values are averaged or otherwise combined to provide an overall sleep probability metric value, and the overall sleep probability metric value is compared to a threshold to identify the time that the patient falls asleep.

[0012] Other sleep quality metrics that may be determined include total time sleeping per day, the amount or percentage of time sleeping during nighttime or daytime hours per day, and the number of apnea and/or arousal events per night. In some embodiments, which sleep state the patient is in, e.g., rapid eye movement (REM), or one of the nonrapid eye movement (NREM) states (S1, S2, S3, S4) may be determined based on physiological parameters monitored by the medical device, and the amount of time per day spent in these various sleep states may be a sleep quality metric. Because they provide the most "refreshing" type of sleep, the amount of time spent in one or both of the S3 and S4 sleep states, in particular, may be determined as a sleep quality metric. In some embodiments, average or median values of one or more sleep quality metrics over greater periods of time, e.g., a week or a month, may be determined as the value of the sleep quality metric. Further, in embodiments in which values for a plurality of the sleep quality metrics are determined, a value for an overall sleep quality metric may be determined based on the values for the plurality of individual sleep quality metrics.

[0013] In some embodiments, the medical device delivers a therapy. At any given time, the medical device delivers the therapy according to a current set of therapy parameters. For example, in embodiments in which the medical device is a neurostimulator, a therapy parameter set may include a pulse amplitude, a pulse width, a pulse rate, a duty cycle, and an indication of active electrodes. Different therapy parameter sets may be selected, e.g., by the patient via a programming device or a the medical device according to a schedule, and parameters of one or more therapy parameter sets may be adjusted by the patient to create new therapy parameter sets. In other words, over time, the medical device delivers the therapy according to a plurality of therapy parameter sets.

[0014] In embodiments in which the medical device determines sleep quality metric values, the medical device may identify the current therapy parameter set when a value of one or more sleep quality metrics is collected, and may associate that value with the therapy parameter set. For example, for each available therapy parameter set the medical device may store a representative value of each of one or more sleep quality metrics in a memory with an indication of the therapy programs with which that representative value is associated. A representative value of sleep quality metric for a therapy parameter set may be the mean or median of collected sleep quality metric values that have been associated with that therapy parameter set. In other embodiments in which a programming device or other computing device determines sleep quality metric values, the medical device may associate recorded physiological parameter values with the current therapy parameter set in the memory. Further, in embodiments in which a separate monitoring device records physiological parameter values or determines sleep quality metric values, the monitoring device may mark recorded physiological parameter values or sleep quality metric values with a current time in a memory, and the medical device may store an indication of a current therapy parameter set and time in a memory. A programming device of other computing device may receive indications of the physiological parameter values or sleep quality metrics and associated times from the monitoring device, and indications of the therapy parameter sets and associated times from the medical device, and may associate the physiological parameter values or sleep quality metrics with the therapy parameter set that was delivered by the medical device when the physiological parameter values or sleep quality metrics were collected.

[0015] A programming device or other computing device according to the invention may be capable of wireless communication with the medical device, and may receive sleep quality metric values or recorded physiological parameter values from the medical device or a separate monitoring device. In either case, when the computing device either receives or determines sleep quality metric values, the computing device may provide sleep quality information to a user based on the sleep quality metric values. For example, the computing device may be a patient programmer, and may provide a message to the patient related to sleep quality. The patient programmer may, for example, suggest that the patient visit a clinician for prescription of sleep medication or for an adjustment to the therapy delivered by the medical device. As other examples, the patient programmer may suggest that the patient increase the intensity of therapy delivered by the medical device during nighttime hours relative to previous nights, or select a different therapy parameter set for use during sleep than the patient had selected during previous nights. Further, the patient programmer may provide a message that indicates the quality of sleep to the patient to, for example, provide the patient with an objective indication of whether his or her sleep quality is good, adequate, or poor.

[0016] In other embodiments, the computing device is a clinician programmer that presents information relating to the quality of the patient's sleep to a clinician. The clinician programmer may present, for example, a trend diagram of values of one or more sleep quality metrics over time. As other examples, the clinician programmer may present a histogram or pie chart illustrating percentages of time that a sleep quality metric was within various value ranges.

[0017] As indicated above, the computing device may receive representative values for one or more sleep quality metrics or the physiological parameter values from the therapy delivering medical device or separate monitoring device. The computing device may receive information identifying the therapy parameter set with which the representative values are associated, or may itself associate received physiological parameter or sleep quality metric values with therapy parameter sets based on time information received from one or more devices. In embodiments in which the computing device receives physiological parameter values, the computing device may determine sleep quality metric values associated with the plurality of parameter sets based on the physiological parameter values, and representative sleep quality metric values for each of the therapy parameter sets based on the sleep quality metric values associated with the therapy parameter sets. In some embodiments, the computing device may determine the variability of one or more of the physiological parameters based on the physiological parameter values received from the medical device or monitoring device, and may determine sleep quality metric values based on the physiological parameter variabilities.

[0018] The computing device may display a list of the therapy parameter sets to the clinician ordered according to their associated representative sleep quality metric values. Such a list may be used by the clinician to identify effective or ineffective therapy parameter sets. Where a plurality of sleep quality metric values are determined, the programming device may order the list according to values of a user-selected one of the sleep quality metrics.

[0019] In other embodiments, a system according to the invention does not include a programming or other computing device. For example, an external medical device according to the invention may include a display, determine sleep quality metric values, and display sleep quality information to a user via the display based on the sleep quality metric values.

[0020] In one embodiment, the invention is directed to a method in which at least one physiological parameter of a patient is monitored. A value of a metric that is indicative of sleep quality is determined based on the at least one physiological parameter. A current therapy parameter set used by a medical device to delivery a therapy to the patient is identified, and the sleep quality metric value is associated with the current therapy parameter set.

[0021] In another embodiment, the invention is directed to a medical system comprising a medical device, and monitor, and a processor. The medical device delivers a therapy to a patient, and the monitor monitors at least one physiological parameter of a patient based on a signal received from at least one sensor. The processor determines a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, identifies a current therapy parameter set, and associates the sleep quality metric value with the current therapy parameter set. The medical device may comprise the monitor.

[0022] In another embodiment, the invention is directed to a medical system comprising means for monitoring at least one physiological parameter of a patient, means for determining a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, means for identifying a current therapy parameter set used by a medical device to delivery therapy to the patient, and means for associating the sleep quality metric value with the current therapy parameter set.

[0023] In another embodiment, the invention is directed to a medical system comprising an implantable medical device and an external programming device including a display. The implantable medical device delivers a therapy to a patient, monitors at least one physiological parameter of the patient, and determines a plurality of values of a metric that is indicative of sleep quality based on the at least one physiological parameter. The external programming device receives sleep quality metric values from the implantable medical device, and presents sleep quality information to a user via the display based on the sleep quality metric values.

[0024] In another embodiment, the invention is directed to a programming device comprising a telemetry circuit, a user interface including a display, and a processor. The processor receives sleep quality metric values from a medical device via the telemetry circuit. The medical device delivers therapy according to a plurality of therapy parameter sets, and associates each of the sleep quality metric values with a current therapy parameter set. The processor receives information identifying the plurality of therapy parameter sets and the sleep quality metric values associated with the therapy parameter sets from the medical device, presents a list of the therapy parameter sets and the associated sleep quality metric values to a user, and orders the list according to the associated sleep quality metric values.

[0025] In another embodiment, the invention is directed to a computer-readable medium comprising program instructions. The program instructions cause a programmable processor to receive sleep quality metric values from a medical device that delivers therapy according to a plurality of parameter sets, and associates each of the sleep quality metric values with a current therapy parameter set. The instructions further cause a processor to receive information identifying the plurality of therapy parameter sets and the sleep quality metric values associated with the therapy parameter sets from the medical device, present a list of the therapy parameter sets and the associated sleep quality metric values to a user, and order the list of therapy parameter sets according to the associated sleep quality metric values.

[0026] In another embodiment, the invention is directed to a method in which a plurality of signals are monitored, each of the signals generated by a sensor as a function of at least one physiological parameter of a patient. When the patient is attempting to sleep is identified. When the patient is asleep is identified based on at least one of the signals. A value of a metric that is indicative of sleep quality is determined based on the identifications of when the patient is attempting to sleep and asleep.

[0027] In another embodiment, the invention is directed to a medical system comprising a plurality of sensors and a

processor. Each of the plurality of sensors generates a signal as a function of at least one physiological parameter of a patient. The processor monitors the signals generated by the sensors, identifies when the patient is attempting to sleep, identifies when the patient is asleep based on at least one of the signals, and determines a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and asleep.

[0028] The invention may be capable of providing one or more advantages. For example, by providing information related to the quality of a patient's sleep to a clinician and/or the patient, a system according to the invention can improve the course of treatment of an ailment of the patient, such as chronic pain. Using the sleep quality information provided by the system, the clinician and/or patient can, for example, make changes to the therapy provided by a medical device in order to better address symptoms which are disturbing the patient's sleep. Further, a clinician may choose to prescribe a therapy that will improve the patient's sleep, such as a sleep inducing medication, in situations where poor sleep quality is increasing symptoms experienced by the patient.

[0029] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0030] **FIG. 1** is a conceptual diagram illustrating an example system that includes an implantable medical device that collects sleep quality information according to the invention.

[0031] **FIG. 2** is a block diagram further illustrating the example system and implantable medical device of **FIG. 1**.

[0032] **FIG. 3** is a block diagram illustrating an example memory of the implantable medical device of **FIG. 1**.

[0033] **FIG. 4** is a flow diagram illustrating an example method for collecting sleep quality information that may be employed by an implantable medical device.

[0034] **FIG. 5** is a flow diagram illustrating an example method for associating sleep quality information with therapy parameter sets that may be employed by an implantable medical device.

[0035] **FIG. 6** is a block diagram illustrating an example clinician programmer.

[0036] **FIG. 7** is a flow diagram illustrating an example method for presenting sleep quality information to a clinician that may be employed by a clinician programmer.

[0037] **FIG. 8** illustrates an example list of therapy parameter sets and associated sleep quality information that may be presented by a clinician programmer.

[0038] **FIG. 9** is a flow diagram illustrating an example method for displaying a list of therapy parameter sets and associated sleep quality information that may be employed by a clinician programmer.

[0039] **FIG. 10** is a block diagram illustrating an example patient programmer.

[0040] **FIG. 11** is a flow diagram illustrating an example method for presenting a sleep quality message to a patient that may be employed by a patient programmer.

[0041] **FIG. 12** is a conceptual diagram illustrating a monitor that monitors values of one or more physiological parameters of the patient instead of, or in addition to, a therapy delivering medical device.

DETAILED DESCRIPTION

[0042] **FIG. 1** is a conceptual diagram illustrating an example system **10** that includes an implantable medical device (IMD) **14** that collects information relating to the quality of sleep experienced by a patient **12** according to the invention. Sleep quality information collected by IMD **14** is provided to a user, such as a clinician or the patient. Using the sleep quality information collected by IMD **14**, a current course of therapy for an ailment of patient **12** may be evaluated, and an improved course of therapy for the ailment may be identified.

[0043] In the illustrated example system **10**, IMD **14** takes the form of an implantable neurostimulator that delivers neurostimulation therapy in the form of electrical pulses to patient **12**. However, the invention is not limited to implementation via an implantable neurostimulator. For example, in some embodiments of the invention, an implantable pump or implantable cardiac rhythm management device, such as a pacemaker, may collect sleep quality information. Further, the invention is not limited to implementation via an IMD. In other words, any implantable or external medical device may collect sleep quality information according to the invention.

[0044] In the example of **FIG. 1**, IMD **14** delivers neurostimulation therapy to patient **12** via leads **16**A and **16**B (collectively "leads **16**"). Leads **16** may, as shown in **FIG. 1**, be implanted proximate to the spinal cord **18** of patient **12**, and IMD **14** may deliver spinal cord stimulation (SCS) therapy to patient **12** in order to, for example, reduce pain experienced by patient **12**. However, the invention is not limited to the configuration of leads **16** shown in **FIG. 1** or the delivery of SCS therapy. For example, one or more leads **16** may extend from IMD **14** to the brain (not shown) of patient **12**, and IMD **14** may deliver deep brain stimulation (DBS) therapy to patient **12** to, for example, treat tremor or epilepsy. As further examples, one or more leads **16** may be implanted proximate to the pelvic nerves (not shown) or stomach (not shown), and IMD **14** may deliver neurostimulation therapy to treat incontinence or gastroparesis.

[0045] IMD **14** delivers therapy according to a set of therapy parameters, i.e., a set of values for a number of parameters that define the therapy delivered according to that therapy parameter set. In embodiments where IMD **14** delivers neurostimulation therapy in the form of electrical pulses, the parameters in each parameter set may include voltage or current pulse amplitudes, pulse widths, pulse rates, and the like. Further, each of leads **16** includes electrodes (not shown in **FIG. 1**), and a therapy parameter set may include information identifying which electrodes have been selected for delivery of pulses, and the polarities of the selected electrodes. Therapy parameter sets used by IMD **14** may include a number of parameter sets programmed by a clinician (not shown), and parameter sets representing adjustments made by patient **12** to these preprogrammed sets.

[0046] System **10** also includes a clinician programmer **20**. A clinician (not shown) may use clinician programmer **20** to program therapy for patient **12**, e.g., specify a number of therapy parameter sets and provide the parameter sets to IMD **14**. The clinician may also use clinician programmer **20** to retrieve information collected by IMD **14**. The clinician may use clinician programmer **20** to communicate with IMD **14** both during initial programming of IMD **14**, and for collection of information and further programming during follow-up visits.

[0047] Clinician programmer **20** may, as shown in **FIG. 1**, be a handheld computing device. Clinician programmer **20** includes a display **22**, such as a LCD or LED display, to display information to a user. Clinician programmer **20** may also include a keypad **24**, which may be used by a user to interact with clinician programmer **20**. In some embodiments, display **22** may be a touch screen display, and a user may interact with clinician programmer **20** via display **22**. A user may also interact with clinician programmer **20** using peripheral pointing devices, such as a stylus or mouse. Keypad **24** may take the form of an alphanumeric keypad or a reduced set of keys associated with particular functions.

[0048] System **10** also includes a patient programmer **26**, which also may, as shown in **FIG. 1**, be a handheld computing device. Patient **12** may use patient programmer **26** to control the delivery of therapy by IMD **14**. For example, using patient programmer **26**, patient **12** may select a current therapy parameter set from among the therapy parameter sets preprogrammed by the clinician, or may adjust one or more parameters of a preprogrammed therapy parameter set to arrive at the current therapy parameter set.

[0049] Patient programmer **26** may include a display **28** and a keypad **30**, to allow patient **12** to interact with patient programmer **26**. In some embodiments, display **28** may be a touch screen display, and patient **12** may interact with patient programmer **26** via display **28**. Patient **12** may also interact with patient programmer **26** using peripheral pointing devices, such as a stylus, mouse, or the like.

[0050] However, clinician and patient programmers **20**, **26** are not limited to the hand-held computer embodiments illustrated in **FIG. 1**. Programmers **20**, **26** according to the invention may be any sort of computing device. For example, a programmer **20**, **26** according to the invention may be a tablet-based computing device, a desktop computing device, or a workstation.

[0051] IMD **14**, clinician programmer **20** and patient programmer **26** may, as shown in **FIG. 1**, communicate via wireless communication. Clinician programmer **20** and patient programmer **26** may, for example, communicate via wireless communication with IMD **14** using radio frequency (RF) telemetry techniques known in the art. Clinician programmer **20** and patient programmer **26** may communicate with each other using any of a variety of local wireless communication techniques, such as RF communication according to the 802.11 or Bluetooth specification sets, infrared communication according to the IRDA specification set, or other standard or proprietary telemetry protocols.

[0052] Clinician programmer **20** and patient programmer **26** need not communicate wirelessly, however. For example, programmers **20** and **26** may communicate via a wired connection, such as via a serial communication cable, or via exchange of removable media, such as magnetic or optical disks, or memory cards or sticks. Further, clinician programmer **20** may communicate with one or both of IMD **14** and patient programmer **26** via remote telemetry techniques known in the art, communicating via a local area network (LAN), wide area network (WAN), public switched telephone network (PSTN), or cellular telephone network, for example.

[0053] As mentioned above, IMD **14** collects information relating to the quality of sleep experienced by patient **12**. Specifically, as will be described in greater detail below, IMD **14** monitors one or more physiological parameters of patient **12**, and determines values for one or more metrics that indicate the quality of sleep based on values of the physiological parameters. Example physiological parameters that IMD **14** may monitor include activity level, posture, heart rate, ECG morphology, respiration rate, respiratory volume, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid (CSF), muscular activity and tone, core temperature, subcutaneous temperature, arterial blood flow, the level of melatonin within one or more bodily fluids, brain electrical activity, and eye motion. In some external medical device embodiments of the invention, galvanic skin response may additionally or alternatively be monitored. Further, in some embodiments, IMD **14** additionally or alternatively monitors the variability of one or more of these parameters. In order to monitor one or more of these parameters, IMD **14** may include or be coupled to one or more sensors (not shown in **FIG. 1**), each of which generates a signal as a function of one or more of these physiological parameters.

[0054] For example, IMD **14** may determine sleep efficiency and/or sleep latency values. Sleep efficiency and sleep latency are example sleep quality metrics. IMD **14** may measure sleep efficiency as the percentage of time while patient **12** is attempting to sleep that patient **12** is actually asleep. IMD **14** may measure sleep latency as the amount of time between a first time when patient **12** begins attempting to fall asleep and a second time when patient **12** falls asleep.

[0055] IMD **14** may identify the time at which patient begins attempting to fall asleep in a variety of ways. For example, IMD **14** may receive an indication from the patient that the patient is trying to fall asleep via patient programmer **26**. In other embodiments, IMD **14** may monitor the activity level of patient **12**, and identify the time when patient **12** is attempting to fall asleep by determining whether patient **12** has remained inactive for a threshold period of time, and identifying the time at which patient **12** became inactive. In still other embodiments, IMD **14** may monitor the posture of patient **12**, and may identify the time when the patient **12** becomes recumbent, e.g., lies down, as the time when patient **12** is attempting to fall asleep. In these embodiments, IMD **14** may also monitor the activity level of patient **12**, and confirm that patient **12** is attempting to sleep based on the activity level.

[0056] As another example, IMD **14** may determine the time at which patient **12** is attempting to fall asleep based on the level of melatonin within one or more bodily fluids of patient **12**, such as the patient's blood, cerebrospinal fluid (CSF), or interstitial fluid. IMD **14** may also determine a

melatonin level based on metabolites of melatonin located in the saliva or urine of the patient. Melatonin is a hormone secreted by the pineal gland into the bloodstream and the CSF as a function of exposure of the optic nerve to light, which synchronizes the patient's circadian rhythm. In particular, increased levels of melatonin during evening hours may cause physiological changes in patient **12**, which, in turn, may cause patient **12** to attempt to fall asleep.

[**0057**] IMD **14** may, for example, detect an increase in the level of melatonin in a bodily fluid, and estimate the time that patient **12** will attempt to fall asleep based on the detection. For example, IMD **14** may compare the melatonin level or rate of change in the melatonin level to a threshold level, and identify the time that threshold value is exceeded. IMD **14** may identify the time that patient **12** is attempting to fall asleep as the time that the threshold is exceeded, or some amount of time after the threshold is exceeded.

[**0058**] IMD **14** may identify the time at which patient **12** has fallen asleep based on the activity level of the patient and/or one or more of the other physiological parameters that may be monitored by IMD **14** as indicated above. For example, IMD **14** may identify a discernable change, e.g., a decrease, in one or more physiological parameters, or the variability of one or more physiological parameters, which may indicate that patient **12** has fallen asleep. In some embodiments, IMD **14** determines a sleep probability metric value based on a value of a physiological parameter monitored by the medical device. In such embodiments, the sleep probability metric value may be compared to a threshold to identify when the patient has fallen asleep. In some embodiments, a sleep probability metric value is determined based on a value of each of a plurality of physiological parameters, the sleep probability values are averaged or otherwise combined to provide an overall sleep probability metric value, and the overall sleep probability metric value is compared to a threshold to identify the time that the patient falls asleep.

[**0059**] Other sleep quality metrics include total time sleeping per day, and the amount or percentage of time sleeping during nighttime or daytime hours per day. In some embodiments, IMD **14** may be able to detect arousal events and apneas occurring during sleep based on one or more monitored physiological parameters, and the number of apnea and/or arousal events per night may be determined as a sleep quality metric. Further, in some embodiments IMD **14** may be able to determine which sleep state patient **12** is in based on one or more monitored physiological parameters, e.g., rapid eye movement (REM), S1, S2, S3, or S4, and the amount of time per day spent in these various sleep states may be a sleep quality metric.

[**0060**] The S3 and S4 sleep states may be of particular importance to the quality of sleep experienced by patient **12**. Interruption from reaching these states, or inadequate time per night spent in these states, may cause patient **12** to not feel rested. For this reason, the S3 and S4 sleep states are believed to provide the "refreshing" part of sleep.

[**0061**] In some cases, interruption from reaching the S3 and S4 sleep states, or inadequate time per night spent in these states has been demonstrated to cause normal subjects to exhibit some symptoms of fibromyalgia. Also, subjects with fibromyalgia usually do not reach these sleep states. For these reasons, in some embodiments, IMD **14** may determine an amount or percentage of time spent in one or both of the S3 and S4 sleep states as a sleep quality metric.

[**0062**] In some embodiments, IMD **14** may determine average or median values of one or more sleep quality metrics over greater periods of time, e.g., a week or a month, as the value of the sleep quality metric. Further, in embodiments in which IMD **14** collects values for a plurality of the sleep quality metrics identified above, IMD **14** may determine a value for an overall sleep quality metric based on the collected values for the plurality of sleep quality metrics. IMD **14** may determine the value of an overall sleep quality metric by applying a function or look-up table to a plurality of sleep quality metric values, which may also include the application of weighting factors to one or more of the individual sleep quality metric values.

[**0063**] In some embodiments, IMD **14** may identify the current set of therapy parameters when a value of one or more sleep quality metrics is collected, and may associate that value with the current therapy parameter sets. For example, for each of a plurality therapy parameter sets used over time by IMD **14** to deliver therapy to patient **12**, IMD **14** may store a representative value of each of one or more sleep quality metrics in a memory with an indication of the therapy parameter set with which that representative value is associated. A representative value of sleep quality metric for a therapy parameter set may be the mean or median of collected sleep quality metric values that have been associated with that therapy parameter set.

[**0064**] One or both of programmers **20**, **26** may receive sleep quality metric values from IMD **14**, and may provide sleep quality information to a user based on the sleep quality metric values. For example, patient programmer **26** may provide a message to patient **12**, e.g., via display **28**, related to sleep quality based on received sleep quality metric values. Patient programmer **26** may, for example, suggest that patient **12** visit a clinician for prescription of sleep medication or for an adjustment to the therapy delivered by IMD **14**. As other examples, patient programmer **26** may suggest that patient **12** increase the intensity of therapy delivered by IMD **14** during nighttime hours relative to previous nights, or select a different therapy parameter set for use by IMD **14** than the patient had selected during previous nights. Further, patient programmer **26** may report the quality of the patient's sleep to patient **12** to, for example, provide patient **12** with an objective indication of whether his or her sleep quality is good, adequate, or poor.

[**0065**] Clinician programmer **20** may receive sleep quality metric values from IMD **14**, and present a variety of types of sleep information to a clinician, e.g., via display **22**, based on the sleep quality metric values. For example, clinician programmer **20** may present a graphical representation of the sleep quality metric values, such as a trend diagram of values of one or more sleep quality metrics over time, or a histogram or pie chart illustrating percentages of time that a sleep quality metric was within various value ranges.

[**0066**] In embodiments in which IMD **14** associates sleep quality metric values with therapy parameter sets, clinician programmer **20** may receive representative values for one or more sleep quality metrics from IMD **14** and information identifying the therapy parameter sets with which the representative values are associated. Using this information, clinician programmer **20** may display a list of the therapy parameter sets to the clinician ordered according to their associated representative sleep quality metric values. The

clinician may use such a list to identify effective or ineffective therapy parameter sets. Where a plurality of sleep quality metric values are collected, clinician programmer **20** may order the list according to values of a user-selected one of the sleep quality metrics. In this manner, the clinician may quickly identify the therapy parameter sets producing the best results in terms of sleep quality.

[**0067**] **FIG. 2** is a block diagram further illustrating system **10**. In particular, **FIG. 2** illustrates an example configuration of IMD **14** and leads **16**A and **16**B. **FIG. 2** also illustrates sensors **40**A and **40**B (collectively "sensors **40**") that generate signals as a function of one or more physiological parameters of patient **12**. As will be described in greater detail below, IMD **14** monitors the signals to determine values for one or more metrics that are indicative of sleep quality.

[**0068**] IMD **14** may deliver neurostimulation therapy via electrodes **42**A-D of lead **16**A and electrodes **42**E-H of lead **16**B (collectively "electrodes **42**"). Electrodes **42** may be ring electrodes. The configuration, type and number of electrodes **42** illustrated in **FIG. 2** are merely exemplary. For example, leads **16**A and **16**B may each include eight electrodes **42**, and the electrodes **42** need not be arranged linearly on each of leads **16**A and **16**B.

[**0069**] Electrodes **42** are electrically coupled to a therapy delivery module **44** via leads **16**A and **16**B. Therapy delivery module **44** may, for example, include an output pulse generator coupled to a power source such as a battery. Therapy delivery module **44** may deliver electrical pulses to patient **12** via at least some of electrodes **42** under the control of a processor **46**, which controls therapy delivery module **44** to deliver neurostimulation therapy according to to a current therapy parameter set. However, the invention is not limited to implantable neurostimulator embodiments or even to IMDs that deliver electrical stimulation. For example, in some embodiments a therapy delivery module **44** of an IMD may include a pump, circuitry to control the pump, and a reservoir to store a therapeutic agent for delivery via the pump.

[**0070**] Processor **46** may include a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or the like. Memory **48** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, and the like. In some embodiments, memory **48** stores program instructions that, when executed by processor **46**, cause IMD **14** and processor **46** to perform the functions attributed to them herein.

[**0071**] Each of sensors **40** generates a signal as a function of one or more physiological parameters of patient **12**. IMD **14** may include circuitry (not shown) that conditions the signals generated by sensors **40** such that they may be analyzed by processor **46**. For example, IMD **14** may include one or more analog to digital converters to convert analog signals generated by sensors **40** into digital signals usable by processor **46**, as well as suitable filter and amplifier circuitry. Although shown as including two sensors **40**, system **10** may include any number of sensors.

[**0072**] Further, as illustrated in **FIG. 2**, sensors **40** may be included as part of IMD **14**, or coupled to IMD **14** via leads **16**. Sensors **40** may be coupled to IMD **14** via therapy leads **16**A and **16**B, or via other leads **16**, such as lead **16**C depicted in **FIG. 2**. In some embodiments, a sensor **40** located outside of IMD **14** may be in wireless communication with processor **46**. Wireless communication between sensors **40** and IMD **14** may, as examples, include RF communication or communication via electrical signals conducted through the tissue and/or fluid of patient **12**.

[**0073**] As discussed above, exemplary physiological parameters of patient **12** that may be monitored by IMD **14** to determine values of one or more sleep quality metrics include activity level, posture, heart rate, ECG morphology, respiration rate, respiratory volume, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity and tone, core temperature, subcutaneous temperature, arterial blood flow, the level of melatonin within a bodily fluid of patient **12**, electrical activity of the brain of the patient, and eye motion. Further, as discussed above, in some external medical device embodiments of the invention, galvanic skin response may additionally or alternatively be monitored. Sensors **40** may be of any type known in the art capable of generating a signal as a function of one or more of these parameters.

[**0074**] In some embodiments, in order to determine one or more sleep quality metric values, processor **46** determines when patient **12** is attempting to fall asleep. For example, processor **46** may identify the time that patient begins attempting to fall asleep based on an indication received from patient **12**, e.g., via clinician programmer **20** and a telemetry circuit **50**. In other embodiments, processor **46** identifies the time that patient **12** begins attempting to fall asleep based on the activity level of patient **12**.

[**0075**] In such embodiments, IMD **14** may include one or more sensors **40** that generate a signal as a function of patient activity. For example, sensors **40** may include one or more accelerometers, gyros, mercury switches, or bonded piezoelectric crystals that generates a signal as a function of patient activity, e.g., body motion, footfalls or other impact events, and the like. Additionally or alternatively, sensors **40** may include one or more electrodes that generate an electromyogram (EMG) signal as a function of muscle electrical activity, which may indicate the activity level of a patient. The electrodes may be, for example, located in the legs, abdomen, chest, back or buttocks of patient **12** to detect muscle activity associated with walking, running, or the like. The electrodes may be coupled to IMD **14** wirelessly or by leads **16** or, if IMD **14** is implanted in these locations, integrated with a housing of IMD **14**.

[**0076**] However, bonded piezoelectric crystals located in these areas generate signals as a function of muscle contraction in addition to body motion, footfalls or other impact events. Consequently, use of bonded piezoelectric crystals to detect activity of patient **12** may be preferred in some embodiments in which it is desired to detect muscle activity in addition to body motion, footfalls, or other impact events. Bonded piezoelectric crystals may be coupled to IMD **14** wirelessly or via leads **16**, or piezoelectric crystals may be bonded to the can of IMD **14** when the IMD is implanted in these areas, e.g., in the back, chest, buttocks or abdomen of patient **12**.

[**0077**] Processor **46** may identify a time when the activity level of patient **12** falls below a threshold activity level value

stored in memory **48**, and may determine whether the activity level remains substantially below the threshold activity level value for a threshold amount of time stored in memory **48**. In other words, patient **12** remaining inactive for a sufficient period of time may indicate that patient **12** is attempting to fall asleep. If processor **46** determines that the threshold amount of time is exceeded, processor **46** may identify the time at which the activity level fell below the threshold activity level value as the time that patient **12** began attempting to fall asleep.

[**0078**] In some embodiments, processor **46** determines whether patient **12** is attempting to fall asleep based on whether patient **12** is or is not recumbent, e.g., lying down. In such embodiments, sensors **40** may include a plurality of accelerometers, gyros, or magnetometers oriented orthogonally that generate signals which indicate the posture of patient **12**. In addition to being oriented orthogonally with respect to each other, each of sensors **40** used to detect the posture of patient **12** may be generally aligned with an axis of the body of patient **12**. In exemplary embodiments, IMD **14** includes three orthogonally oriented posture sensors **40**.

[**0079**] When sensors **40** include accelerometers, for example, that are aligned in this manner, processor **46** may monitor the magnitude and polarity of DC components of the signals generated by the accelerometers to determine the orientation of patient **12** relative to the Earth's gravity, e.g., the posture of patient **12**. In particular, the processor **46** may compare the DC components of the signals to respective threshold values stored in memory **48** to determine whether patient **12** is or is not recumbent. Further information regarding use of orthogonally aligned accelerometers to determine patient posture may be found in a commonly assigned U.S. Pat. No. 5,593,431, which issued to Todd J. Sheldon.

[**0080**] Other sensors **40** that may generate a signal that indicates the posture of patient **12** include electrodes that generate an electromyogram (EMG) signal, or bonded piezoelectric crystals that generate a signal as a function of contraction of muscles. Such sensors **40** may be implanted in the legs, buttocks, chest, abdomen, or back of patient **12**, as described above. The signals generated by such sensors when implanted in these locations may vary based on the posture of patient **12**, e.g., may vary based on whether the patient is standing, sitting, or laying down.

[**0081**] Further, the posture of patient **12** may affect the thoracic impedance of the patient. Consequently, sensors **40** may include an electrode pair, including one electrode integrated with the housing of IMD **14** and one of electrodes **42**, that generates a signal as a function of the thoracic impedance of patient **12**, and processor **46** may detect the posture or posture changes of patient **12** based on the signal. The electrodes of the pair may be located on opposite sides of the patient's thorax. For example, the electrode pair may include one of electrodes **42** located proximate to the spine of a patient for delivery of SCS therapy, and IMD **14** with an electrode integrated in its housing may be implanted in the abdomen of patient **12**.

[**0082**] Additionally, changes of the posture of patient **12** may cause pressure changes with the cerebrospinal fluid (CSF) of the patient. Consequently, sensors **40** may include pressure sensors coupled to one or more intrathecal or intracerebroventricular catheters, or pressure sensors coupled to IMD **14** wirelessly or via lead **16**. CSF pressure changes associated with posture changes may be particularly evident within the brain of the patient, e.g., may be particularly apparent in an intracranial pressure (ICP) waveform.

[**0083**] In some embodiments, processor **46** considers both the posture and the activity level of patient **12** when determining whether patient **12** is attempting to fall asleep. For example, processor **46** may determine whether patient **12** is attempting to fall asleep based on a sufficiently long period of sub-threshold activity, as described above, and may identify the time that patient began attempting to fall asleep as the time when patient **12** became recumbent.

[**0084**] In other embodiments, processor **46** determines when patient **12** is attempting to fall asleep based on the level of melatonin in a bodily fluid. In such embodiments, a sensor **40** may take the form of a chemical sensor that is sensitive to the level of melatonin or a metabolite of melatonin in the bodily fluid, and estimate the time that patient **12** will attempt to fall asleep based on the detection. For example, processor **46** may compare the melatonin level or rate of change in the melatonin level to a threshold level stored in memory **48**, and identify the time that threshold value is exceeded. Processor **46** may identify the time that patient **12** is attempting to fall asleep as the time that the threshold is exceeded, or some amount of time after the threshold is exceeded. Any of a variety of combinations or variations of the above-described techniques may be used to determine when patient **12** is attempting to fall asleep, and a specific one or more techniques may be selected based on the sleeping and activity habits of a particular patient.

[**0085**] Processor **46** may also determine when patient **12** is asleep, e.g., identify the times that patient **12** falls asleep and wakes up, in order to determine one or more sleep quality metric values. The detected values of physiological parameters of patient **12**, such as activity level, heart rate, ECG morphological features, respiration rate, respiratory volume, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity and tone, core temperature, subcutaneous temperature, arterial blood flow, brain electrical activity, eye motion and galvanic skin response may discernibly change when patient **12** falls asleep or wakes up. Some of these physiological parameters may be at low values when patient **12** is asleep. Further, the variability of at least some of these parameters, such as heart rate and respiration rate, may be at a low value when the patient is asleep.

[**0086**] Consequently, in order to detect when patient **12** falls asleep and wakes up, processor **46** may monitor one or more of these physiological parameters, or the variability of these physiological parameters, and detect the discernable changes in their values associated with a transition between a sleeping state and an awake state. In some embodiments, processor **46** may determine a mean or median value for a parameter based on values of a signal over time, and determine whether patient **12** is asleep or awake based on the mean or median value. Processor **46** may compare one or more parameter or parameter variability values to thresholds stored in memory **48** to detect when patient **12** falls asleep or awakes. The thresholds may be absolute values of a physiological parameter, or time rate of change values for the physiological parameter, e.g., to detect sudden changes

in the value of a parameter or parameter variability. In some embodiments, a threshold used by processor **46** to determine whether patient **12** is asleep may include a time component. For example, a threshold may require that a physiological parameter be above or below a threshold value for a period of time before processor **46** determines that patient is awake or asleep.

[**0087**] In some embodiments, in order to determine whether patient **12** is asleep, processor **46** monitors a plurality of physiological parameters, and determines a value of a metric that indicates the probability that patient **12** is asleep for each of the parameters based on a value of the parameter. In particular, the processor **46** may apply a function or look-up table to the current, mean or median value, and/or the variability of each of a plurality of physiological parameters to determine a sleep probability metric for each of the plurality of physiological parameters. A sleep probability metric value may be a numeric value, and in some embodiments may be a probability value, e.g., a number within the range from 0 to 1, or a percentage value.

[**0088**] Processor **46** may average or otherwise combine the plurality of sleep probability metric values to provide an overall sleep probability metric value. In some embodiments, processor **46** may apply a weighting factor to one or more of the sleep probability metric values prior to combination. Processor **46** may compare the overall sleep probability metric value to one or more threshold values stored in memory **48** to determine when patient **12** falls asleep or awakes. Use of sleep probability metric values to determine when a patient is asleep based on a plurality of monitored physiological parameters is described in greater detail in a commonly-assigned and copending U.S. patent application Ser. No. _____ by Ken Heruth and Keith Miesel, entitled "DETECTING SLEEP," which was assigned Attorney Docket No. 1023-360US02 and filed on Mar. 16, 2005, and is incorporated herein by reference in its entirety.

[**0089**] To enable processor **46** to determine when patient **12** is asleep or awake, sensors **40** may include, for example, activity sensors as described above. In some embodiments, the activity sensors may include electrodes or bonded piezoelectric crystals, which may be implanted in the back, chest, buttocks, or abdomen of patient **12** as described above. In such embodiments, processor **46** may detect the electrical activation and contractions of muscles associated with gross motor activity of the patient, e.g., walking, running or the like via the signals generated by such sensors. Processor **46** may also detect spasmodic or pain related muscle activation via the signals generated by such sensors. Spasmodic or pain related muscle activation may indicate that patient **12** is not sleeping, e.g., unable to sleep, or if patient **12** is sleeping, may indicate a lower level of sleep quality.

[**0090**] As another example, sensors **40** may include electrodes located on leads or integrated as part of the housing of IMD **14** that generate an electrogram signal as a function of electrical activity of the heart of patient **12**, and processor **46** may monitor the heart rate of patient **12** based on the electrogram signal. In other embodiments, a sensor may include an acoustic sensor within IMD **14**, a pressure or flow sensor within the bloodstream or cerebrospinal fluid of patient **12**, or a temperature sensor located within the bloodstream of patient **12**. The signals generated by such sensors may vary as a function of contraction of the heart of patient **12**, and can be used by IMD **14** to monitor the heart rate of patient **12**.

[**0091**] In some embodiments, processor **46** may detect, and measure values for one or more ECG morphological features within an electrogram generated by electrodes as described above. ECG morphological features may vary in a manner that indicates whether patient **12** is asleep or awake. For example, the amplitude of the ST segment of the ECG may decrease when patient **12** is asleep. Further, the amplitude of QRS complex or T-wave may decrease, and the widths of the QRS complex and T-wave may increase when patient **12** is asleep. The QT interval and the latency of an evoked response may increase when patient **12** is asleep, and the amplitude of the evoked response may decrease when patient **12** is asleep.

[**0092**] In some embodiments, sensors **40** may include an electrode pair, including one electrode integrated with the housing of IMD **14** and one of electrodes **42**, that generates a signal as a function of the thoracic impedance of patient **12**, as described above. The thoracic impedance signal varies as a function of respiration by patient **12**. In other embodiments, sensors **40** may include a strain gage, bonded piezoelectric element, or pressure sensor within the blood or cerebrospinal fluid that generates a signal that varies based on patient respiration. An electrogram generated by electrodes as discussed above may also be modulated by patient respiration, and may be used as an indirect representation of respiration rate.

[**0093**] Sensors **40** may include electrodes that generate an electromyogram (EMG) signal as a function of muscle electrical activity, as described above, or may include any of a variety of known temperature sensors to generate a signal as a function of a core or subcutaneous temperature of patient **12**. Such electrodes and temperature sensors may be incorporated within the housing of IMD **14**, or coupled to IMD **14** wirelessly via leads. Sensors **40** may also include a pressure sensor within, or in contact with, a blood vessel. The pressure sensor may generate a signal as a function of the a blood pressure of patient **12**, and may, for example, comprise a Chronicle Hemodynamic Monitor™ commercially available from Medtronic, Inc. of Minneapolis, Minn. Further, certain muscles of patient **12**, such as the muscles of the patient's neck, may discernibly relax when patient **12** is asleep or within certain sleep states. Consequently, sensors **40** may include strain gauges or EMG electrodes implanted in such locations that generate a signal as a function of muscle tone.

[**0094**] Sensors **40** may also include optical pulse oximetry sensors or Clark dissolved oxygen sensors located within, as part of a housing of, or outside of IMD **14**, which generate signals as a function of blood oxygen saturation and blood oxygen partial pressure respectively. In some embodiments, system **10** may include a catheter with a distal portion located within the cerebrospinal fluid of patient **12**, and the distal end may include a Clark dissolved oxygen sensor to generate a signal as a function of the partial pressure of oxygen within the cerebrospinal fluid. Embodiments in which an IMD comprises an implantable pump, for example, may include a catheter with a distal portion located in the cerebrospinal fluid.

[**0095**] In some embodiments, sensors **40** may include one or more intraluminal, extraluminal, or external flow sensors

positioned to generate a signal as a function of arterial blood flow. A flow sensor may be, for example, an electromagnetic, thermal convection, ultrasonic-Doppler, or laser-Doppler flow sensor. Further, in some external medical device embodiments of the invention, sensors **40** may include one or more electrodes positioned on the skin of patient **12** to generate a signal as a function of galvanic skin response.

[**0096**] Additionally, in some embodiments, sensors **40** may include one or more electrodes positioned within or proximate to the brain of patient **12**, which detect electrical activity of the brain. For example, in embodiments in which IMD **14** delivers stimulation or therapeutic agents to the brain, processor **46** may be coupled to electrodes implanted on or within the brain via a lead **16**. In other embodiments, processor **46** may be wirelessly coupled to electrodes that detect brain electrical activity.

[**0097**] For example, one or more modules may be implanted beneath the scalp of the patient, each module including a housing, one or more electrodes, and circuitry to wirelessly transmit the signals detected by the one or more electrodes to IMD **14**. In other embodiments, the electrodes may be applied to the patient's scalp, and electrically coupled to a module that includes circuitry for wirelessly transmitting the signals detected by the electrodes to IMD **14**. The electrodes may be glued to the patient's scalp, or a head band, hair net, cap, or the like may incorporate the electrodes and the module, and may be worn by patient **12** to apply the electrodes to the patient's scalp when, for example, the patient is attempting to sleep. The signals detected by the electrodes and transmitted to IMD **14** may be electroencephalogram (EEG) signals, and processor **46** may process the EEG signals to detect when patient **12** is asleep using any of a variety of known techniques, such as techniques that identify whether a patient is asleep based on the amplitude and/or frequency of the EEG signals.

[**0098**] Also, the motion of the eyes of patient **12** may vary depending on whether the patient is sleeping and which sleep state the patient is in. Consequently, sensors **40** may include electrodes place proximate to the eyes of patient **12** to detect electrical activity associated with motion of the eyes, e.g., to generate an electro-oculography (EOG) signal. Such electrodes may be coupled to IMD **14** via one or more leads **16**, or may be included within modules that include circuitry to wirelessly transmit detected signals to IMD **14**. Wirelessly coupled modules incorporating electrodes to detect eye motion may be worn externally by patient **12**, e.g., attached to the skin of patient **12** proximate to the eyes by an adhesive when the patient is attempting to sleep.

[**0099**] Processor **46** may also detect arousals and/or apneas that occur when patient **12** is asleep based on one or more of the above-identified physiological parameters. For example, processor **46** may detect an arousal based on an increase or sudden increase in one or more of heart rate, heart rate variability, respiration rate, respiration rate variability, blood pressure, or muscular activity as the occurrence of an arousal. Processor **46** may detect an apnea based on a disturbance in the respiration rate of patient **12**, e.g., a period with no respiration.

[**0100**] Processor **46** may also detect arousals or apneas based on sudden changes in one or more of the ECG morphological features identified above. For example, a sudden elevation of the ST segment within the ECG may indicate an arousal or an apnea. Further, sudden changes in the amplitude or frequency of an EEG signal, EOG signal, or muscle tone signal may indicate an apnea or arousal. Memory **48** may store thresholds used by processor **46** to detect arousals and apneas. Processor **46** may determine, as a sleep quality metric value, the number of apnea events and/or arousals during a night.

[**0101**] Further, in some embodiments, processor **46** may determine which sleep state patient **12** is in during sleep, e.g., REM, S1, S2, S3, or S4, based on one or more of the monitored physiological parameters. In some embodiments, memory **48** may store one or more thresholds for each of sleep states, and processor **46** may compare physiological parameter or sleep probability metric values to the thresholds to determine which sleep state patient **12** is currently in. Further, in some embodiments, processor **46** may use any of a variety of known techniques for determining which sleep state patient is in based on an EEG signal, which processor **46** may receive via electrodes as described above, such as techniques that identify sleep state based on the amplitude and/or frequency of the EEG signals. In some embodiments, processor **46** may also determine which sleep state patient is in based on an EOG signal, which processor **46** may receive via electrodes as described above, either alone or in combination with an EEG signal, using any of a variety of techniques known in the art. Processor **46** may determine, as sleep quality metric values, the amounts of time per night spent in the various sleep states. As discussed above, inadequate time spent in deeper sleep states, e.g., S3 and S4, is an indicator of poor sleep quality. Consequently, in some embodiments, processor **46** may determine an amount or percentage of time spent in one or both of the S3 and S4 sleep states as a sleep quality metric.

[**0102**] **FIG. 3** further illustrates memory **48** of IMD **14**. As illustrated in **FIG. 3**, memory **48** stores information describing a plurality of therapy parameter sets **60**. Therapy parameter sets **60** may include parameter sets specified by a clinician using clinician programmer **20**. Therapy parameter sets **60** may also include parameter sets that are the result of patient **12** changing one or more parameters of one of the preprogrammed therapy parameter sets via patient programmer **26**.

[**0103**] Memory **48** may also include parameter information **62** recorded by processor **46**, e.g., physiological parameter values, or mean or median physiological parameter values. Memory **48** stores threshold values **64** used by processor **46** in the collection of sleep quality metric values, as discussed above. In some embodiments, memory **48** also stores one or more functions or look-up tables (not shown) used by processor **46** to determine sleep probability metric values, or to determine an overall sleep quality metric value.

[**0104**] Further, processor **46** stores determined values **66** for one or more sleep quality metrics within memory **48**. Processor **46** may collect sleep quality metric values **66** each time patient **12** sleeps, or only during selected times that patient **12** is asleep. Processor **46** may store each sleep quality metric value determined within memory **48** as a sleep quality metric value **66**, or may store mean or median sleep quality metric values over periods of time such as weeks or months as sleep quality metric values **66**. Further, processor **46** may apply a function or look-up table to a plurality of sleep quality metric values to determine overall

sleep quality metric value, and may store the overall sleep quality metric values within memory **48**. The application of a function or look-up table by processor **46** for this purpose may involve the use or weighting factors for one or more of the individual sleep quality metric values.

[**0105**] In some embodiments, processor **46** identifies which of therapy parameter sets **60** is currently selected for use in delivering therapy to patient **12** when a value of one or more sleep quality metrics is collected, and may associate that value with the current therapy parameter set. For example, for each of the plurality of therapy parameter sets **60**, processor **46** may store a representative value of each of one or more sleep quality metrics within memory **48** as a sleep quality metric value **66** with an indication of which of the therapy parameter sets that representative value is associated with. A representative value of sleep quality metric for a therapy parameter set may be the mean or median of collected sleep quality metric values that have been associated with that therapy parameter set.

[**0106**] As shown in **FIG. 2**, IMD **14** also includes a telemetry circuit **50** that allows processor **46** to communicate with clinician programmer **20** and patient programmer **26**. Processor **46** may receive information identifying therapy parameter sets **60** preprogrammed by the clinician and threshold values **64** from clinician programmer **20** via telemetry circuit **50** for storage in memory **48**. Processor **46** may receive an indication of the therapy parameter set **60** selected by patient **12** for delivery of therapy, or adjustments to one or more of therapy parameter sets **60** made by patient **12**, from patient programmer **26** via telemetry circuit **50**. Programmers **20**, **26** may receive sleep quality metric values **66** from processor **46** via telemetry circuit **50**.

[**0107**] **FIG. 4** is a flow diagram illustrating an example method for collecting sleep quality information that may be employed by IMD **14**. IMD **14** monitors the posture, activity level, and/or melatonin level of patient **12**, or monitors for an indication from patient **12**, e.g., via patient programmer **26** (**70**), and determines whether patient **12** is attempting to fall asleep based on the posture, activity level, melatonin level, and/or a patient indication, as described above (**72**). If IMD **14** determines that patient **12** is attempting to fall asleep, IMD **14** identifies the time that patient **12** began attempting to fall asleep using any of the techniques described above (**74**), and monitors one or more of the various physiological parameters of patient **12** discussed above to determine whether patient **12** is asleep (**76**, **78**).

[**0108**] In some embodiments, IMD **14** compares parameter values or parameter variability values to one or more threshold values **64** to determine whether patient **12** is asleep. In other embodiments, IMD **14** applies one or more functions or look-up tables to determine one or more sleep probability metric values based on the physiological parameter values, and compares the sleep probability metric values to one or more threshold values **64** to determine whether patient **12** is asleep. While monitoring physiological parameters (**76**) to determine whether patient **12** is asleep (**78**), IMD **14** may continue to monitor the posture and/or activity level of patient **12** (**70**) to confirm that patient **12** is still attempting to fall asleep (**72**).

[**0109**] When IMD **14** determines that patient **12** is asleep, e.g., by analysis of the various parameters contemplated herein, IMD **14** will identify the time that patient **12** fell asleep (**80**). While patient **12** is sleeping, IMD **14** will continue to monitor physiological parameters of patient **12** (**82**). As discussed above, IMD **14** may identify the occurrence of arousals and/or apneas based on the monitored physiological parameters (**84**). Further, IMD **14** may identify the time that transitions between sleep states, e.g., REM, S1, S2, S3, and S4, occur based on the monitored physiological parameters (**84**).

[**0110**] Additionally, while patient **12** is sleeping, IMD **14** monitors physiological parameters of patient **12** (**82**) to determine whether patient **12** has woken up (**86**). When IMD **14** determines that patient **12** is awake, IMD **14** identifies the time that patient **12** awoke (**88**), and determines sleep quality metric values based on the information collected while patient **12** was asleep (**90**).

[**0111**] For example, one sleep quality metric value IMD **14** may calculate is sleep efficiency, which IMD **14** may calculate as a percentage of time during which patient **12** is attempting to sleep that patient **12** is actually asleep. IMD **14** may determine a first amount of time between the time IMD **14** identified that patient **12** fell asleep and the time IMD **14** identified that patient **12** awoke. IMD **14** may also determine a second amount of time between the time IMD **14** identified that patient **12** began attempting to fall asleep and the time IMD **14** identified that patient **12** awoke. To calculate the sleep efficiency, IMD **14** may divide the first time by the second time.

[**0112**] Another sleep quality metric value that IMD **14** may calculate is sleep latency, which IMD **14** may calculate as the amount of time between the time IMD **14** identified that patient **12** was attempting to fall asleep and the time IMD **14** identified that patient **12** fell asleep. Other sleep quality metrics with values determined by IMD **14** based on the information collected by IMD **14** in the illustrated example include: total time sleeping per day, at night, and during daytime hours; number of apnea and arousal events per occurrence of sleep; and amount of time spent in the various sleep states, e.g., one or both of the S3 and S4 sleep states. IMD **14** may store the determined values as sleep quality metric values **66** within memory **48**.

[**0113**] IMD **14** may perform the example method illustrated in **FIG. 4** continuously, e.g., may monitor to identify when patient **12** is attempting to sleep and asleep any time of day, each day. In other embodiments, IMD **14** may only perform the method during evening hours and/or once every N days to conserve battery and memory resources. Further, in some embodiments, IMD **14** may only perform the method in response to receiving a command from patient **12** or a clinician via one of programmers **20**, **26**. For example, patient **12** may direct IMD **14** to collect sleep quality information at times when the patient believes that his or her sleep quality is low or therapy is ineffective.

[**0114**] **FIG. 5** is a flow diagram illustrating an example method for associating sleep quality information with therapy parameter sets **60** that may be employed by IMD **14**. IMD **14** determines a value of a sleep quality metric according to any of the techniques described above (**100**). IMD **14** also identifies the current therapy parameter set, e.g., the therapy parameter set **60** used by IMD **14** to control delivery of therapy when patient **12** was asleep (**102**), and associates the newly determined value with the current therapy parameter set **60**.

[0115] Among sleep quality metric values **66** within memory **48**, IMD **14** stores a representative value of the sleep quality metric, e.g., a mean or median value, for each of the plurality of therapy parameter sets **60**. IMD **14** updates the representative values for the current therapy parameter set based on the newly determined value of the sleep quality metric. For example, a newly determined sleep efficiency value may be used to determine a new average sleep efficiency value for the current therapy parameter set **60**.

[0116] **FIG. 6** is a block diagram further illustrating clinician programmer **20**. A clinician may interact with a processor **110** via a user interface **112** in order to program therapy for patient **12**. Further, processor **110** may receive sleep quality metric values **66** from IMD **14** via a telemetry circuit **114**, and may generate sleep quality information for presentation to the clinician via user interface **112**. User interface **112** may include display **22** and keypad **24**, and may also include a touch screen or peripheral pointing devices as described above. Processor **110** may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like.

[0117] Clinician programmer **20** also includes a memory **116**. Memory **116** may include program instructions that, when executed by processor **110**, cause clinician programmer **20** to perform the functions ascribed to clinician programmer **20** herein. Memory **116** may include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0118] **FIG. 7** is a flow diagram illustrating an example method for presenting sleep quality information to a clinician that may be employed by clinician programmer **20**. Clinician programmer **20** receives sleep quality metric values **66** from IMD **14**, e.g., via telemetry circuit **114** (**120**). The sleep quality metric values **66** may be daily values, or mean or median values determined over greater periods of time, e.g., weeks or months.

[0119] Clinician programmer **20** may simply present the values to the clinician via display **22** in any form, such as a table of average values, or clinician programmer **20** may generate a graphical representation of the sleep quality metric values (**122**). For example, clinician programmer **20** may generate a trend diagram illustrating sleep quality metric values **66** over time, or a histogram, pie chart, or other graphic illustration of percentages of sleep quality metric values **66** collected by IMD **14** that were within ranges. Where clinician programmer **20** generates a graphical representation of the sleep quality metric values **66**, clinician programmer **20** presents the graphical representation to the clinician via display **22** (**124**).

[0120] **FIG. 8** illustrates an example list **130** of therapy parameter sets and associated sleep quality metric values that may be presented to a clinician by clinician programmer **20**. Each row of example list **130** includes an identification of one of therapy parameter sets **60**, the parameters of the set, and a representative value for one or more sleep quality metrics associated with the identified therapy parameter set, such as sleep efficiency, sleep latency, or both. The example list **130** includes representative values for sleep efficiency, sleep latency, and "deep sleep," e.g., the average amount of time per night spent in either of the S3 and S4 sleep states.

[0121] **FIG. 9** is a flow diagram illustrating an example method for displaying a list **130** of therapy parameter sets and associated sleep quality information that may be employed by clinician programmer **20**. According to the example method, clinician programmer **20** receives information identifying the plurality of therapy parameter sets **60** stored in memory **48** of IMD **14**, and one or more representative sleep quality metric values associated with each of the therapy parameter sets (**140**). Clinician programmer **20** generates a list **130** of the therapy parameter sets **60** and any associated representative sleep quality metric values (**142**), and orders the list according to a selected sleep quality metric (**144**). For example, in the example list **130** illustrated in **FIG. 8**, the clinician may select whether list **130** should be ordered according to sleep efficiency or sleep latency via user interface **112** of clinician programmer **20**.

[0122] **FIG. 10** is a block diagram further illustrating patient programmer **26**. Patient **12** may interact with a processor **150** via a user interface **152** in order to control delivery of therapy, i.e., select or adjust one or more of therapy parameter sets **60** stored by IMD **14**. Processor **150** may also receive sleep quality metric values **66** from IMD **14** via a telemetry circuit **154**, and may provide messages related to sleep quality to patient **12** via user interface **152** based on the received values. User interface **152** may include display **28** and keypad **30**, and may also include a touch screen or peripheral pointing devices as described above.

[0123] In some embodiments, processor **150** may determine whether to provide a message related to sleep quality to patient **12** based on the received sleep quality metric values. For example, processor **150** may periodically receive sleep quality metric values **66** from IMD **14** when placed in telecommunicative communication with IMD **14** by patient **12**, e.g., for therapy selection or adjustment. Processor **150** may compare these values to one or more thresholds **156** stored in a memory **158** to determine whether the quality of the patient's sleep is poor enough to warrant a message.

[0124] Processor **150** may present messages to patient **12** as text via display, and/or as audio via speakers included as part of user interface **152**. The message may, for example, direct patient **12** to see a physician, increase therapy intensity before sleeping, or select a different therapy parameter set before sleeping than the patient had typically selected previously. In some embodiments, the message may indicate the quality of sleep to patient **12** to, for example, provide patient **12** with an objective indication of whether his or her sleep quality is good, adequate, or poor. Further, in some embodiments processor **150** may, like clinician programmer **20**, receive representative sleep quality metric values. In such embodiments, processor **150** may identify a particular one or more of therapy parameter sets **60** to recommend to patient **12** based on representative sleep quality metric values associated with those programs.

[0125] Processor **150** may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or the like. Memory **158** may also include program instructions that, when executed by processor **150**, cause patient programmer **26** to perform the functions ascribed to patient programmer **26** herein. Memory **158** may include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM,

hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0126] **FIG. 11** is a flow diagram illustrating an example method for presenting a sleep quality message to patient **12** that may be employed by patient programmer **26**. According to the illustrated example method, patient programmer **26** receives a sleep quality metric value from IMD **14** (**160**), and compares the value to a threshold value **156** (**162**). Patient programmer **26** determines whether the comparison indicates poor sleep quality (**164**). If the comparison indicates that the quality of sleep experienced by patient **12** is poor, patient programmer **26** presents a message related to sleep quality to patient **12** (**166**).

[0127] Various embodiments of the invention have been described. However, one skilled in the art will recognize that various modifications may be made to the described embodiments without departing from the scope of the invention. For example, although described herein primarily in the context of treatment of pain with an implantable neurostimulator, the invention is not so limited. The invention may be embodied in any implantable medical device, such as a cardiac pacemaker, an implantable pump, or an implantable monitor that does not itself deliver a therapy to the patient. Further, the invention may be implemented via an external, e.g., non-implantable, medical device.

[0128] Additionally, the invention is not limited to embodiments in which a programming device receives information from the medical device, or presents information to a user. Other computing devices, such as handheld computers, desktop computers, workstations, or servers. May receive information from the medical device and present information to a user as described herein with reference to programmers **20**, **26**. A computing device, such as a server, may receive information from the medical device and present information to a user via a network, such as a local area network (LAN), wide area network (WAN), or the Internet. In some embodiments, the medical device is an external medical device, and may itself include a display to present information to a user.

[0129] As another example, the invention may be embodied in a trial neurostimulator, which is coupled to percutaneous leads implanted within the patient to determine whether the patient is a candidate for neurostimulation, and to evaluate prospective neurostimulation therapy parameter sets. Similarly, the invention may be embodied in a trial drug pump, which is coupled to a percutaneous catheter implanted within the patient to determine whether the patient is a candidate for an implantable pump, and to evaluate prospective therapeutic agent delivery parameter sets. Sleep quality metric values collected by the trial neurostimulator or pump may be used by a clinician to evaluate the prospective therapy parameter sets, and select parameter sets for use by the later implanted non-trial neurostimulator or pump. In particular, a trial neurostimulator or pump may determine representative values of one or more sleep quality metrics for each of a plurality of prospective therapy parameter sets, and a computing device, such as a clinician programmer, may present a list of prospective parameter sets and associated representative values to a clinician. The clinician may use the list to identify potentially efficacious parameter sets, and may program a permanent implantable neurostimulator or pump for the patient with the identified parameter sets.

[0130] Further, the invention is not limited to embodiments in which an implantable or external medical device that delivers therapy to a patient determines sleep quality metric values. Instead a medical device according to the invention may record values for one or more physiological parameters, and provide the physiological parameter values to a computing device, such as one or both of programmers **20**, **26**. In such embodiments, the computing device, and more particularly a processor of the computing device, e.g., processors **110**, **150**, employs any of the techniques described herein with reference to IMD **14** in order to determine sleep quality metric values based on the physiological parameter values received from the medical device. The computing device may receive physiological parameter values from the medical device in real time, or may monitor physiological parameters of the patient by receiving and analyzing physiological parameter values recorded by the medical device over a period of time. In some embodiments, in addition to physiological parameter values, the medical device provides the computing device information identifying times at which the patient indicated that he or she was attempting to fall asleep, which the computing device may use to determine one or more sleep quality metric values as described herein.

[0131] In some embodiments, the medical device may associate recorded physiological parameter values with current therapy parameter sets. The medical device may provide information indicating the associations of recorded physiological parameter values and therapy parameter sets to the computing device, e.g., programmer **20** or **26**. The computing device may determine sleep quality metric values and representative sleep quality metric values for each of the plurality of therapy parameter sets based on the physiological parameter values associated with the therapy parameter sets, as described herein with reference to IMD **14**.

[0132] Additionally, the invention is not limited to embodiments in which the therapy delivering medical device monitors the physiological parameters of the patient described herein. In some embodiments, a separate monitoring device monitors values of one or more physiological parameters of the patient instead of, or in addition to, a therapy delivering medical device. The monitor may include a processor **46** and memory **48**, and may be coupled to sensors **40**, as illustrated above with reference to IMD **14** and **FIGS. 2 and 3**. The monitor may identify sleep quality metric values based on the values of the monitored physiological parameter values, or may transmit the physiological parameter values to a computing device for determination of the sleep quality metric values. In some embodiments, an external computing device, such as a programming device, may incorporate the monitor.

[0133] **FIG. 12** is a conceptual diagram illustrating a monitor **170** that monitors values of one or more physiological parameters of the patient instead of, or in addition to, a therapy delivering medical device. In the illustrated example, monitor **170** is configured to be attached to or otherwise carried by a belt **172**, and may thereby be worn by patient **12**. FIG. **12** also illustrates various sensors **40** that may be coupled to monitor **170** by leads, wires, cables, or wireless connections, such as EEG electrodes **174**A-C placed on the scalp of patient **12**, a plurality of EOG electrodes **176**A and **176**B placed proximate to the eyes of patient **12**, and one or more EMG electrodes **178** placed on

the chin or jaw the patient. The number and positions of electrodes **174**, **176** and **178** illustrated in **FIG. 12** are merely exemplary. For example, although only three EEG electrodes **174** are illustrated in **FIG. 1**, an array of between 16 and 25 EEG electrodes **174** may be placed on the scalp of patient **12**, as is known in the art. EEG electrodes **174** may be individually placed on patient **12**, or integrated within a cap or hair net worn by the patient.

[**0134**] In the illustrated example, patient **12** wears an ECG belt **180**. ECG belt **180** incorporates a plurality of electrodes for sensing the electrical activity of the heart of patient **12**. The heart rate and, in some embodiments, ECG morphology of patient **12** may monitored by monitor **170** based on the signal provided by ECG belt **180**. Examples of suitable belts **180** for sensing the heart rate of patient **12** are the "M" and "F" heart rate monitor models commercially available from Polar Electro. In some embodiments, instead of belt **180**, patient **12** may wear of plurality of ECG electrodes attached, e.g., via adhesive patches, at various locations on the chest of the patient, as is known in the art. An ECG signal derived from the signals sensed by such an array of electrodes may enable both heart rate and ECG morphology monitoring, as is known in the art.

[**0135**] As shown in **FIG. 12**, patient **12** may also wear a respiration belt **182** that outputs a signal that varies as a function of respiration of the patient. Respiration belt **182** may be a plethysmograpy belt, and the signal output by respiration belt **182** may vary as a function of the changes is the thoracic or abdominal circumference of patient **12** that accompany breathing by the patient. An example of a suitable belt **182** is the TSD201 Respiratory Effort Transducer commercially available from Biopac Systems, Inc. Alternatively, respiration belt **182** may incorporate or be replaced by a plurality of electrodes that direct an electrical signal through the thorax of the patient, and circuitry to sense the impedance of the thorax, which varies as a function of respiration of the patient, based on the signal. In some embodiments, ECG and respiration belts **180** and **182** may be a common belt worn by patient **12**, and the relative locations of belts **180** and **182** depicted in **FIG. 12** are merely exemplary.

[**0136**] In the example illustrated by **FIG. 12**, patient **12** also wears a transducer **184** that outputs a signal as a function of the oxygen saturation of the blood of patient **12**. Transducer **184** may be an infrared transducer. Transducer **184** may be located on one of the fingers or earlobes of patient **12**. Sensors **40** coupled to monitor **170** may additionally or alternatively include any of the variety of sensors described above that monitor any one or more of activity level, posture, heart rate, ECG morphology, respiration rate, respiratory volume, blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity and tone, core temperature, subcutaneous temperature, arterial blood flow, brain electrical activity, eye motion, and galvanic skin response.

[**0137**] The invention may also be embodied as a computer-readable medium that includes instructions to cause a processor to perform any of the methods described herein. These and other embodiments are within the scope of the following claims.

1. A method comprising:

monitoring at least one physiological parameter of a patient;

determining a value of a metric that is indicative of sleep quality based on the at least one physiological parameter;

identifying a current therapy parameter used by a medical device to deliver a therapy to a patient; and

associating the sleep quality metric value with the current therapy parameter set.

2. The method of claim 1, wherein monitoring at least one physiological parameter comprises monitoring at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

3. A medical system comprising:

a medical device that delivers a therapy to a patient;

a monitor that monitors at least one physiological parameter of the patient based on a signal received from at least one sensor; and

a processor that determines a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, identifies a current therapy parameter set used by the medical device to deliver the therapy to the patient, and associates the sleep quality metric value with the current therapy parameter set.

4. The medical system of claim 3, wherein the monitor monitors at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity within a brain of the patient or eye motion.

5. The medical system of claim 3, further comprising a computing device to present sleep quality information to a user based on the sleep quality metric values determined by the processor.

6. The medical system of claim 5, wherein the user comprises a clinician, and the computing device comprises a clinician programmer that presents at least one of a trend diagram, a histogram or a pie chart to the clinician based on the sleep quality metric values.

7. The medical system of claim 5, wherein the user comprises a patient, and the computing device comprises a patient programmer that presents a message related to sleep quality to the patient based on the sleep quality metric values.

8. The medical system of claim 3,

wherein the processor determines a plurality of values of the sleep quality metric over time, and associates each of the determined values of the sleep quality metric with a current therapy parameter set, and

wherein, for each of a plurality of therapy parameter sets, the processor determines a representative value of the sleep quality metric based on the values of the sleep quality metric associated with the therapy parameter set,

the system further comprising a computing device that presents a list of the therapy parameter sets and the associated representative values to a user, and orders

the list of therapy parameter sets according to the associated representative values.

9. The medical system of claim 3,

wherein the processor determines a plurality of values over time for each of a plurality of metrics that are indicative of sleep quality, and associates each of the determined values with a current therapy parameter set, and

wherein, for each of the plurality of therapy parameter sets, the processor determines a representative value for each of the sleep quality metrics based on the values of that sleep quality metric associated with the therapy parameter set,

the system further comprising a computing device that presents a list of the therapy parameter sets and the associated representative values to a user, and orders the list of therapy parameter sets according to the representative values of a user-selected one of the sleep quality metrics.

10. The medical system of claim 3, wherein the processor comprises a processor of at least one of the medical device and the monitor.

11. The medical system of claim 3, further comprising a computing device, wherein the processor comprises a processor of the computing device.

12. The medical system of claim 3, wherein the medical device comprises the monitor.

13. A method comprising:

monitoring a plurality of signals, each of the signals generated by a sensor as a function of at least one physiological parameter of a patient;

identifying when the patient is attempting to sleep;

identifying when the patient is asleep based on at least one of the signals; and

determining a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and asleep,

wherein identifying when the patient is asleep comprises identifying when the patient is asleep based on at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity within a brain of the patient or eye motion.

14. A medical system comprising:

a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient; and

a processor that monitors the signals generated by the sensors, identifies when the patient is attempting to sleep, identifies when the patient is asleep based on at least one of the signals, and determines a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and asleep, wherein the processor identifies when the patient is asleep based on at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity within a brain of the patient or eye motion.

15. A medical system comprising:

a plurality of sensors, each of the sensors generating a signal as a function of at least one physiological parameter of a patient;

a computing device that monitors the signals generated by the sensors, identifies when the patient is attempting to sleep, identifies when the patient is asleep based on at least one of the signals, and determines a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and asleep.

16. The medical system of claim 15, wherein the computing device comprises a programming device.

17. The medical system of claim 15, wherein the computing device receives the signals generated by the sensors via a network.

18. The medical system of claim 17, wherein the computing device comprises a server.

* * * * *

专利名称(译)	通过医疗设备收集睡眠质量信息		
公开(公告)号	US20050215847A1	公开(公告)日	2005-09-29
申请号	US11/081811	申请日	2005-03-16
[标]申请(专利权)人(译)	HERUTH KENNETH ŧ MIESEL KEITH一个		
申请(专利权)人(译)	HERUTH KENNETH ŧ MIESEL KEITH一个		
当前申请(专利权)人(译)	HERUTH KENNETH ŧ MIESEL KEITH一个		
[标]发明人	HERUTH KENNETH T MIESEL KEITH A		
发明人	HERUTH, KENNETH T. MIESEL, KEITH A.		
IPC分类号	A61B5/0476 A61B5/11 A61M5/142 A61M5/172 A61N1/05 A61N1/34 A61N1/36 A61N1/365 A61N1/372 A61M21/00 A61B5/00 A61B5/04		
CPC分类号	A61B5/0476 A61N1/36139 A61B5/1118 A61B5/4815 A61M5/14276 A61M5/1723 A61N1/36071 A61N1/36521 A61N1/36542 A61N1/36557 A61N1/36078 A61N1/36135 A61B5/686 A61B5/6826 A61B5/1116 A61N1/3614 A61B3/113 A61B5/01 A61B5/0402 A61N1/36514 A61N1/3702 A61N1/37247		
优先权	60/553783 2004-03-16 US		
外部链接	Espacenet USPTO		

摘要(译)

诸如可植入医疗设备，监视器和计算设备的医疗设备中的至少一个确定用于指示患者睡眠质量的一个或多个度量的值。睡眠效率，睡眠潜伏期和在较深睡眠状态中花费的时间是可以确定其值的示例性睡眠质量度量。在一些实施例中，确定的睡眠质量度量值与当前治疗参数集相关联。在一些实施例中，编程设备基于所确定的睡眠质量度量值值向用户呈现睡眠质量信息。例如，临床医生可以使用由编程设备呈现的睡眠质量信息来评估由医疗设备递送给患者的治疗的有效性，调整由医疗设备递送的治疗，或者规定不由医疗设备，以提高患者的睡眠质量。