US 20090306740A1

(19) **United States**

(12) **Patent Application Publication**

Heruth et al.

(10) **Pub. No.: US 2009/0306740 A1**

(43) **Pub. Date: Dec. 10, 2009**

(54) **CONTROLLING THERAPY BASED ON SLEEP QUALITY**

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

Correspondence Address:
SHUMAKER & SIEFFERT , P.A
1625 RADIO DRIVE , SUITE 300
WOODBURY, MN 55125 (US)

(73) Assignee: **Medtronic, Inc.**, Minneapolis, MN (US)

(21) Appl. No.: **12/544,727**

(22) Filed: **Aug. 20, 2009**

Related U.S. Application Data

(63) Continuation of application No. 11/081,155, filed on Mar. 16, 2005, now Pat. No. 7,590,455, which is a continuation-in-part of application No. 10/825,953, filed on Apr. 15, 2004, now Pat. No. 7,366,572.

(60) Provisional application No. 60/553,777, filed on Mar. 16, 2004.

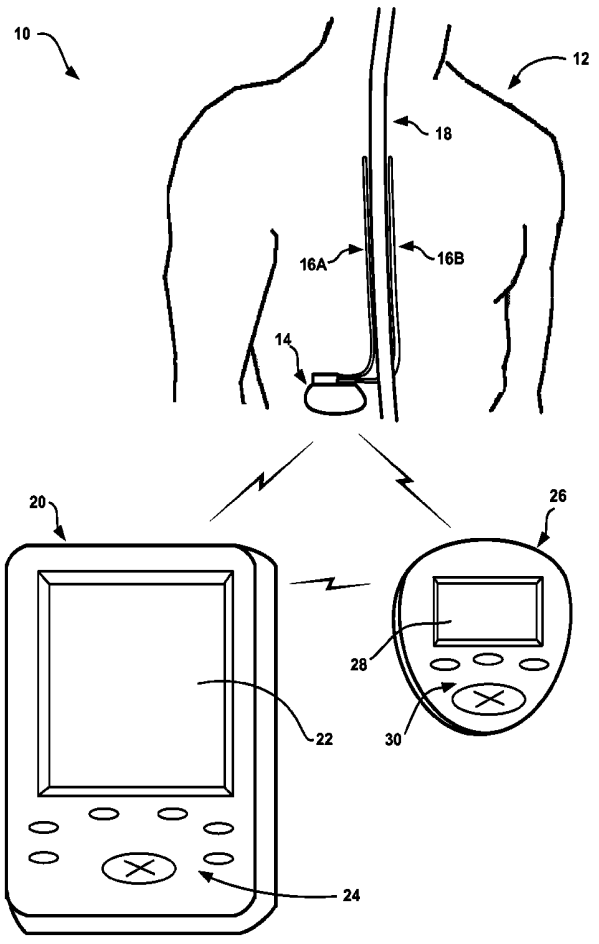
Publication Classification

(51) **Int. Cl.**
A61N 1/34 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **607/46**; 600/300

(57) **ABSTRACT**

A medical device, such as an implantable medical device (IMD), determines values for one or more metrics that indicate the quality of a patient's sleep, and controls delivery of a therapy based on the sleep quality metric values. For example, the medical device may compare a sleep quality metric value with one or more threshold values, and adjust the therapy based on the comparison. In some embodiments, the medical device adjusts the intensity of therapy based on the comparison, e.g., increases the therapy intensity when the comparison indicates that the patient's sleep quality is poor. In some embodiments, the medical device automatically selects one of a plurality of therapy parameter set available for use in delivering therapy based on a comparison sleep quality metric values associated with respective therapy parameter sets within the plurality of available therapy parameter sets.



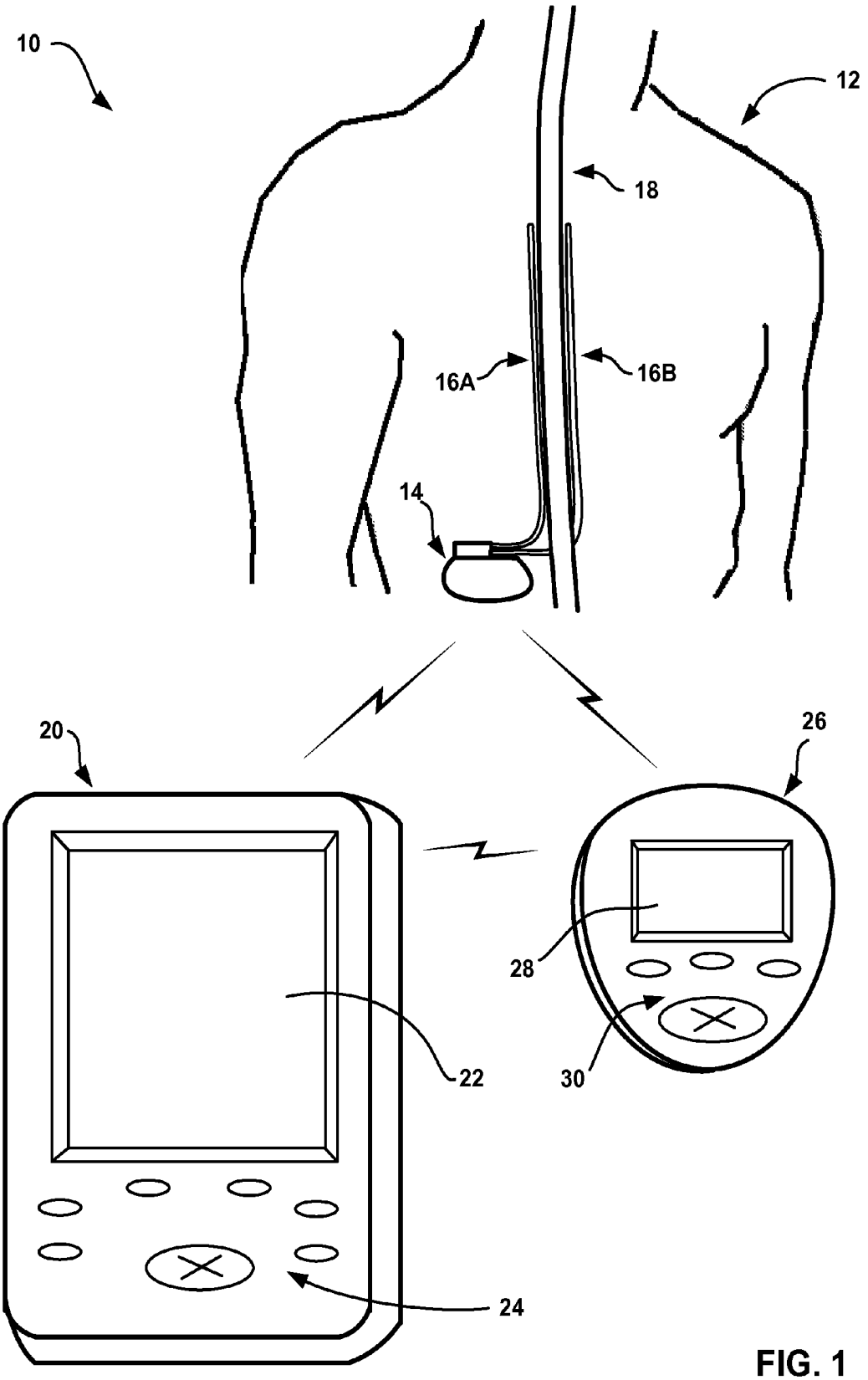


FIG. 1

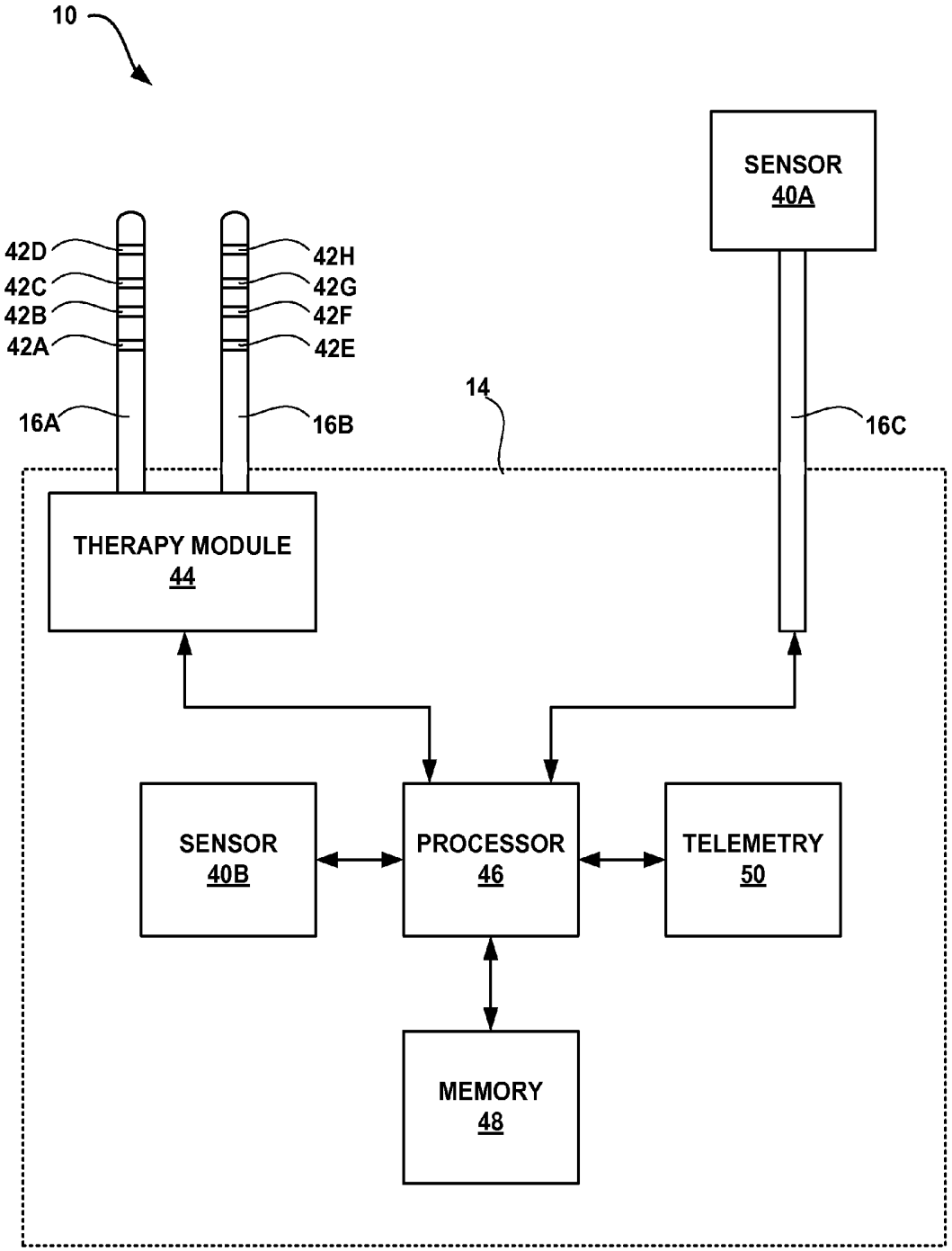

10
SENSOR
40A
42D
42C
42B
42A
42H
42G
42F
42E
14
16A
16B
16C
THERAPY MODULE
44
SENSOR
40B
PROCESSOR
46
TELEMETRY
50
MEMORY
48

FIG. 2

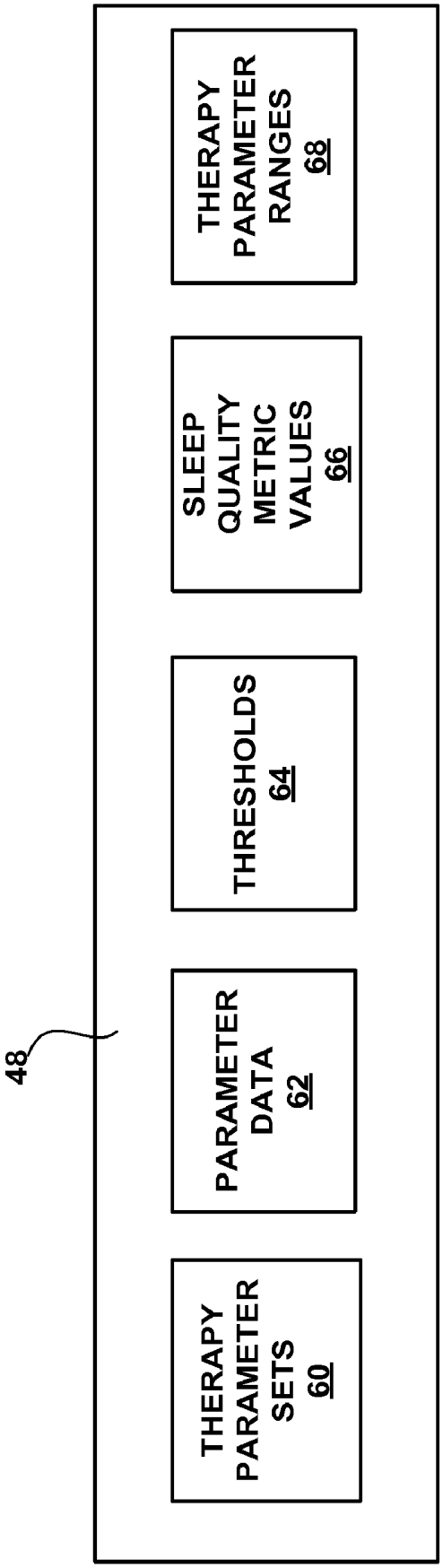

48
THERAPY PARAMETER SETS 60
PARAMETER DATA 62
THRESHOLDS 64
SLEEP QUALITY METRIC VALUES 66
THERAPY PARAMETER RANGES 68

FIG. 3

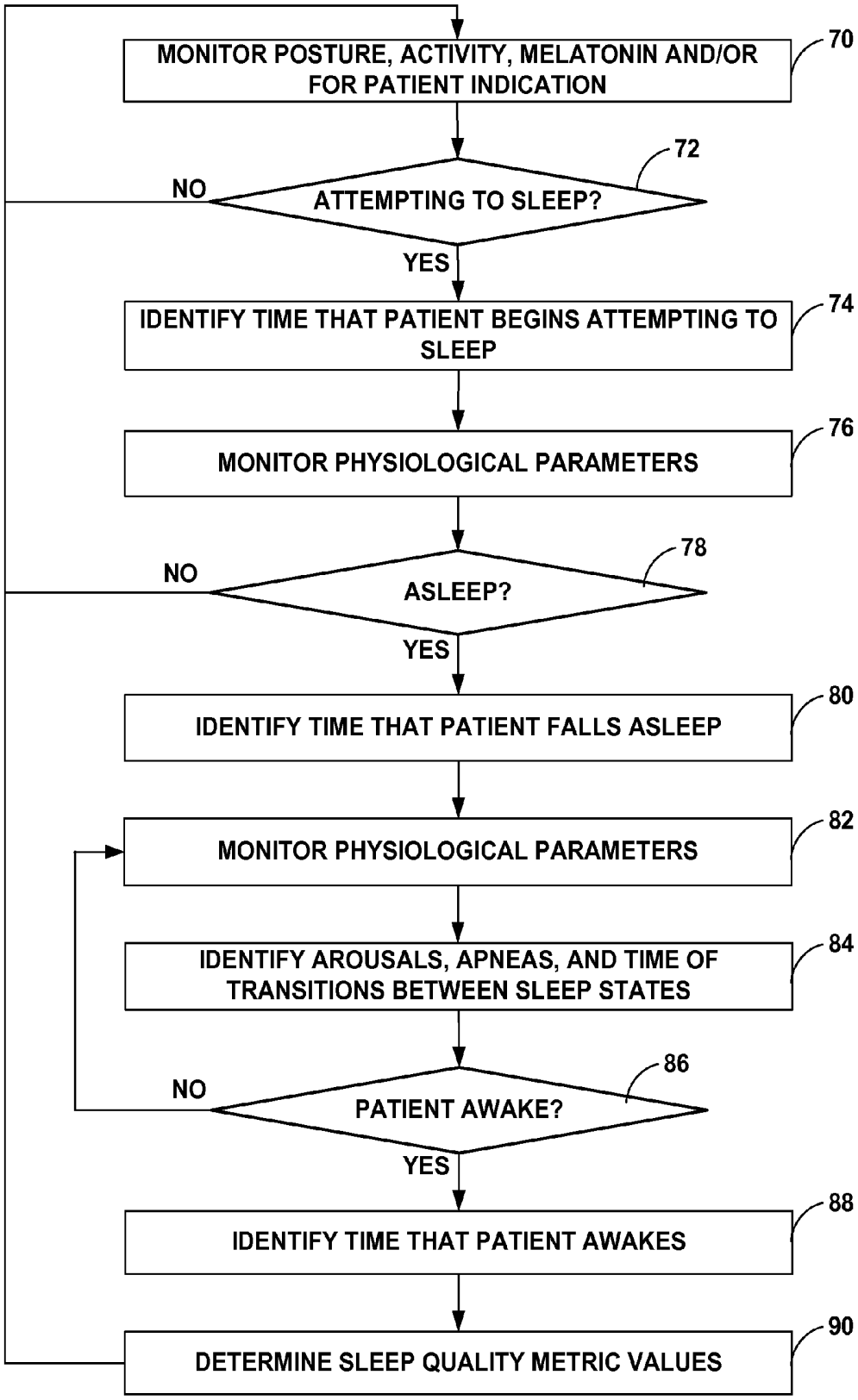

MONITOR POSTURE, ACTIVITY, MELATONIN AND/OR FOR PATIENT INDICATION
70
ATTEMPTING TO SLEEP?
72
NO
YES
IDENTIFY TIME THAT PATIENT BEGINS ATTEMPTING TO SLEEP
74
MONITOR PHYSIOLOGICAL PARAMETERS
76
ASLEEP?
78
NO
YES
IDENTIFY TIME THAT PATIENT FALLS ASLEEP
80
MONITOR PHYSIOLOGICAL PARAMETERS
82
IDENTIFY AROUSALS, 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

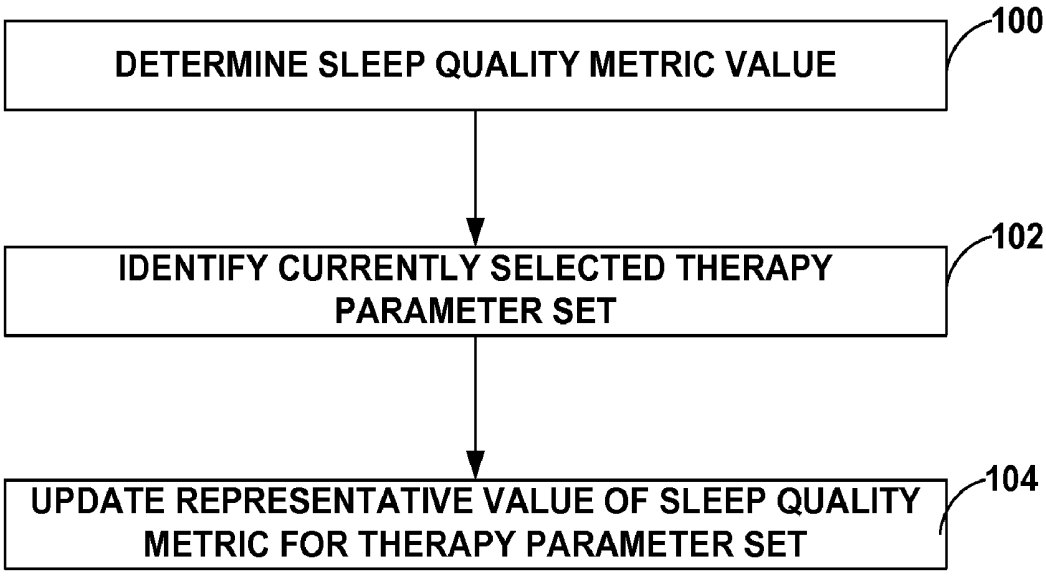

DETERMINE SLEEP QUALITY METRIC VALUE
100
IDENTIFY CURRENTLY SELECTED THERAPY PARAMETER SET
102
UPDATE REPRESENTATIVE VALUE OF SLEEP QUALITY METRIC FOR THERAPY PARAMETER SET
104

FIG. 5

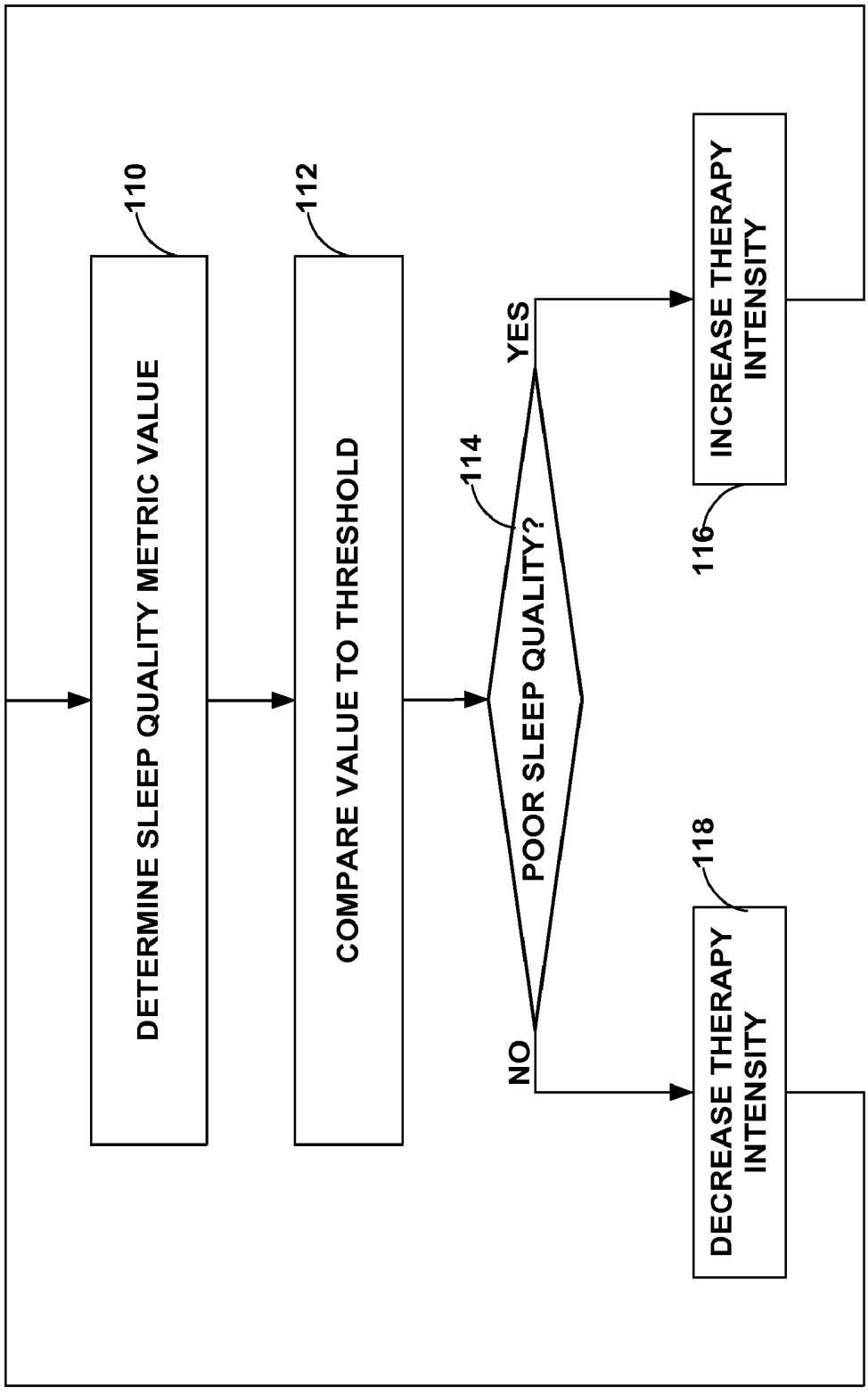

DETERMINE SLEEP QUALITY METRIC VALUE
110
COMPARE VALUE TO THRESHOLD
112
POOR SLEEP QUALITY?
114
YES
NO
INCREASE THERAPY INTENSITY
116
DECREASE THERAPY INTENSITY
118

FIG. 6

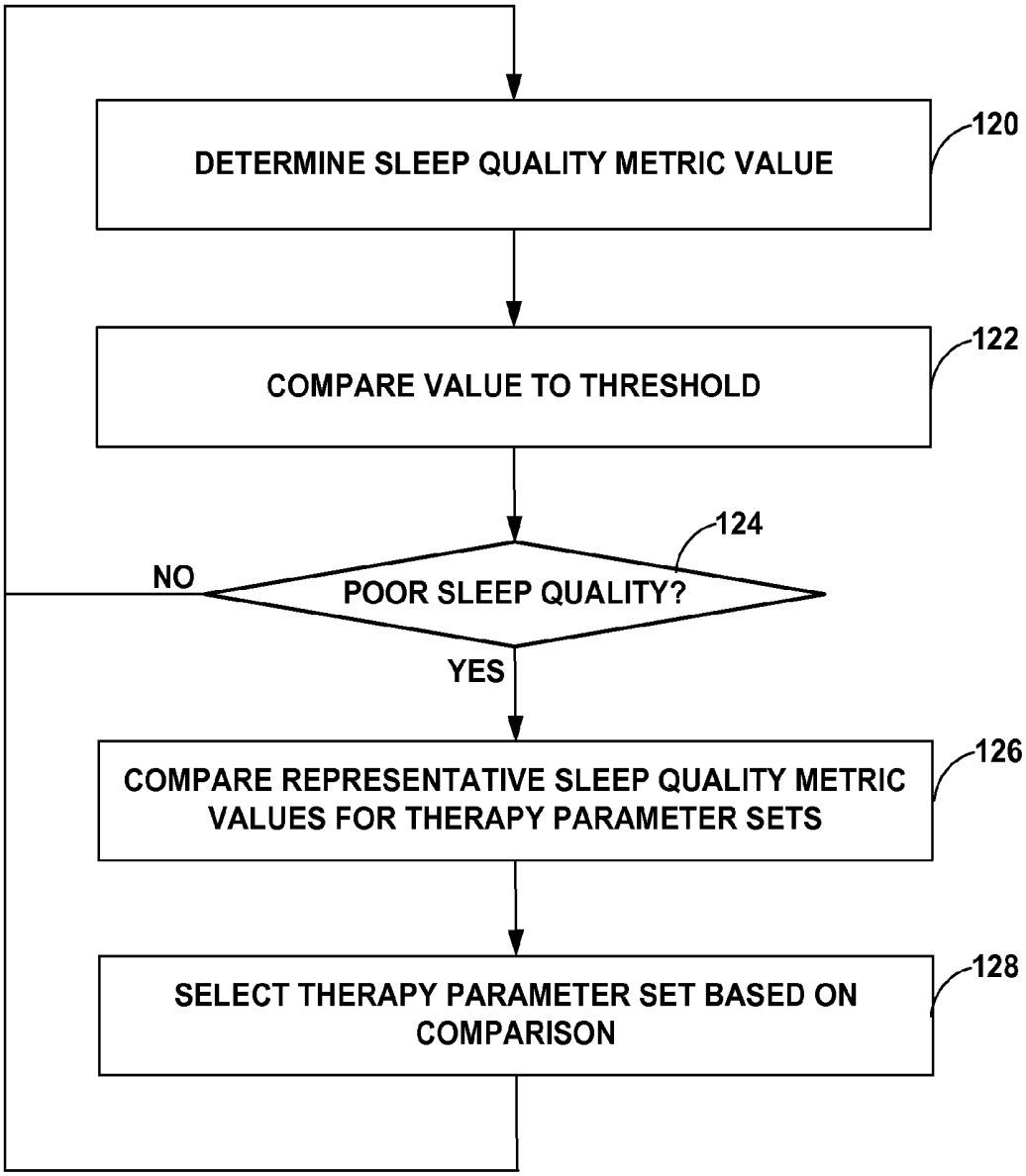

DETERMINE SLEEP QUALITY METRIC VALUE
120
COMPARE VALUE TO THRESHOLD
122
124
POOR SLEEP QUALITY?
NO
YES
COMPARE REPRESENTATIVE SLEEP QUALITY METRIC VALUES FOR THERAPY PARAMETER SETS
126
SELECT THERAPY PARAMETER SET BASED ON COMPARISON
128

FIG. 7

CONTROLLING THERAPY BASED ON SLEEP QUALITY

[0001] This application is a continuation of U.S. patent application Ser. No. 11/081,155, filed Mar. 16, 2005, which is a continuation-in-part of U.S. patent application Ser. No. 10/825,953, filed Apr. 15, 2004, which claims the benefit of U.S. Provisional Application No. 60/553,777, filed Mar. 16, 2004. The entire content of each of these applications is incorporated herein by reference.

TECHNICAL FIELD

[0002] The invention relates to medical devices and, more particularly, to medical devices that deliver a therapy.

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 the nonrapid eye movement (NREM) sleep state. 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 controlling delivery of a therapy to a patient by a medical device, such as an implantable medical device (IMD), based on the quality of sleep experienced by a patient. In particular, a medical device according to the invention determines values for one or more metrics that indicate the quality of a patient's sleep, and controls delivery of a therapy based on the sleep quality metric values. A medical device according to the invention may be able to adjust the therapy to address symptoms causing disturbed sleep or symptoms that are worsened by disturbed sleep, such as chronic pain.

[0006] The medical device monitors one or more physiological parameters of the patient in order to determine values for the one or more sleep quality metrics. 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 some embodiments, the medical device additionally or alternatively monitors the variability of one or more of these parameters. In order to monitor one or more of these parameters, the medical device may include, be coupled to, or be in wireless communication with one or more sensors, each of which outputs a signal as a function of one or more of these physiological parameters.

[0007] Sleep efficiency and sleep latency are example sleep quality metrics for which a medical device according to the invention 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 begins attempting to sleep and a second time when the patient falls asleep.

[0008] The time when the patient begins attempting to fall asleep may be determined in a variety of ways. For example, the medical device may receive an indication from the patient that the patient is trying to fall asleep, e.g., via a patient programming device in embodiments in which the medical device is an implantable medical device. In other embodiments, the medical device may monitor the activity level of the patient, determining whether the patient has remained inactive for a threshold period of time, and identify the time at which the patient became inactive as the time at which the patient begin attempting to fall asleep. In still other embodiments, the medical device may monitor patient posture, and 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 in which the medical device determines when the patient is recumbent, the medical device may also monitor patient activity, and the medical may confirm that the patient is attempting to sleep based on the patient's activity level.

[0009] As another example, the medical 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 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 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.

[0010] The medical device may determine the time at which the patient 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 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, the medical device may determine a sleep probability metric value based on a value of a physiological parameter. In such embodiments, the medical device may compare the sleep probability metric value to a threshold to identify when

the patient has fallen asleep. In some embodiments, the medical device may determine a plurality of sleep probability metric values based on a value of each of a plurality of physiological parameters, average or otherwise combine the plurality of sleep probability metric values to provide an overall sleep probability metric value, and compare the overall sleep probability metric value to a threshold to identify the time that the patient falls asleep.

[0011] Other sleep quality metrics that the medical device may determine 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, the medical device may be able to determine 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), and the amount of time per day spent in these various sleep states may be determined as 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, the medical device 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 the medical device collects values for a plurality of the sleep quality metrics identified above, the medical device may determine a value for an overall sleep quality metric based on the collected values for the plurality of sleep quality metrics.

[0012] The medical device controls delivery of therapy based on determined sleep quality metric values. For example, the medical device may compare a current, a mean, a median, or an overall sleep quality metric value with one or more threshold values, and adjust the therapy based on the comparison. In some embodiments, the medical device adjusts the intensity of therapy based on the comparison, e.g., increases the therapy intensity when the comparison indicates that the patient's sleep quality is poor. In embodiments in which the medical device is a neurostimulator, for example, the pulse amplitude, pulse width, pulse rate, or duty cycle of delivered neurostimulation can be adjusted. As another example, in embodiments in which the medical device is a pump, the dosage or infusion rate of a therapeutic agent delivered by the pump can be adjusted.

[0013] In some embodiments, the medical device delivers therapy according to a current set of therapy parameters. The current therapy parameter set may be a selected one of a plurality of therapy parameter sets specified by a clinician. The currently selected therapy one of these preprogrammed parameter sets may be selected by a processor of the medical device, e.g., according to a therapy schedule, or by the patient using a patient programmer. A current therapy parameter set may also be the result of the patient modifying one or more parameters of a preprogrammed parameter set. In either case, the medical device identifies the current therapy parameter set when a value of one or more sleep quality metrics is collected, and may associate that value with the current therapy parameter set.

[0014] For example, for each of a plurality of therapy parameter sets, 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 parameter set with which the 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 some embodiments, the medical device controls delivery of therapy according to sleep quality metric values by automatically selecting one of the plurality therapy parameter sets for use in delivering therapy based on a comparison of their representative sleep quality metric values, e.g., automatically selects the therapy parameter set whose representative values indicate the highest sleep quality.

[0015] In one embodiment, the invention is directed to a method in which at least one physiological parameter of a patient is monitored via a medical device that delivers a therapy to a patient. A value of a metric that is indicative of sleep quality is determined based on the at least one physiological parameter. Delivery of the therapy by the medical device is controlled based on the sleep quality metric value. Monitoring at least one physiological parameter may comprise monitoring at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

[0016] In another embodiment, the invention is directed to a medical device comprising a therapy module to deliver a therapy to a patient and a processor. The processor monitors at least one physiological parameter of a patient based on at least one signal received from at least one sensor, determines a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, and controls delivery of the therapy by the therapy module based on the sleep quality metric value. The processor may monitor at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

[0017] In another embodiment, the invention is directed to a computer-readable medium containing instructions. The instructions cause a programmable processor to monitor at least one physiological parameter of a patient via a medical device delivers a therapy to the patient, determine a value of a metric that is indicative of sleep quality based on the at least one physiological parameter, and control delivery of the therapy by the medical device based on the sleep quality metric value. The instructions may cause a programmable processor to monitor at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

[0018] The invention is capable of providing one or more advantages. For example, a medical device according to the invention may be able to adjust the therapy to address symptoms causing disturbed sleep, or symptoms that are worsened by disturbed sleep. Adjusting therapy based on sleep quality information may significantly improve the patient's sleep quality and condition. The ability of a medical device to adjust therapy based on sleep quality may be particularly advantageous in embodiments in which the medical device delivers the therapy to treat chronic pain, which may both disturb sleep and be worsened by disturbed sleep. Moreover, the ability of the medical device to both automatically identify a need for therapy adjustment and automatically adjust the therapy may reduce the need for the patient to make time consuming and expensive clinic visits when the patient's sleep is disturbed or symptoms have worsened.

[0019] 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

[0020] FIG. **1** is a conceptual diagram illustrating an example system that includes an implantable medical device that controls delivery of therapy based on sleep quality information according to the invention.

[0021] FIG. **2** is a block diagram further illustrating the example system and implantable medical device of FIG. **1**.

[0022] FIG. **3** is a block diagram illustrating an example memory of the implantable medical device of FIG. **1**.

[0023] FIG. **4** is a flow diagram illustrating an example method for collecting sleep quality information that may be employed by an implantable medical device.

[0024] FIG. **5** is a flow diagram illustrating an example method for associating sleep quality information with therapy parameter sets that may be employed by a medical device.

[0025] FIG. **6** is a flow diagram illustrating an example method for controlling therapy based on sleep quality information that may be employed by a medical device.

[0026] FIG. **7** is a flow diagram illustrating another example method for controlling therapy based on sleep quality information that may be employed by a medical device.

DETAILED DESCRIPTION

[0027] FIG. **1** is a conceptual diagram illustrating an example system **10** that includes an implantable medical device (IMD) **14** that controls delivery of a therapy to a patient **12** based on sleep quality information. In particular, as will be described in greater detail below, IMD **14** determines values for one or more metrics that indicate the quality of sleep experienced by patient **12**, and controls delivery of the therapy based on the sleep quality metric values. IMD **14** may be able to adjust the therapy to address symptoms causing disturbed sleep, or symptoms that are worsened by disturbed sleep. In exemplary embodiments, IMD **14** delivers a therapy to treat chronic pain, which may both negatively impact the quality of sleep experienced by patient **12**, and be worsened by inadequate sleep quality.

[0028] 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**. 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**.

[0029] However, the invention is not limited to the configuration of leads **16** shown in FIG. **1**, or to 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.

[0030] Moreover, the invention is not limited to implementation via an implantable neurostimulator, or even implementation via an IMD. For example, in some embodiments of the invention, an implantable or external or cardiac rhythm management device, such as a pacemaker, may control delivery of a therapy based on sleep quality information. In other words, any implantable or external medical device that delivers a therapy may control delivery of the therapy based on collected sleep quality information according to the invention.

[0031] In the example of FIG. **1**, 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 for 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.

[0032] In other non-neurostimulator embodiments of the invention, the IMD may still deliver therapy according to a therapy parameter set. For example, implantable pump IMD embodiments may deliver a therapeutic agent to a patient according to a therapy parameter set that includes, for example, a dosage, an infusion rate, and/or a duty cycle.

[0033] 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.

[0034] 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, mouse, or the like. Keypad **24** may take the form of an alphanumeric keypad or a reduced set of keys associated with particular functions.

[0035] 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.

[0036] Patient programmer **26** may also 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.

[0037] 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 a tablet-based computing device, a desktop computing device, or a workstation.

[0038] 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.

[0039] 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.

[0040] As mentioned above, IMD **14** controls delivery of a therapy, e.g., neurostimulation, to patient **12** based on the quality sleep experienced by the patient. In particular, as will be described in greater detail below, IMD **14** determines values for one or more metrics that indicate the quality of sleep experienced by patient **12**. IMD **14** controls delivery of the therapy to patient **12**, e.g., adjusts the therapy, based on the sleep quality metric values.

[0041] IMD **14** monitors one or more physiological parameters of the patient in order to determine values for the one or more sleep quality metrics. 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. Some external medical device embodiments of the invention may additionally or alternatively monitor galvanic skin response. 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, be coupled to, or be in wireless communication with one or more sensors (not shown in FIG. **1**), each of which outputs a signal as a function of one or more of these physiological parameters.

[0042] 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 sleep and a second time when patient **12** falls asleep, e.g., as an indication of how long it takes patient **12** to fall asleep.

[0043] 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] In some embodiments, IMD **14** compares a current, a mean, a median, or an overall sleep quality metric value with one or more threshold values, and adjusts the therapy delivered by IMD **14** based on the comparison. In such embodiments, IMD **14** may adjust the intensity of the therapy based on the comparison. For example, IMD **14** may increase the intensity of the therapy when the comparison indicates that the sleep quality experienced by patient **12** is poor in order to address the symptoms which are disturbing the patient's sleep, and/or to address the increase in symptoms which may result from the disturbed sleep.

[0052] For example, in embodiments such that illustrated by FIG. **1** in which IMD **14** is a neurostimulator, IMD **14** may increase the pulse amplitude, pulse width, pulse rate, or duty cycle, e.g., duration, of delivered neurostimulation. As another example, in embodiments in which an IMD is an implantable pump, the IMD may increase the dosage, infusion rate, or duty cycle of a therapeutic agent delivered by the pump. IMD **14** may adjust such parameters within ranges specified by a clinician or a manufacturer of IMD **14**.

[0053] In some embodiments, IMD **14** may iteratively and incrementally increase the intensity so long as the comparison indicates poor sleep quality. In other embodiments, IMD **14** may substantially increase the intensity of the therapy when the comparison indicates poor sleep quality in order to more quickly identify an efficacious operating point. In some embodiments, IMD **14** may gradually decrease the intensity of the therapy so long as the comparison indicates that the sleep quality experienced by patient **12** is adequate to, for example, conserve the energy stored by a battery of IMD **14**. In other embodiments, the amount by which IMD **14** increases or decreases the intensity of therapy may be proportional to the difference or ratio between the current sleep quality metric value and the threshold value.

[0054] In some embodiments, IMD **14** 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 current therapy parameter set. For example, for each of a plurality of therapy parameter sets, 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 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 some embodiments, IMD **14** controls delivery of therapy according to sleep quality metric values by automatically selecting one of the plurality of therapy parameter sets for use in delivering therapy based on a comparison of their representative sleep quality metric values, e.g., automatically select the therapy parameter set whose representative sleep quality metric values indicate the highest sleep quality.

[0055] 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 output signals as a function of one or more physiological parameters of patient **12**.

[0056] 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.

[0057] 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 one or more neurostimulation therapy parameter sets selected from available parameter sets stored in a memory **48**. 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 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, and a processor of the IMD may control delivery of a therapeutic agent by the pump according to an infusion parameter set selected from among a plurality of infusion parameter sets stored in a memory.

[0058] IMD **14** may also include a telemetry circuit **50** that enables processor **46** to communicate with programmers **20**,

26. Via telemetry circuit 50, processor 46 may receive therapy parameter sets specified by a clinician from clinician programmer 20 for storage in memory 48. Processor 46 may also receive therapy parameter set selections and therapy adjustments made by patient 12 using patient programmer 26 via telemetry circuit 50. In some embodiments, processor 46 may provide diagnostic information recorded by processor 46 and stored in memory 48 to one of programmers 20, 26 via telemetry circuit 50.

[0059] 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.

[0060] Each of sensors 40 outputs 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 output 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 output 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.

[0061] 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 16A and 16B, or via other leads 16, such as lead 16C depicted in FIG. 2. In some embodiments, a sensor 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.

[0062] 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, brain electrical activity, and eye motion. Further, as discussed above, external medical device embodiments of the invention may additionally or alternatively monitor galvanic skin response. Sensors 40 may be of any type known in the art capable of outputting a signal as a function of one or more of these parameters.

[0063] 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.

[0064] 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.

[0065] 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 housing of IMD 14 when the IMD is implanted in these areas, e.g., in the back, chest, buttocks or abdomen of patient 12.

[0066] 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.

[0067] 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.

[0068] 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.

[0069] 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.

[0070] 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**.

[0071] 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 a 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.

[0072] 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. Any of a variety of combinations or variations of these 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.

[0073] 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.

[0074] 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.

[0075] 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.

[0076] 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 value 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 level.

[0077] 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. 11/081,786, by Ken Heruth and Keith Miesel, entitled "DETECTING SLEEP," which was filed on Mar. 16, 2005, and is incorporated herein by reference in its entirety.

[0078] 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.

[0079] As another example, sensors **40** may include electrodes located on leads or integrated as part of the housing of IMD **14** that output 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 sensor within the bloodstream or cerebrospinal fluid of patient **12**, or a temperature sensor located within the bloodstream of patient **12**. The signals output 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**.

[0080] 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.

[0081] 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 outputs a signal as a function of the thoracic impedance of patient **12**, as described above, which 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 outputs a signal that varies based on patient respiration. An electrogram output by electrodes as discussed above may also be modulated by patient respiration, and may be used as an indirect representation of respiration rate.

[0082] Sensors **40** may include electrodes that output 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 output 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 or via leads. Sensors **40** may also include a pressure sensor within, or in contact with, a blood vessel. The pressure sensor may output 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.

[0083] 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 output 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 sensor to output 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.

[0084] In some embodiments, sensors **40** may include one or more intraluminal, extraluminal, or external flow sensors positioned to output a signal as a function of arterial blood flow. A flow sensor may be, for example, and 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 output a signal as a function of galvanic skin response.

[0085] Additionally, in some embodiments, sensors **40** may include one or more electrodes positioned within or proximate to the brain of patient, which detect electrical activity of the brain. For example, in embodiments in which IMD **14** delivers stimulation or other therapy 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.

[0086] 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.

[0087] 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.

[0088] 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.

[0089] 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.

[0090] 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.

[0091] FIG. **3** further illustrates memory **48** of IMD **14**. As illustrated in FIG. **3**, memory **48** stores 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**.

[0092] Memory **48** may also include parameter information **60** 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.

[0093] 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.

[0094] 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 parameter set. For example, for each available therapy parameter set **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 therapy parameter set 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 parameter set.

[0095] In some embodiments, as discussed above, processor **46** may adjust the intensity of the therapy delivered by therapy module **44** based on one or more sleep quality metric values **66**. In particular, processor **46** may adjust one or more therapy parameters, such as pulse amplitude, pulse width, pulse rate, and duty cycle to adjust the intensity of the stimulation. In some embodiments, memory **48** may store parameter ranges **68** specified by a clinician or the manufacturer of IMD **14**, and processor **46** may adjust parameters within the specified ranges.

[0096] In some embodiments, processor **46** may iteratively and incrementally increase the intensity so long as the comparison indicates poor sleep quality. In other embodiments, processor **46** may substantially increase the intensity of the therapy when the comparison indicates poor sleep quality in order to more quickly identify an efficacious operating point. In some embodiments, processor **46** may gradually decrease the intensity of the therapy so long as the comparison indicates that the sleep quality experienced by patient **12** is adequate to, for example, conserve the energy stored by a battery of IMD **14**. In other embodiments, the amount by which processor **46** increases or decreases the intensity of therapy may be proportional to the difference or ratio between the current sleep quality metric value and a threshold value.

[0097] 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).

[0098] 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).

[0099] 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).

[0100] 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).

[0101] 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.

[0102] 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.

[0103] 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.

[0104] 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.

[0105] 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.

[0106] FIG. 6 is a flow diagram illustrating an example method for controlling therapy based on sleep quality information that may be employed by IMD 14. IMD 14 determines a value 66 of a sleep quality metric according to any of the techniques described above (110). The sleep quality metric value 66 may be a current value, mean value, median value, or an overall value, as described above.

[0107] IMD 14 compares the value 66 of the sleep quality metric to one or more threshold values (112), and may determine whether the sleep quality experienced by patient 12 is poor based on the comparison (114). For example, IMD 14 may determine that the sleep quality is poor if the sleep quality metric value 66 falls below a threshold value, or has decreased by greater than a threshold amount over a period of time. In some embodiments, IMD 14 may compare values 66 for a plurality of sleep quality metrics to respective thresholds to determine whether patient 12 is experiencing poor sleep quality.

[0108] If patient 12 is experiencing poor sleep quality, IMD 14 may increase the intensity of therapy, e.g., increase a pulse amplitude, pulse width, pulse rate, duty cycle, dosage, or infusion rate (116). On the other hand, if the sleep quality is adequate, IMD 14 may decrease the intensity of the therapy (118). IMD 14 may adjust the intensity of therapy by adjusting the values of therapy parameters within ranges 68, as discussed above.

[0109] IMD 14 need not increase and decrease the intensity of therapy by the same amount, e.g., at the same rate. For example, IMD 14 may increase therapy intensity at a greater rate than it decreases therapy intensity to provide patient 12 more immediate relief when sleep quality is poor, and to avoid frequent reduction of the therapy intensity below a point at which sleep quality begins to decline. When adjusting the intensity of therapy, IMD 14 may either temporarily or per-

manently adjust one or more parameters of the currently selected therapy parameter set **60**.

[0110] In some embodiments, IMD **14** may iteratively and incrementally increase the intensity so long as the comparison indicates poor sleep quality. In other embodiments, IMD **14** may substantially increase the intensity of the therapy when the comparison indicates poor sleep quality in order to more quickly identify an efficacious operating point. In some embodiments, IMD **14** may gradually decrease the intensity of the therapy so long as the comparison indicates that the sleep quality experienced by patient **12** is adequate to, for example, conserve the energy stored by a battery of IMD **14**. In other embodiments, the amount by which IMD **14** increases or decreases the intensity of therapy may be proportional to the difference or ratio between the current sleep quality metric value and the threshold value.

[0111] FIG. **7** is a flow diagram illustrating another example method for controlling therapy based on sleep quality information that may be employed by IMD **14**. In particular, FIG. **7** illustrates a method that may be employed by IMD **14** in embodiments in which IMD **14** stores associates sleep quality metric values **66** with therapy parameter sets **60**, and stores representative values **66** of the sleep quality metrics for the therapy parameter sets **60**. IMD **14** determines a value **66** of a sleep quality metric (**120**), and compares the value **66** to a threshold **64** (**122**) to determine whether patient **12** is experiencing poor sleep quality (**124**), as described above with reference to FIG. **6**.

[0112] If the comparison indicates that the sleep quality experienced by patient **12** is poor, IMD **14** compares the representative values **66** of the sleep quality metrics (**126**), and automatically selects one of the therapy parameter sets **60** for use in controlling delivery of therapy based on the comparison (**128**). IMD **14** may, for example, select the therapy parameter set **60** with the "best" representative value or values in order to provide the therapy most likely to improve the quality of the patient's sleep. In some embodiments, IMD **14** may detect subsequent times when patient **12** is sleeping using the techniques described above, and may automatically activate the selected therapy parameter set at those times. IMD **14** may use the selected therapy parameter set in this manner for a specified time period, e.g., a number of days, or until patient **12** overrides the selection via patient programmer **26**.

[0113] Various embodiments of the invention have been described. However one skilled in the art will appreciate 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 or implantable pump, the invention is not so limited. Moreover, the invention is not limited to implantable medical devices. The invention may be embodied in any implantable or external medical device that delivers therapy to treat any ailment of symptom of a patient. 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 via a medical device that delivers a chronic pain therapy to the patient;

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

controlling delivery of the chronic pain therapy by the medical device based on the sleep quality metric value,

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.

2. The method of claim **1**, wherein the sleep quality metric comprises sleep efficiency, and determining the value of the sleep quality metric comprises:

identifying when the patient is attempting to sleep;

identifying when the patient is asleep; and

determining a percentage of time that the patient is asleep while the patient is attempting to sleep.

3. The method of claim **1**, wherein the sleep quality metric comprises sleep latency, and determining the value of the sleep quality metric comprises:

identifying a first time when the patient begins attempting to sleep;

identifying a second time when the patient falls asleep; and

determining an amount of time between the first and second times.

4. The method of claim **1**, wherein determining the value of the sleep quality metric comprises:

identifying when the patient is within a sleep state; and

determining an amount of time that the patient was within the sleep state.

5. The method of claim **4**, wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state.

6. The method of claim **1**, wherein controlling delivery of the therapy comprises:

comparing the sleep quality metric value to a threshold value; and

adjusting the therapy based on the comparison.

7. The method of claim **6**, wherein adjusting the therapy comprises adjusting the therapy in an amount proportional to at least one of a difference and a ratio between the sleep quality metric value and the threshold value.

8. The method of claim **6**, wherein adjusting the therapy comprises increasing the intensity of the therapy at a first rate and decreasing the intensity of the therapy at a second rate.

9. The method of claim **1**, wherein the therapy comprises neurostimulation.

10. The method of claim **1**, wherein the therapy comprises spinal cord stimulation.

11. The method of claim **1**, further comprising:

determining a plurality of values of the sleep quality metric over time;

associating each of the determined values of the sleep quality metric with a current therapy parameter set; and

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

wherein controlling the therapy comprises automatically selecting one of the therapy parameter sets for delivery of the therapy based on the representative sleep quality metric values for the therapy parameter sets.

12. A medical device comprising:

a therapy module to deliver a chronic pain therapy to a patient; and

a processor to monitor at least one physiological parameter of a patient based on at least one signal received from at least one sensor, determine a value of a metric that is indicative of sleep quality based on the at least one

physiological parameter, and control delivery of the chronic pain therapy by the therapy module based on the sleep quality metric value,

wherein the processor monitors at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

13. The medical device of claim **12**, wherein the sleep quality metric comprises sleep efficiency, and the processor identifies when the patient is attempting to sleep, identifies when the patient is asleep, and determines a percentage of time that the patient is asleep while the patient is attempting to sleep as the value of the sleep quality metric.

14. The medical device of claim **12**, wherein the sleep quality metric comprises sleep latency, and the processor identifies a first time when the patient begins attempting to sleep, identifies a second time when the patient falls asleep, and determines an amount of time between the first and second times as the value of the sleep quality metric.

15. The medical device of claim **12**, wherein the processor identifies when the patient is within a sleep state, and determines an amount of time that the patient was within the sleep state as the value of the sleep quality metric.

16. The medical device of claim **15**, wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state.

17. The medical device of claim **12**, wherein the processor compares the sleep quality metric value to a threshold value, and adjusts the therapy based on the comparison.

18. The medical device of claim **17**, wherein the processor adjusts the therapy in an amount proportional to at least one of a difference and a ratio between the sleep quality metric value and the threshold value.

19. The medical device of claim **18**, wherein the processor increases the intensity of the therapy at a first rate and decreases the intensity of the therapy at a second rate.

20. The medical device of claim **12**,

further comprising a memory to store information identifying a plurality of therapy parameter sets,

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 one of the therapy parameter sets,

wherein, for each of the 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, and stores the representative value of the sleep quality metric in association with the therapy parameter set within the memory, and

wherein the processor automatically selects one of the therapy parameter sets for delivery of the therapy based on the representative sleep quality metric values for the therapy parameter sets.

21. The medical device of claim **12**, wherein the medical device comprises at least one of an implantable neurostimulator or an implantable pump.

22. The medical device of claim **12**, wherein the therapy comprises spinal cord stimulation.

23. A computer-readable medium comprising instructions that cause a programmable processor to:

monitor at least one physiological parameter of a patient via a medical device that delivers a chronic pain therapy to the patient;

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

control delivery of the chronic pain therapy by the medical device based on the sleep quality metric value,

wherein the instructions that cause a programmable processor to monitor at least one physiological parameter comprise instructions that cause a programmable processor to monitor at least one of electrocardiogram morphology, subcutaneous temperature, muscular tone, electrical activity of a brain of the patient or eye motion.

24. The medium of claim **23**, wherein the instructions that cause a programmable processor to control delivery of the therapy comprise instructions that cause the programmable processor to:

compare the sleep quality metric value to a threshold value; and

adjust the therapy based on the comparison.

25. The medium of claim **23**, further comprising instructions that cause the processor to:

determine a plurality of values of the sleep quality metric over time;

associate each of the determined values of the sleep quality metric with a current therapy parameter set; and

for each of the therapy parameter sets, determine a representative value of the sleep quality metric based on the values of the sleep quality metric associated with the therapy parameter set, and

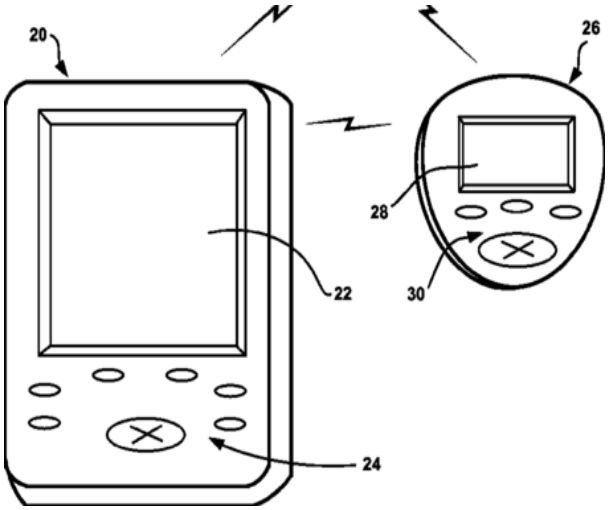
wherein the instructions that cause the programmable processor to control the therapy comprise instructions that cause the programmable processor to automatically select one of the therapy parameter sets for delivery of the therapy based on the representative sleep quality metric values for the therapy parameter sets.

26. The medium of claim **23**, wherein the therapy comprises neurostimulation.

27. The medium of claim **23**, wherein the therapy comprises spinal cord stimulation.

* * * * *

专利名称(译)	根据睡眠质量控制治疗		
公开(公告)号	US20090306740A1	公开(公告)日	2009-12-10
申请号	US12/544727	申请日	2009-08-20
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司，INC.		
当前申请(专利权)人(译)	美敦力公司，INC.		
[标]发明人	HERUTH KENNETH T MIESEL KEITH A		
发明人	HERUTH, KENNETH T. MIESEL, KEITH A.		
IPC分类号	A61N1/34 A61B5/00 A61B5/02 A61B5/04 A61M5/142 A61M5/172 A61N1/05 A61N1/36 A61N1/365 A61N1/372		
CPC分类号	A61B5/02 A61B5/04 A61B5/4815 A61M5/14276 A61M5/1723 A61N1/36557 A61M2230/63 A61N1/36071 A61N1/365 A61N1/36521 A61N1/36542 A61M2230/06		
优先权	60/553777 2004-03-16 US		
其他公开文献	US8335568		
外部链接	Espacenet USPTO		

摘要(译)

诸如可植入医疗设备（IMD）的医疗设备确定指示患者睡眠质量的一个或多个度量的值，并基于睡眠质量度量值控制治疗的递送。例如，医疗设备可以将睡眠质量度量值与一个或多个阈值进行比较，并基于该比较来调整治疗。在一些实施例中，医疗设备基于比较来调整治疗强度，例如，当比较指示患者的睡眠质量差时，增加治疗强度。在一些实施例中，医疗设备基于与多个可用治疗参数集内的相应治疗参数集相关联的比较睡眠质量度量值，自动选择可用于递送治疗的多个治疗参数集中的一个。