about these side effects of the breathing therapy may be helpful in tailoring a therapy regimen for the patient. The monitoring device may monitor the impact of the CPAP therapy on the patient based on one or more sensed conditions indicative of the impact of the therapy on the patient.

In one example, the one or more sensed conditions 5262 relate to sleep and may be used to detect 5264 sleep and/or arousals from sleep. The monitoring unit implemented in an implantable cardiac device may monitor 5266 the impact of the CPAP therapy on the patient by monitoring the patient's sleep. For example, the monitoring unit may monitor the total time the patient spends sleeping, the number of arousals experienced by the patient in one night, and/or the depth of the arousals. In one implementation the cardiac device may calculate the number of arousals experienced by the patient per hour (A/h).

The therapy effectiveness and impact information may be transmitted 5268 to the CPAP device and/or an APM server. The information may be used to automatically or manually adjust the therapy delivered to the patient. For example, if the AHI is high, the breathing therapy pressure may be adjusted upward to provide a more effective therapy. If the patient experiences an arousal rate, e.g., A/h, greater than a threshold without experiencing sleep disordered breathing episodes, the therapy may be determined to be too aggressive. The breathing therapy pressure may be adjusted downward to provide a disordered breathing therapy that is more comfortable to the patient and allows the patient to sleep with fewer interruptions.

Feedback System for Sleep Disordered Breathing Therapy

Aspects of the invention that include disordered breathing therapy feedback are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving a feedback system for disordered breathing therapy are directed to methods and systems configured to monitor, diagnose, and/or

provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

One embodiment of the invention involves an individual system 123 (Figure 1B) for developing feedback using monitored conditions for controlling sleep disordered breathing therapy. The sleep disordered breathing therapy feedback system 123may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Various embodiments of present invention involve methods and systems for developing and providing feedback information for sleep disordered breathing therapy. In accordance with one embodiment, a method of controlling sleep disordered breathing therapy includes monitoring one or more patient conditions using a monitoring device having circuitry disposed within an implantable housing. Feedback information for controlling sleep disordered breathing therapy is developed based on the one or more monitored conditions. The feedback information is provided to a device delivering therapy to treat sleep disordered breathing. The housing of the therapy device is separate from the implantable housing of the monitoring device.

In accordance with another embodiment of the invention, a method of adjusting sleep disordered breathing therapy includes monitoring one or more patient conditions using a monitoring device having circuitry disposed within an implantable housing. Feedback information for controlling sleep disordered breathing therapy is developed based on the one or more monitored conditions. The feedback information is provided to a device delivering therapy to treat sleep disordered breathing. The housing of the therapy

device is separate from the implantable housing of the monitoring device. The sleep disordered breathing therapy is adjusted using the feedback information.

Yet another embodiment of the invention involves a medical system for controlling sleep disordered breathing therapy. The medical system includes a monitoring unit having components disposed within an implantable housing. The monitoring unit is configured to monitor one or more patient conditions. A processor is coupled to the monitoring unit. The processor is configured to provide feedback information related to sleep disordered breathing therapy delivered to a patient based on the one or more monitored conditions. Components of a therapy device delivering the disordered breathing therapy are disposed within a therapy device housing. The therapy device housing is separate from the implantable housing of the monitoring device.

A further embodiment of the invention involves a medical system for providing sleep disordered breathing therapy. The medical system includes a monitoring unit having components disposed within an implantable housing. The monitoring unit configured to monitor one or more patient conditions. The system also includes a therapy device having components disposed within a housing that is separate from the implantable housing of the monitoring device. The therapy device is configured to deliver sleep disordered breathing therapy. A processor is coupled to the monitoring unit and the therapy device. The processor is configured to provide feedback information related to the sleep disordered breathing therapy based on the one or more patient conditions.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy system that utilizes feedback of sensed conditions for controlling sleep disordered breathing therapy. The coordinated system includes, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy includes a system 123 configured to develop feedback based on sensed conditions associated with disordered breathing therapy. The disordered breathing therapy feedback system 123 includes a monitoring unit having components disposed within an implantable housing, the monitoring unit configured to monitor one or

more patient conditions, and a processor coupled to the monitoring unit. The processor is configured to provide feedback information related to sleep disordered breathing therapy delivered to a patient based on the one or more monitored conditions, wherein components of a therapy device delivering the disordered breathing therapy are disposed within a therapy device housing and the therapy device housing is separate from the implantable housing of the monitoring device.

The implantable and respiratory therapy devices 181, 184 may operate cooperatively based on system 123 feedback information from delivered respiratory therapy. For example, system 123 feedback information from delivered respiratory therapy may allow the implantable and respiratory therapy devices 181, 184 to operate cooperatively to adjust sleep disordered breathing therapy.

Sleep disordered breathing disorders may be more effectively monitored and/or treated using a coordinated approach. Various embodiments of the invention are implemented using medical systems employing two or more patient-external and/or patient-internal medical devices. The medical devices may communicate or otherwise operate in concert to provide more comprehensive patient monitoring for disordered breathing.

Embodiments of the invention are directed to methods and systems utilizing an implantable device to monitor conditions associated with sleep disordered breathing. Feedback for controlling sleep disordered breathing therapy is provided based on the monitored conditions. Various types of therapy have been used to treat sleep disordered breathing. Positive airway pressure devices, e.g., continuous positive airway pressure (CPAP) devices are among the most frequently used mechanical respiration therapy devices employed for treating sleep disordered breathing. Sleep disordered breathing has also been treated using muscle and/or nerve stimulation therapy. For example, a treatment for obstructive sleep apnea involves compensating for the decreased muscle activity by electrical activation of the tongue muscles. The hypoglossal (HG) nerve innervates the protrusor and retractor tongue muscles. In one approach, an appropriately applied electrical stimulation to the hypoglossal nerve, for example, may prevent backward movement of the tongue, thus preventing the tongue from obstructing the airway.

Central sleep apnea may also be treated by phrenic nerve pacing, also referred to as diaphragmatic pacing. Phrenic nerve pacing uses an electrode implanted in the chest to stimulate the phrenic nerve. The phrenic nerve is generally known as the motor nerve of the diaphragm. It runs through the thorax, along the heart, and then to the diaphragm.

Diaphragmatic pacing involves the use of electronic stimulation of the phrenic nerve to control the patient's diaphragm and induce a respiratory cycle. Pacing the phrenic nerve may be accomplished by surgically placing a nerve cuff on the phrenic nerve, and then delivering an electric stimulus. The electric stimulus of the phrenic nerve then causes the diaphragm to induce a respiratory cycle.

Recently, cardiac pacing therapy has been used as a therapy for disordered breathing. Cardiac pacing therapy may be implemented using an implanted electrical pulse generator coupled to endocardiac leads inserted into one or more heart chambers. Cardiac pacing for sleep disordered breathing treatment may include pacing one or more heart chambers, and may involve pacing at a rate above a lower rate limit during sleep and/or during episodes of disordered breathing, for example.

Drug therapy may also be used to treat disordered breathing. Drugs may be delivered to the patient through one or more automatically controllable drug delivery devices, e.g., a drug pump, a controllable nebulizer, or an electrically activated drug patch, for example.

The block diagram of Figure 53 illustrates an example of medical system 5300 including a fully or partially implantable device 5301 that may be used to monitor patient conditions and to develop feedback information for a device delivering sleep disordered breathing therapy in accordance with embodiments of the invention. The medical device 5301 that may be coupled to an array of data acquisition devices, including patient-internal sensors 5311, patient-external sensors 5312, patient input devices 5313, and/or other information systems 5314 as described in more detail above.

Patient conditions monitored by the implantable device may include both physiological and non-physiological contextual conditions affecting the patient. Table 1 above provides a representative set of patient conditions that may be monitored by the device 5301 in accordance with embodiments of the invention. Table 1 also provides illustrative sensing methods that may be employed to sense the conditions. It will be appreciated that patient conditions and detection methods other than those listed in Table 1 may be used and are considered to be within the scope of the invention.

The implantable device 5301 of Figure 53 includes monitoring circuitry 5337 for processing signals received from the sensors, 5311, 5312, patient input devices 5313, and/or other information system 5314. The monitoring circuitry 5337 may include one or more a detection units 5324, 5326, 5328 that detect the occurrence of various physiological events. For example, the circuitry 5327 may include one or more of a disordered breathing

detector 5324, a sleep detector 5328, and/or a therapy usage detector 5326. Other event detection components may also be included. The monitoring circuitry 5327 may be used to calculate various indices, e.g., AHI, %PB, and/or arousals per unit time, used for evaluating therapy efficacy, and/or therapy impact. The monitoring circuitry 5327 may compare the patient's therapy usage to a prescribed therapy to determine therapy compliance. The monitoring circuitry 5327 communicates with a therapy feedback unit 5325 that develops feedback information based on the monitored conditions, the detected events, and/or the calculated indices.

In one exemplary implementation, the disordered breathing detector 5324 may be coupled to a respiration sensor. The disordered breathing detector 5324 may use the respiration signal developed by the respiration sensor to detect disordered breathing events based on the inspiratory and expiratory phases of the patient's respiration cycles, for example. The sleep detector 5328 may analyze various inputs from the patient-internal sensors 5311, patient-external sensors 5312, patient input devices 5313, other information systems 5314 to detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and arousals from sleep.

The monitoring circuitry 5327 includes a memory 5336 for storing information derived from signals produced by the patient-internal sensors 5311, patient-external sensors 5312, patient input devices 5313, and/or other information systems 5314. The memory 5336 may also store information about detected events, e.g., sleep and disordered breathing events, and/or information related to calculated indices characterizing various events such as sleep and/or disordered breathing events. The stored data may be transferred to the feedback unit 5325 and used to develop feedback information to control disordered breathing therapy. The stored data may be retrieved by another component of the medical device 5301 for later use, or may be transmitted to a separate device 5340 for storage, further processing, trending, analysis and/or display, for example. In one scenario, the stored data can be downloaded to a separate device periodically or on command. The stored data may be presented to the patient's health care professional on a real-time basis, or as a long-term, e.g., month long or year long, trend of daily measurements.

The medical device 5301 may optionally include a therapy unit. In some examples described herein, the medical device 5301 comprises a cardiac therapy device configured to deliver cardiac electrical stimulation therapy using a cardiac pulse generator 5375 and electrical stimulation electrodes 5352.

The medical device 5301 may further include a communications unit 5306 that controls communications between the medical device 5301 and other devices or systems. For example, the communications unit 5306 may be used to provide wireless or wired communications links between the medical device 5301 and one or more of the patient-internal sensors 5311, patient-external sensors 5312, patient input devices 5313, and information systems 5314.

The communications unit 5306 may also facilitate communications between the medical device 5301 and a remote device 5340 such as the sleep disordered breathing therapy device, a programmer, and/or an APM system. The wireless connections coupling the medical device 5301 to various other devices and systems may utilize a variety of wireless protocols, including, for example, Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol.

Detecting the onset, termination, duration, stages, and quality of sleep experienced by a patient may be employed in connection with monitoring patient conditions and providing feedback for sleep disordered breathing therapy. Patients suffering from sleep apnea, or other types of sleep disordered breathing, may be treated with for sleep disordered breathing only during periods of sleep. Monitoring patient conditions and/or development of feedback information may involve determining if the patient is asleep and/or detecting various sleep-related processes, such as arousals from sleep and/or REM or non-REM sleep stages.

In addition, patient sleep may be monitored and information associated with patient sleep may be used to assess an impact of breathing therapy on the patient. Therapy impact data may be used to develop feedback information used to adjust the therapy. The implantable monitoring device 5301 may include a sleep detector 5328 for detecting when the patient is asleep and various stages and/or processes of sleep. Various methods of sleep detection implementable in an implanted device involve sensing one or more conditions indicative of sleep. The sleep-related conditions may be compared to a threshold to determine if the patient is asleep.

The sleep-related conditions may be sensed or derived using patient-external or implantable sensors and analyzed by a sleep detector of the implantable monitoring device or by circuitry within the APM communication unit (i.e., a supervisor device that co-ordinates diagnostics between various sensors. For example, sleep detection may be implemented in an implantable cardiac rhythm management system configured as a pacemaker/defibrillator or an ITCS device.

Sleep detection may involve sensing one or more conditions indicative of sleep. A representative set of sleep-related conditions include body movement, heart rate, QT interval, eye movement, respiration rate, transthoracic impedance, tidal volume, minute ventilation, body posture, brain activity, cardiac activity, muscle tone, body temperature, time of day, historical sleep times, blood pressure, and blood gas concentration, proximity to bed, for example.

Sleep may be detected by comparing levels of the one or more sleep-related conditions to one or more sleep thresholds. For example, sleep may be detected by monitoring the patient's heart rate. When the patient's heart rate decreases below a sleep threshold, the patient may be determined to be asleep. Sleep may also be detected by monitoring the patient's activity. If the patient's activity decreases below a sleep threshold, then the patient may be determined to be asleep. Another method of detecting sleep involves monitoring the patient's minute ventilation. If the patient's minute ventilation falls below a sleep threshold, then the patient may be determined to be asleep.

Sleep may be detected by comparing multiple sleep-related conditions to multiple thresholds. For example, the patient may be determined to be asleep if the patient's activity, sensed by an accelerometer, falls below an activity sleep threshold and the patient's heart rate, sensed by cardiac electrodes, falls below a heart rate sleep threshold.

Sleep may also be detected using one sleep-related condition to modify the sleep threshold of another sleep-related condition. A first sleep-related condition may be sensed. The level of the sleep-related condition may be compared to a sleep threshold to determine the onset and termination of sleep. A second sleep-related condition may be used to adjust the sleep threshold. Additional sleep-related conditions may optionally be sensed to confirm the onset or termination of the sleep condition.

A sleep detector 5328 (Figure 53) may be configured to compare the levels of one or more sleep-related conditions to one or more thresholds. In one implementation, the one sleep related condition may be compared to a sleep threshold or other index to detect sleep. In another implementation, multiple sleep-related conditions may be compared to multiple thresholds or indices. In a further implementation, one or more of the sleep-related conditions may be used to adjust the sleep thresholds or indices. Furthermore, the onset or termination of sleep may be confirmed using an additional number of sleep-related conditions.

The sleep-related conditions may be sensed using implantable sensors and/or patient-external sensors, for example. In one embodiment, patient activity may be

compared to a sleep threshold to determine when the patient is asleep. A low level of activity is indicative that the patient is sleeping. Patient activity may be sensed, for example, using an accelerometer positioned on or in the housing of an implantable cardiac device, or in another convenient location. The accelerometer signal may be correlated with activity level or workload.

A second sleep-related condition may be used to adjust the sleep threshold. In one embodiment, the patient's minute ventilation is used to adjust the sleep threshold. The patient's respiration may be sensed using a transthoracic impedance sensor. Transthoracic impedance may be used to derive various parameters associated with respiration, including, for example, tidal volume and/or minute ventilation. A transthoracic impedance sensor may be integrated into an implantable cardiac device with intracardiac electrodes, for example. Impedance driver circuitry generates a current that flows through the blood between the impedance drive electrode and a can electrode on the housing of the cardiac device. The voltage at an impedance sense electrode relative to the can electrode changes as the transthoracic impedance changes.

As illustrated in the flowchart of Figures 54A and 54B, embodiments of the invention are directed to monitoring 5410 one or more patient conditions using an implantable monitoring device. Feedback information is developed 5412 based on the monitored conditions. The feedback information is provided 5414 to a device delivering therapy to treat sleep disordered breathing. The monitoring device and the therapy device have separate housings. Components of the monitoring device are disposed within an implantable housing. The therapy device may comprise a housing that is implantable or patient-external. The feedback information may be used to adjust 5420 (Figure 54B) the sleep disordered breathing therapy. The feedback information may comprise control signals indicating the sleep disordered breathing therapy should be initiated, modified, or terminated.

In one implementation, the feedback control signals are provided to the therapy device by the monitoring unit. Therapy adjustment based on the feedback information is made automatically by the therapy device. In other implementations, information related to the monitored conditions is transmitted from the monitoring device to a physician or medical decision network.

In one scenario, the medical decision network may develop the feedback control signals and transmit the feedback control signals to the therapy device. In another scenario, a physician may determine the feedback adjustments to be made to the therapy and may

operate a programmer or other device to transfer the feedback control information to the therapy device.

In various implementations, the implantable device may monitor one or more patient conditions indicative of the severity of sleep disordered breathing events, the effectiveness of the sleep disordered breathing therapy, and/or the impact of the therapy on the patient. The implantable device may monitor conditions indicative of interactions between the sleep disordered breathing therapy and other therapies delivered to the patient. Based on the monitored conditions, feedback information is provided to the therapy device. The feedback information may be used to adjust the therapy to enhance therapy effectiveness, to reduce an impact of the therapy, to avoid or reduce therapy interactions, and/or to accomplish other therapeutic goals.

In one embodiment, the implantable device may develop the feedback information and transmit the feedback information directly to the sleep disordered breathing therapy device. The feedback information may be used by the therapy device to automatically adjust the therapy delivered to the patient. In another embodiment, both the implantable monitoring device and the therapy device may be communicatively coupled to a separate medical device, such as a device programmer or patient management system.

In one approach, the implantable device may transmit information about the sensed patient conditions to the separate medical device. The separate medical device may develop the feedback information. The feedback information and /or information related to the monitored conditions may be printed, displayed and/or stored. The feedback information may be used to manually or automatically adjust the sleep disordered breathing therapy. For example, the separate medical device may transmit the feedback information to the therapy device. The feedback information may be used by the therapy device to automatically adjust the sleep disordered breathing therapy.

In another approach, the feedback information may be developed by the monitoring device based on the sensed conditions. The feedback information may be transmitted from the monitoring device to the therapy device through the separate medical device. The feedback information may be used by the therapy device to automatically adjust the sleep disordered breathing therapy.

The flowchart of Figure 54C illustrates a method of providing feedback information in accordance with an embodiment of the invention. The monitoring device senses 5430 one or more patient conditions associated with sleep. Sleep is detected 5432 based on the sleep-related conditions. The monitoring device senses 5434 one or more conditions

associated with disordered breathing during sleep. One or more disordered breathing events occurring during sleep are detected 5436. Characteristics of the sleep disordered breathing events, such as, severity, frequency, and/or duration, may be determined 5438. Determination of the one or more characteristics of the sleep disordered breathing events may involve calculation of one or more indices characterizing the disordered breathing events. The indices may include, for example, an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB), among other indices. Feedback information is provided 5440 to a device delivering therapy for sleep disordered breathing based on the one or more characteristics of the sleep disordered breathing events.

Another embodiment of the invention is illustrated in the flowchart of Figure 54D. According to this method, one or more patient conditions are sensed 5450 using the implantable monitoring device. Information related to the patient conditions is transmitted 5452 to an advanced patient management (APM) system.

Feedback information based on the patient conditions is developed 5454 using the APM system. The feedback information is transmitted 5456 from the APM system to a therapy device delivering therapy for sleep disordered breathing. The sleep disordered breathing therapy is adjusted 5458 based on the feedback information.

Figure 54E is a flowchart illustrating a method for providing sleep disordered breathing therapy feedback information based on an effectiveness of the sleep disordered breathing therapy. The patient's respiration is sensed 5460 and a respiration waveform is generated 5462. The sensed respiration waveform is used to detect 5464 disordered breathing events. An apnea/hypopnea index (AHI) is calculated 5466 based on the detected disordered breathing events. The AHI is used to assess the effectiveness 5468 of the sleep disordered breathing therapy. A lower AHI indicates more effective breathing treatment than a relatively higher AHI, for example. Feedback information is developed 5468 based on the disordered breathing index. The feedback information is transmitted 5470 to the therapy device. The therapy device uses the feedback information to adjust 5472 the sleep disordered breathing therapy.

In accordance with one embodiment, feedback for the sleep breathing therapy may be based on therapy effectiveness and impact to the patient. The flowchart of Figure 54F illustrates an example method that may involve the use of circuitry disposed within the housing of an implantable cardiac rhythm management (CRM) device to monitor breathing therapy delivered by an external breathing therapy device. In one example, therapy for sleep disordered breathing is delivered to the patient using a continuous positive airway

pressure (CPAP) device. The effectiveness of the breathing therapy and the impact of the therapy on the patient are monitored by an implantable CRM device.

Sensors coupled to monitoring circuitry disposed within the cardiac device housing may sense one or more patient conditions related to therapy effectiveness. For example, a condition modulated by patient respiration may be sensed and a respiration waveform signal generated 5474. Monitoring circuitry disposed within the housing of the cardiac device may detect 5476 disordered breathing episodes based on the respiration signal. The monitoring circuitry may determine therapy effectiveness based on the severity, frequency and/or duration of sleep disordered breathing episodes experienced by the patient. In one implementation, the monitoring circuitry disposed within the CRM may calculate 5478 an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB) indicative of the frequency of disordered breathing episodes. The effectiveness of the sleep disordered breathing therapy is determined based on the sleep disordered breathing index 5480. If the AHI and/or %PB are relatively low, the breathing therapy may be determined to be effective. If the AHI and/or %PB are relatively high, then the breathing therapy may be determined to be ineffective.

A CPAP device typically includes a respiratory mask, e.g., a nasal of facial mask, worn by the patient to facilitate delivery or air or other gas to the patient's airway. The respiratory mask may be inconvenient and/or uncomfortable for the patient to wear and may keep the patient awake. Further, delivery of positive airway pressure may inhibit sleep, or cause the patient to arouse frequently. Information about these side effects of the breathing therapy may be helpful in tailoring a therapy regimen for the patient. The CRM may monitor one or more conditions indicative of an impact of the CPAP therapy on the patient.

Impact of the CPAP therapy may be determined based on information related to sleep quality. Sensors coupled to the monitoring circuitry within the CRM are configured to sense 5482 one or more conditions related to sleep. The sleep related conditions are used to detect 5484 sleep and/or arousals from sleep. The monitoring circuitry within the CRM determines 5486 the impact of the CPAP therapy on the patient by monitoring the patient's sleep. For example, the monitoring circuitry may monitor the total time the patient spends sleeping, the number of arousals experienced by the patient in one night, the number of arousals correlated to sleep disordered breathing events, and/or the depth of the arousals. In various implementations the monitoring unit may calculate various indices characterizing sleep and/or one or more composite indices based on indices related to sleep

and indices related to sleep disordered breathing. In one example, the monitoring unit calculates the number of arousals experienced by the patient per hour (A/h).

Feedback information is developed 5488 based on the therapy effectiveness and impact information. The feedback information may be transmitted to the therapy device and used to automatically adjust the therapy delivered to the patient. For example, if the AHI is high, the breathing therapy pressure may be adjusted upward to provide a more effective therapy. If the patient experiences an arousal rate greater than a threshold without experiencing sleep disordered breathing episodes, the therapy may be determined to be too aggressive. The breathing therapy pressure may be adjusted downward to provide a disordered breathing therapy that is more comfortable to the patient and allows the patient to sleep better.

Diagnosis and/or Therapy using Blood Chemistry/Expired Gas Parameter Analysis

Aspects of the invention that include diagnosis and/or therapy using blood chemistry/expired gas parameter analysis are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include diagnosis and/or therapy using blood chemistry/expired gas parameter analysis are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may

implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention may incorporate medical gas therapy systems and methods, such as systems and methods for diagnosis and/or therapy using measurement of expired gases and/or blood gases. Embodiments may include systems and methods for detecting and/or diagnosing disorders, such as disordered breathing, a pulmonary disorder, and/or a cardiac disorder, and providing therapy based on one or more conditions or parameters influenced by such diseases/disorders, such as blood gas concentrations, expired gas concentrations, or blood acid-base balance (i.e., hydrogen ion concentration). Methods of providing disordered breathing therapy may involve determining one or more parameters influence by disordered breathing, which may include one or more of blood gas concentration, expired respiratory gas concentration, or blood hydrogen ion concentration, also known as pH. Respiratory and cardiac therapies may be adjusted based on the one or more detected parameters.

In certain embodiments, a disordered breathing therapy method may involve sensing at least one of an expired respiratory gas concentration, a blood gas concentration, or blood pH. Respiratory and cardiac therapies may be adjusted based on one or more of these parameters. In other embodiments, a medical system includes a detector configured to detect blood gas concentration, expired respiratory gas concentration, or hydrogen ion concentration. The medical system further includes a therapy delivery system. The therapy delivery system includes a respiratory therapy delivery device configured to deliver respiratory therapy to a patient and a cardiac therapy delivery device configured to deliver cardiac therapy to the patient. A therapy controller is coupled to the respiratory therapy delivery device and the cardiac therapy delivery device and is configured to adjust respiratory and cardiac therapies based on the detected blood gas concentration, expired gas concentration, and/or blood pH.

Systems and methods that employ diagnosis and/or therapy using blood chemistry/expired gas parameter analysis 130 (Figure 1C) may be implemented as a stand-alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D. Various embodiments involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes diagnosis and/or therapy using blood chemistry/expired gas parameter analysis 130. The coordinated

system may include, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

The implantable and respiratory therapy devices 181, 184 may, for example, operate cooperatively based on detected blood gas concentration, expired gas concentration, and/or blood pH. For example, detection of detected blood gas concentration, expired gas concentration, and/or blood pH and/or deviation of same from pre-established thresholds may allow the implantable and respiratory therapy devices 181, 184 to operate cooperatively to adjust one or both of respiratory and cardiac therapies.

Many patients suffering from obstructive sleep apnea (OSA) have intermittent oxygen desaturation associated with periods of apnea or hypopnea. Oxygen saturation levels below 90% are considered harmful. Usually, treatment is directed at correcting the apnea, which may in turn prevent hypoxemia. Unfortunately, many patients fail or are not candidates for nasal continuous positive airway pressure (CPAP) or surgical correction of their OSA. For these patients, oxygen administration for the correction of OSA-related nocturnal hypoxemia may reduce symptoms of OSA. Oxygen therapy has also been successfully used to treat central apneas as well, including Cheyne-Stokes respiration (CSR). Systems of the present invention may controls gas therapy using one or more patient-internal sensors, one or more patient-external sensors, and/or an implanted device.

Gas therapy, such as oxygen therapy, continuous positive airway pressure therapy, or other therapies provided to a patient through the pulmonary system, may mitigate a patient's suffering from a number of respiratory disorders. Some lung diseases, such as emphysema, sarcoidosis, and chronic obstructive pulmonary disorder, reduce lung function to the extent that supplemental oxygen is needed to continue normal bodily functions. For many patients with end stage lung disease, oxygen therapy allows the patients to get the oxygen they need, helps them be more active, and may also prevent heart failure.

Gas therapy devices may be used to provide a variety of respiration therapies, including, for example, providing vasodilating agents, continuous positive airway pressure (CPAP), bi-level positive airway pressure (bi-level PAP), proportional positive airway pressure (PPAP), auto-titrating positive airway pressure, ventilation, gas or oxygen

therapies. All types of gas therapy and positive airway pressure devices are referred to generically herein as xPAP devices.

Expired gases or blood gases may be used to adjust cardiac rhythm management (CRM) and/or xPAP therapies to provide more effective treatment of disordered breathing, a pulmonary disorder, and/or a cardiac disorder. The blood gas sensors may be implemented using either a patient-internal sensor or a patient-external sensor. Expired gases may be sensed using a patient-external sensor positioned, for example, on the respiratory mask of the xPAP device. The use of external sensors avoids the stability, reliability, and power consumption problems associated with implanted sensors. The use of implanted sensors resolves compliance issues common to xPAP therapy. The gas concentration in the expired air collected at the very end of expiration (just before inhalation starts) is representative of the blood gas concentration. This provides a non-invasive way of measuring blood gas concentrations.

The blood hydrogen ion concentration (or pH) is related to the relative amount of carbon dioxide and various chemical buffering agents in the blood. The blood pH is therefore closely influenced by respiration. The blood pH is related to the internal respiratory control and is therefore an important indicator of respiratory disorders, including apnea, COPD and others.

Various diseases and disorders, e.g., sleep apnea, are associated with various levels of expired respiratory gases and/or blood gases. The detection of changes in expired gases, blood gases, and/or blood pH may be used in connection with diagnosis of a variety of diseases. Further, expired gas, blood gas concentrations, and/or pH may be used to detect and/or predict episodes of disordered breathing, a pulmonary disorder, and/or a cardiac disorder. Further, detection of expired gas, blood gas concentrations, and/or blood pH may be used to initiate, terminate, or modify respiratory and cardiac therapy.

Embodiments of the invention are directed to systems and methods that acquire and process blood chemistry information in an implantable or partially implantable device. Information acquired from blood gas or pH sensors, for example, may be used in connection with patient monitoring, diagnosis, and therapy. An implantable system may incorporate expired gas, blood gas, and/or pH detection for various purposes, including disease diagnosis and therapy control, among other functions. Systems may include one or more or expired gas, blood gas, and/or pH sensors, which may be implemented as one or more patient-internal and/or one or more patient-external sensors.

The following discussion, with reference to Figures 55 through 59, describes embodiments of the invention involving measurement of expired gases, blood gases or blood pH used for diagnosis and therapy. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein (e.g., in Figures 1B-1D) to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

In accordance with embodiments of the invention, a system controls gas therapy, such as oxygen therapy, using one or more patient-internal sensors, one or more patient-external sensors, and/or an implanted device. The gas therapy may be delivered to the patient, and measurement of exhaled gas concentration may be implemented using a respiratory mask, such as a CPAP mask, for example. The one or more sensors may include, for example, a gas saturation sensor or other implanted sensor for determining the patient's blood gas saturation. The patient's blood gas saturation may be determined externally, e.g., using pulse oximetry techniques, and/or external sensors positioned on a respiratory mask or nasal cannulae.

As is illustrated in Figure 55A, a system 5500 may be configured with one or more sensors 5510 that are configured to sense one or more parameters influence by disordered breathing. The sensors 5510 may be implemented as implantable sensors, patient-external sensors, or both implantable and patient-external sensors. A disordered breathing (DB) therapy controller 5550 may be configured for implantable or patient-external operation. For example, the DB therapy controller 5550 may be implemented as a controller of an xPAP device 5530 or a controller of a cardiac rhythm management device 5520. The DB therapy controller 5550 detects disordered breathing using sense information received from the sensors 5500, and adjusts therapies deliverable by the xPAP and CRM devices 5530, 5520 responsive to the sense information. Adjustment of xPAP and CRM therapies includes, for example, initiation, termination, or modification of such therapies.

In accordance with other embodiments, as illustrated in Figure 55B, a system 5500 may be configured with a patient-external expired gas sensor 5540 used to modify cardiac pacing therapy and respiratory therapy for treating disordered breathing, a pulmonary disorder, and/or a cardiac disorder. The expired gas sensor 5540 may be positioned in an appropriate location on the mask of an xPAP device 5530. In the embodiment illustrated in Figure 55B, the expired gas sensor 5540 is coupled to the xPAP device 5530. Expired gas concentration is measured at the end of expiration. A timing element (not shown) may be

used to coordinate operations with the patient's respiration cycle to make the expired gas concentration measurement at the end of expiration.

The xPAP device 5530 includes a DB therapy controller 5550. The DB therapy controller 5550 detects expired gas, e.g., expired oxygen, and compares concentration of the expired gas to a predetermined threshold or range. When the gas concentration is beyond the threshold or range, the DB therapy controller 5550 may initiate, terminate, or modify a respiratory therapy provided by the xPAP device 5530. Further, the DB therapy controller 5550 may communicate with a CRM device 5520, e.g., through a wireless communication link or other communications mechanism, to initiate, terminate, or modify the electrical stimulation therapy provided by the CRM device 5520.

In other embodiments, as illustrated in Figure 56, a system 5600 includes the DB therapy controller 5550 located within the CRM device 5520. The external expired gas sensor 5540 may wirelessly transmit to the CRM device 5520 sensed signals associated with expired gas concentration. The DB therapy controller 5550 compares the concentration of the expired gas to a predetermined threshold or range. When the gas concentration is beyond the threshold or range, the DB therapy controller 5550 may initiate, terminate, or modify an electrical stimulation therapy provided by the CRM device 5520. Further, the DB therapy controller 5550 may communicate with the xPAP device 5530, e.g., through a wireless communication link or other communications mechanism, to initiate, terminate, or modify a respiratory therapy provided by the xPAP device 5530.

In accordance with yet other embodiments, as illustrated in Figure 57, a system 5700 includes an implanted blood sensor 5760 that provides information used to modify cardiac pacing therapy and respiratory therapy for disordered breathing, a pulmonary disorder, and/or a cardiac disorder. The implanted blood sensor 5760 may include one or both of a blood gas sensor or a blood pH sensor. For example, the blood sensor 5760 may be configured to sense one or more of blood oxygen concentration, blood carbon dioxide concentration, or blood pH.

The blood sensor 5760 may be positioned, for example, on an endocardiac lead implanted in a chamber of the patient's heart and coupled to the CRM device 5520. The CRM device 5520 in this example includes, or otherwise incorporates the functionality of, the DB therapy controller 5550. The DB therapy controller 5550 may detect blood gas concentration, e.g., blood oxygen and/or carbon dioxide concentration, and compare concentration of the blood gas to a predetermined threshold or range. When the blood gas concentration is beyond the threshold or range, the DB therapy controller 5550 may

initiate, terminate, or modify the electrical stimulation therapy provided by the CRM device 5520. Further, the DB therapy controller 5550 may communicate with the xPAP device 5530, e.g., through a wireless communication link or other communications mechanism, to initiate, terminate, or modify the respiratory therapy provided by the xPAP device 5530. An equivalent to the above example could be implemented using a blood pH sensor or a combination of blood gas and blood pH sensors.

In further embodiments, as illustrated in Figure 58, a system 5800 includes the DB therapy controller 5550 within the xPAP device 5530. The blood sensor 5760 may wirelessly transmit to the xPAP device 5530 sensed signals associated with blood gas concentration and/or blood pH. The DB therapy controller 5550 compares the concentration of the expired gas to a predetermined threshold or range. When the gas concentration is beyond the threshold or range, the DB therapy controller 5550 may initiate, terminate, or modify the respiratory therapy provided by the xPAP device 5530. Further, the DB therapy controller 5550 may communicate with the CRM device 5520, e.g., through a wireless communication link or other communications mechanism, to initiate, terminate, or modify the electrical stimulation therapy provided by the CRM device 5520. An equivalent to the above example could be implemented using a blood pH sensor or a combination of blood gas and blood pH sensors.

As is illustrated in the examples shown in Figures 55 through 58, many possible combinations of componentry and nesting or combinations of componentry are possible in accordance with the present invention. The specific configurations shown in Figures 55 through 58 are non-limiting examples of possible configurations of systems in accordance with the present invention.

Figure 59 is a flow chart illustrating a method 5900 of therapy control based on signals from a patient-internal device in accordance with embodiments of the invention. The method 5900 may be useful for controlling systems using combined gas and cardiac therapies, such as those illustrated with reference to Figures 55 through 58. For clarity of understanding, and not by way of limitation, the sensing of blood oxygen level and/or blood pH will be used as an example of one use of the method 5900. For example, an equivalent embodiment could be implemented using blood carbon dioxide level.

Block 5902 provides for the sensing of a blood chemistry parameter, such as blood gas concentration (e.g., blood oxygen level or blood carbon dioxide level) and/or blood pH. An analysis 5904 is made of the sensed blood gas concentration and/or blood pH. For example, a blood oxygen and/or pH level may be compared to a range of acceptable levels

to detect whether the blood gas concentration/pH is within an acceptable range, or whether some disease/disorder is diagnosable. If blood oxygen/pH level is acceptable and no disease/disorder is diagnosed at analysis 5904, the blood gas/pH sensing continues at block 5902. Sensing may occur continuously, intermittently, by-request, periodically, or as otherwise desired.

If a disease/disorder is detected at analysis 5904, a determination 5906 is made, relative to the detected disease/disorder. For example, detecting a blood oxygen below a lower threshold may suggest that more oxygen is needed by the patient. A decision 5908 is made as to whether some modifications and/or therapies are desired to increase the blood oxygen level. For example, if a patient is receiving oxygen therapy and cardiac pacing, the oxygen level administered to the patient may be adjusted and the heart rate may be adjusted. In another embodiment, if the patient is sleeping and wearing a CPAP device, the air pressure may be increased and the heart rate may be increased. In a further embodiment, the patient may be administered a vasodilating agent, or have a level of vasodilating agent therapy modified along with adjustment of the heart rate. Combined therapies may also be performed, such as increasing gas pressure and adding a vasodilating agent, or other desired therapy combination.

If no therapy change is desired, the presence of the disease/disorder may be recorded and monitored, and/or an alert signal may be generated responsive to the detection of the disease/disorder, for example, before returning to the sense block 5902. If a therapy change is desired, the therapy is modified at a block 5910 before again returning to the blood sense block 5902. For example, if a patient is receiving oxygen therapy, the oxygen level administered to the patient is increased, and the method 5900 may be performed again after an appropriate time to determine if the change was effective, or whether other action is necessary.

Information about the patient's blood gas and/or pH levels may be used to enhance sleep monitoring and/or diagnosis of a variety of disorders. Detection of blood gas level and/or pH may be used to diagnose disorders as well as trigger the sleep-time therapy in a respiratory and cardiac device. Data acquired during sleep may assist in diagnosing various sleep-related disorders. The collected data may be stored, displayed, printed, or transmitted to a separate device.

Pulmonary Disease Assessment System

Aspects of the invention are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures including assessment of pulmonary disease. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving pulmonary disease assessment are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve an individual system 136 (Figure 1D) for assessing a presence of a pulmonary disease. The pulmonary disease assessment system 136 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Embodiments of the invention are directed to methods and systems for assessing a presence of pulmonary disease. One embodiment of the invention involves a method for assessing a presence of a pulmonary disease other than a breathing rhythm disorder. The method includes sensing one or more conditions associated with the non-rhythm

pulmonary disease using a respiratory therapy device. The presence of the non-rhythm pulmonary disease is assessed based on the one or more sensed conditions.

According to various aspects of the invention, sensing the one or more sensed conditions may include sensing one or more of respiratory pressure, respiratory flow, and exhaled gas concentration.

The presence of various types of non-rhythm pulmonary diseases may be assessed, including, for example, obstructive pulmonary diseases, restrictive pulmonary diseases, pulmonary vasculature disorders, pleural disorders, and/or other pulmonary diseases or disorders that are not breathing rhythm disorders.

According to another embodiment of the invention, a medical system for assessing a non-rhythm pulmonary disease presence includes a respiratory therapy device having a therapy unit and a sensor system. The therapy unit is configured to deliver respiration therapy to a patient. The sensor system is configured to sense one or more conditions associated with a pulmonary disease other than a breathing rhythm disorder. The system further includes a diagnosis unit coupled to the sensor system. The diagnosis unit is configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy including non-rhythm pulmonary disease assessment. The coordinated system includes, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy further includes a pulmonary disease assessment system. The respiratory therapy device includes a sensor system configured to sense one or more conditions associated with a pulmonary disease other than a breathing rhythm disorder. The system further includes a diagnosis unit coupled to the sensor system and configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions, wherein the implantable device and the patient external respiratory

therapy device operate cooperatively to implement the pulmonary disease assessment system.

Pulmonary disorders may be organized into broad categories encompassing disorders of breathing rhythm and non-rhythm pulmonary diseases and/or disorders. Breathing rhythm disorders include various syndromes characterized by patterns of disordered breathing that produce insufficient respiration, for example, sleep apnea, hypopnea, and Cheyne-Stokes Respiration (CSR), among others. Breathing rhythm disorders are not necessarily accompanied by alteration of pulmonary structures.

Non-rhythm pulmonary diseases or disorders typically involve physical changes to lung structures, such as loss of elasticity of the lung tissue, obstruction of airways with mucus, limitation of the expansion of the chest wall during inhalation, fibrous tissue within the lung, excessive pressure in the pulmonary arteries, and/or other characteristics. Pulmonary diseases or disorders that are not rhythm-related are referred to herein as non-rhythm pulmonary diseases and may include obstructive pulmonary diseases, restrictive pulmonary diseases, infectious and non-infectious pulmonary diseases, pulmonary vasculature disorders, and pleural cavity disorders, for example.

Embodiments of the invention are directed to methods and systems for assessing a presence of non-rhythm pulmonary diseases using a sensor system coupled to a respiratory therapy device. If the non-pulmonary disease is present based on the assessment, then a diagnosis of the non-pulmonary disease may be made. A non-rhythm pulmonary disease assessment system may be used to discriminate between types of non-rhythm pulmonary diseases, e.g., between obstructive pulmonary diseases and restrictive pulmonary diseases. The assessment system may additionally or alternatively be used to discriminate between non-rhythm pulmonary diseases of a particular type, e.g., between asthma and emphysema, both of which are pulmonary diseases of the obstructive type.

If the presence of a non-rhythm pulmonary disease is detected, then the progression of the disease may be monitored. Monitoring the progression of the non-rhythm pulmonary disease may involve, for example, evaluating one or more physiological changes or symptoms associated with the disease. Evaluating the physiological changes or symptoms may be accomplished by periodically sensing for conditions modulated by the symptoms or physiological changes and storing information about the sensed conditions. Monitoring disease progression may involve, for example, monitoring the severity of the disease, disease onset, changes during the course of the disease, regression, disease offset, and/or other aspects of the disease.

Embodiments of the invention utilize the sensor system of a patient-external respiratory therapy device to determine a presence of a non-rhythm pulmonary disease. The respiratory therapy device may comprise, for example, a gas therapy device, nebulizer, ventilator, positive airway pressure device, or other type of external respiration therapy device. In a preferred embodiment, the respiratory therapy device comprises a positive airway pressure device. Continuous positive airway pressure (CPAP) devices are frequently used to treat sleep apnea and/or other breathing rhythm disorders. A CPAP device may be used regularly during a patient's sleep time to prevent or treat sleep disordered breathing events. Use of a CPAP device for treatment of breathing rhythm disorders facilitates detection of non-rhythm pulmonary diseases. The CPAP device provides respiratory sensing functionality on a periodic basis that may be employed to sense conditions indicative of symptoms or physiological changes associated with non-rhythm pulmonary disease.

Figure 60 is a flowchart illustrating a method of assessing a presence of a non-rhythm related pulmonary disease in accordance with embodiments of the invention. The method involves using 6010 a respiratory therapy device to sense conditions associated with the non-rhythm related pulmonary disease and assessing 6020 a presence of the non-rhythm pulmonary disease based on the sensed conditions.

The respiratory therapy device may include one or more sensors used to sense physiological conditions related to non-rhythm pulmonary disease. The respiratory therapy device sensors may include, for example, one or more ventilatory pressure sensors, capable of sensing inspiratory pressure and/or expiratory pressure, one or more ventilatory flow sensors, capable of sensing inspiratory flow and/or expiratory flow, one or more ventilatory gas sensors, capable of sensing exhaled CO2 and/or exhaled O2, among other sensors.

One or more of the physiological conditions sensed by the sensors of the respiratory therapy device may be measured and compared to criteria associated with presence of a non-rhythm pulmonary disorder. In some implementations, the one or more physiological conditions may be trended over time and the trended measurements compared to trend criteria. In some implementations, the criteria depend on relationships between the various measurements acquired using the sensors of the respiratory therapy device.

The measurements collected using the respiratory therapy device sensors may be stored in memory, along with sets of criteria used for assessing the presence of various non-rhythm pulmonary disorders. In one implementation, the memory storing the criteria sets and a diagnostic processor are disposed within the housing of the respiratory therapy

device controller, for example. The diagnostic processor compares the measured conditions to the criteria sets in memory to assess the presence of various non-rhythm pulmonary disorders.

In one implementation, the measurements acquired by the respiratory therapy device may be transmitted to a remote device, such as an advanced patient management system. Diagnostic circuitry within the advanced patient management system may compare the conditions measured by the respiratory therapy device to the criteria sets stored in the APM system to assess the presence of non-rhythm pulmonary disorders.

According to one aspect of the invention, pulmonary function testing may be employed to detect physiological changes associated with the presence of pulmonary disease. Pulmonary function tests performed in a clinical setting may be used to evaluate lung mechanics, gas exchange, pulmonary blood flow, and blood gases and pH. They are used to evaluate patients in the diagnosis of pulmonary disease, assessment of disease development, or evaluation of the risk of pulmonary complications from surgery.

Pulmonary performance may be evaluated based on data acquired by the respiratory therapy device during normal and forced inspiration and expiration. From such data, pulmonary parameters including tidal volume, minute ventilation, forced expiratory volume, forced vital capacity, among other parameters may be determined.

Pulmonary function testing is conventionally performed in a clinical setting and measures values indicative of the ability of the lungs to exchange oxygen and carbon dioxide. The total lung capacity (TLC) is divided into four volumes. The tidal volume ($V_T$) is the volume inhaled or exhaled in normal quiet breathing. The inspiratory reserve volume (IRV) is the maximum volume that can be inhaled following a normal quiet inhalation. The expiratory reserve volume (ERV) is the maximum volume that can be exhaled following a normal quiet exhalation. The residual volume (RV) is the volume remaining in the lungs following a maximal exhalation. The vital capacity (VC) is the maximum volume that can be exhaled following a maximal inhalation; $VC = IRV + V_T + ERV$. The inspiratory capacity (IC) is the maximum volume that can be inhaled following a normal quiet exhalation; $IC = IRV + V_T$. The functional residual capacity (FRC) is the volume remaining in the lungs following a normal quiet exhalation; $FRC = ERV + RV$.

The vital capacity and its components ($V_T$, IRV, ERV, IC) are typically measured using a spirometer, which is a device that measures the volumes of air inhaled and exhaled. The FRC is usually measured by the helium dilution method using a closed spirometry system. A known amount of helium is introduced into the system at the end of a normal

quiet exhalation. When the helium equilibrates throughout the volume of the system, which is equal to the FRC plus the volume of the spirometer and tubing, the FRC is determined from the helium concentration. This test may underestimate the FRC of patients with emphysema. The FRC can be determined quickly and more accurately by body plethysmography. The residual volume and total lung capacity are determined from the FRC.

In the forced vital capacity (FVC) maneuver, the patient exhales as forcefully and rapidly as possible, beginning at maximal exhalation. Several parameters are determined from the spirogram. The FVC is the total volume of air exhaled during the maneuver; it is normally equal to the vital capacity. The forced expiratory volume (FEV) is the volume expired during a specified time period from the beginning of the test. The times used are 0.5, 1, 2, and 3 seconds; corresponding parameters are $FEV_{0.5}$, $FEV_{1.0}$, $FEV_{2.0}$, and $FEV_{3.0}$. The maximal expiratory flow rate (MEFR) is the slope of the line connecting the points where 200 ml and 1200 ml have been exhaled; it is also called $FEF_{200-1200}$ (forced expiratory flow). The maximal midexpiratory flow rate (MMFR, MMF) is the slope of the line connecting the points where 25 per cent and 75 per cent of the FVC have been exhaled; it is also called $FEF_{25-75\%}$.

The Maximal Voluntary Ventilation (MVV) is the maximal volume of air that can be breathed by the patient, expressed in liters per minute; it was formerly called maximal breathing capacity (MBC). The patient breathes as rapidly and deeply as possible for 12 to 15 seconds and the volume exhaled is determined by spirometry.

Various parameters related to pulmonary performance, some of which may be measured using sensors of a respiratory therapy device include, for example, tidal volume, minute ventilation, inspiratory reserve volume, forced expiratory volume (FEV), residual volume, and forced vital capacity (FVC), among other parameters. According to one embodiment, testing of some pulmonary function parameters may be performed using the ventilation pressure and ventilation flow sensors of a CPAP device. The pulmonary function testing may be used, for example, to discriminate between restrictive and obstructive pulmonary disorders.

Because the results of pulmonary function tests vary with size and age, the normal values are calculated using prediction equations or nomograms, which give the normal value for a specific age, height, and sex. The prediction equations are derived using linear regression on the data from a population of normal subjects. The observed values are

usually reported as a percentage of the predicted value. Abnormal test results may show either an obstructive or restrictive pattern. Sometimes, both patterns are present.

The results of pulmonary function testing, along with other measured physiological conditions, may be compared to initial or baseline results to detect changes in the patient's pulmonary status over time. The changes from baseline values may be used to discern a presence of disease processes. Further, over time, a database of information about relevant conditions and specific to the patient is established. The information may be used to develop sets of criteria specific to the patient and associated with the presence of a particular pulmonary disease processes. Thus, in some implementations, the system may learn to recognize the presence of disease based on the history of symptoms and/or physiological changes that occur in a particular patient.

Figure 60B illustrates a normal respiratory pattern, having normal FEV and FVC. Figure 60C illustrates an obstructive pattern. An obstructive pattern occurs when there is airway obstruction from any cause, as in asthma, bronchitis, emphysema, or advanced bronchiectasis; these conditions are grouped together in the nonspecific term chronic obstructive pulmonary disease (COPD). In this pattern, the residual volume is increased and the PV/TLC ratio is markedly increased. Owing to increased airway resistance, the flow rates are decreased. The FEV/FVC ratios, MMFR, and MEFR are all decreased; $FEV_{1.0}$/FVC is less than 75 percent.

Figure 60D illustrates a restrictive pattern. A restrictive pattern occurs when there is a loss of lung tissue or when lung expansion is limited as a result of decreased compliance of the lung or thorax or of muscular weakness. The conditions in which this pattern can occur include pectus excavatum, myasthenia gravis, diffuse idiopathic interstitial fibrosis, and space occupying lesions (tumors, effusions). In this pattern, the vital capacity and FVC are less than 80 per cent of the predicted value, but the FEV/FVC ratios are normal. The TLC is decreased and the RV/TLC ratio is normal.

Embodiments of the invention utilize a patient-external respiratory therapy device to perform periodic pulmonary function testing. A CPAP or other external respiratory device may measure ventalitory pressure, ventilatory airflow, and/or ventalitory gas during periodic, e.g., nightly, therapy sessions. The ventalitory pressure and/or airflow measurements may be used to measure FVC and FEV during forced expiration. From these two parameters, FEV/FVC can be derived to differentiate obstructive versus restrictive respiratory patterns as shown in the Figures 60C and 60D. Other measurements that are possible using the respiratory device sensors include low forced expiratory flow

(FEF), high functional residual capacity (FRC), total lung capacity (TLC), and high residual volume (RV).

In one embodiment, the patient may perform forced expirations while connected to the external respiratory device. During the forced expirations, circuitry in the external respiratory device may collect measurements, including FEV and FVC measurements.

In addition, the forced expiratory flow ($FEF_{25-75\%}$) may be measured. The middle half by volume of the total expiration is marked, and its duration is measured. The $FEF_{25-75\%}$ is the volume in liters divided by the time in seconds. In patients with obstructive diseases, the $FEF_{25-75\%}$ is generally greater than their expected values.

Circuitry incorporated in the CPAP device may be used to compare measured FVC, FEV and $FEF_{25-75\%}$ values derived from the pressure sensor and/or from the airflow sensor with predicted values from normal subjects in accordance with various embodiments. The comparison provides diagnostic information of lung mechanics. Data acquired by the CPAP device may be transmitted from the CPAP device to an advanced patient management (APM) system or other remote device.

Figures 61A—61D are block diagrams of systems that may be used for non-rhythm pulmonary disease assessment in accordance with embodiments of the invention. Figure 61A illustrates an external respiratory therapy device 6110, e.g., a CPAP device, used to sense conditions associated with a non-rhythm pulmonary disease. The sensed conditions are evaluated by circuitry within the external respiratory therapy device 6110 to assess a presence of the non-rhythm pulmonary disease.

The respiratory therapy device 6110 is coupled to one or more sensors 6135 configured to sense one or more conditions modulated by physiological changes and/or symptoms of the non-rhythm pulmonary disease. The sensors of the respiratory device used to sense the conditions may include, for example, ventalitory airflow, ventilatory pressure, ventilatory gas, and/or other conditions modulated by symptoms of the non-rhythm pulmonary disease.

A representative set of symptoms and/or physiological changes associated with non-rhythm pulmonary diseases may involve dyspnea (e.g., non-specific dyspnea, orthopnea, exertional dyspnea, paroxysmal nocturnal dyspnea), abnormal concentrations of blood or respiratory gases (e.g., cyanosis, hypoxemia, hypercapnea, low pCO2, arterial acidosis, high alveolar--arterial pO2 differential), pulmonary function dysfunction (e.g., low forced expiratory volume (FEV), forced vital capacity (FVC), FEV/FVC, low forced expiratory flow (FEF), high functional residual capacity (FRC), total lung capacity (TLC),

high residual volume (RV), high lung compliance, slow exhalation, respiratory failure), other pulmonary conditions (e.g., ventilation-perfusion mismatch), and cardiovascular conditions (e.g., circulatory collapse).

Table 7 lists non-rhythm pulmonary disease symptoms or physiological changes, conditions indicative of the symptoms or physiological changes, and sensors of the respiratory therapy device that may be used to sense the conditions.

TABLE 7

| Symptom or Physiological Change | Condition | Sensor Used |
|---|---|---|
| Non-specific dyspnea<br>Orthopnea<br>Exertional dyspnea<br>Paroxysmal nocturnal dyspnea | Exhaled % CO2 | CO2 sensor |
| | Exhaled % O2 | O2 sensor |
| | Expiratory flow | Flowmeter |
| | Inspiratory flow | Flowmeter |
| Cyanosis<br>Hypoxemia<br>High alveolar-arterial pCO2 differential | Exhaled % O2 | O2 sensor |
| Hypercapnea<br>Low pCO2<br>Arterial acidosis | Exhaled % CO2 | CO2 sensor |
| Low FEV, FVC, FEV/FVC<br>Low FEF<br>High FRC, TLC<br>High RV<br>High lung compliance<br>Slow exhalation | Expiratory flow | Flowmeter |
| | Inspiratory flow | Flowmeter |
| | Expiratory pressure | Pressure sensor |
| | Inspiratory pressure | Pressure sensor |
| Respiratory Failure<br>Ventilation-perfusion mismatch<br>Circulatory collapse | Exhaled % O2 | O2 sensor |
| | Exhaled % CO2 | CO2 sensor |

The one or more sensors 6135 are coupled to sensor signal processor circuitry 6130 which may be configured to energize the sensors and to receive and condition signals generated by the sensors 6135. The sensor signal processor circuitry 6130 may comprise, for example, sensor driver circuitry, filters, sampling circuitry, and A/D converter circuitry. The sensor signals may be averaged, filtered, or otherwise processed by the signal processor circuitry 6130 prior to use by other components of the respiratory therapy device 6110.

The respiratory therapy device 6110, illustrated in Figure 61A as a positive airway pressure (xPAP) device includes a respiration therapy control unit 6120. The respiration therapy control unit 6120 comprises a flow generator 6121 that pulls in air through a filter.

The flow generator 6121 is controlled by the pressure control circuitry 6122 to deliver an appropriate air pressure to the patient. Air flows through tubing 6123 coupled to the xPAP device 6110 and is delivered to the patient's airway through a mask 6124. In one example, the mask 6124 may be a nasal mask covering only the patient's nose. In another example, the mask 6124 covers the patient's nose and mouth. Other air delivery systems are also possible.

Continuous positive airway pressure (CPAP) devices deliver a set air pressure to the patient. The pressure level for the individual patient may be determined during a titration study, for example. Such a study may take place in a sleep lab, and involves determination by a sleep physician or other professional of the optimum airway pressure for the patient. The CPAP device pressure control is set to the determined level. When the patient uses the CPAP device, a substantially constant airway pressure level is maintained by the device. The constant air pressure acts a pneumatic splint to keep soft tissue in the patient's throat from collapsing and obstructing the airway.

Autotitration PAP devices are similar to CPAP devices, however, the pressure controller for autotitration devices automatically determines the air pressure delivered to the patient. Instead of maintaining a constant pressure, the autotitration PAP device evaluates sensor signals and the changing needs of the patient to deliver a variable positive airway pressure. Autotitration PAP and CPAP are often used to treat sleep disordered breathing, for example.

Bi-level positive airway pressure (bi-PAP) devices provide two levels of positive airway pressure. A higher pressure is maintained while the patient inhales. The device switches to a lower pressure during expiration. Bi-PAP devices are used to treat a variety of respiratory dysfunctions, including chronic obstructive pulmonary disease (COPD), respiratory insufficiency, and ALS or Lou Gehrig's disease, among others.

The xPAP device may include a memory 6150 that stores criteria used in the assessment of pulmonary disease. The memory may additionally or alternatively store information related to measurements of the conditions sensed by the xPAP device.

In accordance with various embodiments of the invention, the xPAP device 6110 may include a diagnostic unit 6160 that evaluates patient conditions sensed by the sensors 6135 and assesses a presence of a non-rhythm pulmonary disease. For example, the diagnostic unit 6160 may compare the measured conditions to sets of criteria indicative of non-rhythm pulmonary diseases. If the measured conditions are consistent with a

particular set of criteria, the diagnostic unit may indicate that the non-rhythm pulmonary disease associated with the particular criteria set is present.

The xPAP device 6110 may include a communications unit 6140 for communicating with one or more separate devices 6170, such as a device programmer or a cooperating patient-external or patient-internal monitoring, diagnostic and/or therapeutic device. Communication between cooperating devices allows the xPAP device 6110 to provide information to the cooperating device or devices or to control therapy delivered by the cooperating devices, for example. In one scenario, the xPAP device 6110 may transmit to a cooperating therapy device information about the presence of a non-rhythm pulmonary disease/disorder. The therapy device may adjust therapy delivered by the device based on the presence of the non-rhythm pulmonary disease/disorder. Additionally, or alternatively, the xPAP device 6110 may adjust the respiration therapy delivered to the patient based on the non-rhythm pulmonary disease assessment.

In one implementation, a system for assessment of non-rhythm pulmonary disorders may be used within the structure of an advanced patient management system. In this implementation, an advanced patient management system includes a remote computer system that allows a physician to remotely monitor cardiac, respiratory, and other patient functions. The advanced patient management system may have the capability of assessing the presence of various non-rhythm pulmonary diseases based on respiration measurements acquired by the xPAP device 6110 and transmitted to the APM system.

As previously discussed, the xPAP device 6110 may include a memory 6150 for storing data related to the non-rhythm pulmonary disease. For example, the xPAP device 6110 may initiate collection and storage of data hourly, nightly, weekly, or according to some other time schedule that corresponds to the patient's usage times of the respiratory therapy device. Typically an xPAP device is used nightly for treatment of sleep apnea and/or other breathing rhythm disorders. The xPAP device 6110 may collect data from the sensors 6135 during one or more periods of time that the device is used. The presence of the non-rhythm pulmonary disease may be assessed based on the collected data. Assessment of the presence of the non-rhythm pulmonary disease may involve assessment of the severity of the disease, disease onset, changes during the course of the disease, regression, disease offset, and/or other aspects of the disease.

In one implementation, the diagnosis unit 6160 is a component of the respiratory therapy device 6110, as illustrated in Figure 61A. In another implementation, the diagnosis unit 6160 may be configured as a component of a device 6170 separate from the respiratory

therapy device 6110. The latter implementation is illustrated in the block diagram of Figure 61B. In this implementation, the respiratory therapy device 6110 may transmit information about conditions sensed by the respiratory therapy device 6110 to the diagnosis unit 6160 of a remotely located device 6170. The diagnosis unit 6160 assesses the non-rhythm pulmonary disease presence based on the transmitted information.

The remote device 6170 may comprise a patient-external or patient-internal medical device. The remote device 6170 may be configured, for example, as a cardiac diagnostic and/or therapeutic device. In one configuration, for example, the remote device may comprise a cardiac rhythm management system, such as a pacemaker, defibrillator, and/or cardiac resynchronizer.

The block diagrams of Figures 61C and 61D illustrate other exemplary arrangements that may be used for pulmonary disease assessment in accordance with embodiments of the invention. The system illustrated in Figure 61C includes a respiratory therapy device 6110 and a medical device 6190 remote from the respiratory therapy device 6110. In this example, both the respiratory therapy device 6110 and the medical device 6190 are equipped with sensors 6135, 6136 for sensing conditions associated with symptoms of one or more non-rhythm pulmonary diseases. For example, the respiratory therapy device 6110 and the additional medical device 6190 may each sense a subset of the conditions listed in Table 1. The respiratory therapy device 6110 may transmit its sensed condition information to the medical device 6190 over a wired or wireless communications link. The medical device 6190 includes a diagnostic unit 6160 configured to assess a presence of one or more non-rhythm pulmonary diseases. The diagnostic unit 6160 may assess the non-rhythm pulmonary diseases, for example, by comparing sensed conditions to one or more sets of criteria indicative of the non-rhythm pulmonary diseases as previously described.

The block diagram of Figure 61D illustrates a further exemplary arrangement of a pulmonary disease assessment system. In this example, the system includes a respiratory therapy device 6110 and an additional medical device 6190, e.g., a therapeutic or monitoring device. The respiratory therapy device 6110 and the additional medical device 6190 communicate with a diagnostic unit 6160, such as a diagnostic unit of an APM system. The respiratory therapy device 6110 and the additional medical device 6190 are each equipped with sensors 6135, 6136 for sensing conditions associated with one or more non-rhythm pulmonary diseases. The respiratory therapy device 6110 and the medical device 6190 may transmit sensed condition information to the diagnostic unit 6160 through

wireless or wired communication links. The pulmonary disease diagnostic unit 6160 is configured to use the information transmitted by the respiration therapy device 6110 and the medical device 6190 to assess the presence of one or more non-rhythm pulmonary diseases.

Assessment of conditions indicative of non-rhythm pulmonary diseases/disorders may include assessing the patient's pulmonary function as previously described. The charts provided in Figures 62A—62G illustrate conditions and sensors that may be used to determine physiological changes associated with various non-rhythm pulmonary diseases and disorders. The charts depicted in Figures 62A—62G illustrate relationships between various physiological changes and/or disease symptoms associated with non-rhythm pulmonary diseases. Figure 62A lists representative sets of non-rhythm pulmonary diseases that may be assessed in accordance with embodiments of the invention. The representative set of non-rhythm pulmonary diseases that may be assessed includes, for example, obstructive pulmonary diseases (e.g., chronic bronchitis, emphysema, asthma), restrictive pulmonary diseases (e.g., sarcoidosis, pulmonary fibrosis, pneumoconiosis), infections pulmonary diseases (e.g., bronchitis, pneumonia, bronchiolitis, tuberculosis, and bronchiectasis), pulmonary vasculature diseases (e.g., pulmonary hypertension, pulmonary edema, pulmonary embolism, atalectasis), and diseases of the pleural cavity (e.g., pleural effusion, pneumothorax, and hemothorax).

The non-rhythm pulmonary diseases listed in Figure 62A are cross-referenced with the physiological changes and/or symptoms associated with the non-rhythm pulmonary disease. The physiological changes and/or symptoms are cross referenced with conditions indicative of the physiological changes and/or symptoms. Sensors used to sense the conditions indicative of the physiological changes or symptoms are provided in Figure 62A. Sensors of the respiratory therapy device may include, for example, ventilation gas, ventilation flow and/or ventilation pressure sensors, or other sensors for example.

The left section 6202 of Figure 62A illustrates various conditions that may be sensed using sensors of a respiratory therapy device (CPAP), a cardiac device (CRM), or an external non-CPAP, non-CRM device. The top section 6201 lists various conditions that may be sensed and information about sensors used to sense the conditions. The center section 6204 of Figure 62A provides physiological changes and/or symptoms that may be evaluated using the conditions listed in the left section 6202. The right section 6203 of Figure 62A provides pulmonary diseases/disorders. The presence of the pulmonary

diseases/disorders of the right section 6203 may be assessed based on the physiological changes and/or symptoms of the center section 6204.

For legibility, the left and right sections 6202, 6203 of Figure 62A are divided into six portions, Figures 62B—62G. Figure 62B represents the upper left portion 6210 of the left section 6202 of Figure 62A. Figure 62C represents the upper right portion 6212 of the left section 6202 of Figure 62A. Figure 62D represents the lower left portion 614 of the left section 6202 of Figure 3A. Figure 3E represents the lower right portion 6216 of the left section 6202 of Figure 62A. Figure 62F represents the upper portion 6220 of the right section 603 of Figure 62A. Figure 62G represents the lower portion 6222 of the right section 6203 of Figure 62A. Relevant portions of the center section 6204 and the top section 6201 of Figure 62A appear in each of the Figures 62B—62G for convenience.

An example of how Figures 62A—62N may be used follows. Referring to Figures 62F and 62G, the restrictive pulmonary disorder pneumoconiosis produces the physiological changes non-specific dyspnea (Figure 62F) and cough (Figure 62G). Non-specific dyspnea (Figure 62F) and cough (Figure 62G) are indicated by marks in the column denoted pneumoconiosis in Figures 3F and 3G, respectively. Non-specific dyspnea may be detected based on one or more of the conditions listed in the row for non-specific dyspnea illustrated in Figures 62B and 62D. The conditions include duration of symptoms , abnormal breathing/coughing , blood pO2, inspiratory flow , expiratory flow, exhaled % CO2 and exhaled % O2, illustrated in Figure 62D. The conditions also include arterial/venous pO2, blood pCO2, blood pO2, exhalation time, inspiration time, minute ventilation, tidal volume, respiration rate, and/or respiration sounds illustrated in Figure 62B.

The presence of a disorder/disease, such as those listed in Figures 62A—62G, may be assessed by based on physiological changes and/or symptoms associated with the disorder/disease. The physiological changes and/or symptoms may be detected using conditions sensed by a sensor system of a respiratory therapy alone or in combination with the sensor systems of other therapeutic or diagnostic medical devices. If the sensed conditions indicate that the physiological changes or symptoms of a disease or disorder are consistent with a threshold level, the presence of the disease or disorder may be determined.

In another example, assessment of disease presence may be based on relative changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. For example, assessment of a presence of a disease or disorder may be

accomplished by evaluating the changes in conditions indicative of physiological changes or symptoms caused by the disease. The changes in the one or more conditions may be compared to threshold criteria. If changes in the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold levels, a presence of the disease or disorder may be determined.

In a further example, the threshold criteria may involve relationships between the conditions indicative of physiological changes or symptoms caused by the disease. The presence of a disease may be assessed by evaluating relationships between conditions indicative of physiological changes or symptoms caused by the disease. For example, assessment of a disease may involve the determination that levels or amounts of two or more conditions have a certain relationship with one another. If relationships between the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold relationship criteria, the disease or disorder may be present.

In accordance with various embodiments of the invention, the presence of a non-rhythm pulmonary disease, such as those listed in Figures 62A-62G, may be assessed by evaluating conditions indicative of the non-rhythm pulmonary disease sensed using a respiration therapy device. In one example, the presence of a non-rhythm pulmonary disease may be assessed by comparing conditions indicative of physiological changes or symptoms caused by the disease to threshold criteria. If the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold levels, the system may determine that the non-rhythm pulmonary disease or disorder is present.

In another example, assessment of disease presence may be based on relative changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. For example, diagnosis of a non-rhythm pulmonary disease may be effected by evaluating the changes in conditions indicative of physiological changes or symptoms caused by the disease. The changes in the one or more conditions may be compared to threshold criteria. If changes in the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold levels, the non-rhythm pulmonary disease or disorder may be present.

In a further example, the threshold criteria may involve relationships between the conditions indicative of physiological changes or symptoms caused by the disease. The presence of a non-rhythm pulmonary disease may be assessed by evaluating relationships between conditions indicative of physiological changes or symptoms caused by the disease.

For example, assessment of a disease may involve the determination that levels or amounts of two or more conditions have a certain relationship with one another. If relationships between the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold relationship criteria, the non-rhythm pulmonary disease or disorder may be present.

Figure 63A illustrates a system for assessing a presence of a non-rhythm pulmonary disease/disorder in accordance with embodiments of the invention. The system includes a diagnosis processor 6320 that receives information from a sensing system of a respiratory device 6321. The sensing system 6321 measures one or more conditions associated with a non-rhythm pulmonary disease or disorder. In some embodiments, the diagnosis processor may also receive sensory information from another device 6322, such as a cardiac therapy device.

The diagnosis processor 6320 accesses a criteria library 6310. The criteria library 6310 stores sets of criteria 6311—6314 respectively associated with various non-pulmonary diseases/disorders. Figures 63B—63K illustrate criteria sets that may be used to assess a presence of non-rhythm pulmonary disease in accordance with embodiments of the invention. The exemplary criteria sets may be used to assess the presence of chronic bronchitis (Figure 63B), emphysema (Figure 63C), asthma (Figure 63D), pulmonary fibrosis (Figure 63E), pulmonary hypertension (Figure 63F), pulmonary edema (Figure 63G), pulmonary embolism (Figure 63H), atelectasis (Figure 63I), and hemothorax (Figure 63J). The charts of Figures 63A-63J list physiological changes or symptoms associated with the non-rhythm pulmonary disease in the left hand column, conditions used to detect the particular physiological change or symptom in the middle column, and the respiration therapy device sensor used to sense the condition in the right hand column.

Using Figure 63J as a representative example, the presence of atelectasis may be assessed based on the symptoms non-specific dyspnea, hypoxemia, and/or hypercapnia. Non-specific dyspnea may be detected based on one or more of the following criteria: exhaled % CO2, exhaled % O2, expiratory flow, and/or inspiratory flow. The levels of one or more of these conditions may be compared to threshold levels for assessment of atelectasis. Other symptoms associated with atelectasis include hypoxemia, which may be determined based on comparison of the patient's exhaled % O2 to a threshold criterion, and hypercapnia, which may be determined based on comparison of the patient's exhaled % CO2 to a threshold criterion.

The criteria listed in Figures 63B—63J involve conditions that may be detected using sensors of a respiratory therapy device, such as a CPAP device. The non-rhythm pulmonary disease assessment system described herein may use one or more additional sensors and/or devices other than the respiratory therapy device to enhance disease assessment, such as those indicated in Figures 62A—62G. In one example, conditions detected using an external respiratory therapy device, e.g., CPAP device, may be used along with conditions detected using an implantable cardiac device, e.g., pacemaker or defibrillator to assess the presence of a non-rhythm pulmonary disease. In another example, conditions detected using an external respiratory therapy device, e.g., CPAP device, may be used along with conditions detected using an additional external device.

Figure 63K illustrates an exemplary criteria set for assessing a presence of tuberculosis. Tuberculosis may be assessed based on conditions sensed using a respiratory therapy device in addition to conditions sensed using other devices. Figure 63K lists physiological changes or symptoms associated with tuberculosis in the left hand column, conditions used to assess a presence of tuberculosis in the middle column, and the respiration therapy device sensor or other device sensor used to sense the condition in the right hand column.

Figure 64A is a flowchart illustrating a method for assessing a presence of a non-rhythm pulmonary disease/disorder in accordance with embodiments of the invention. The processes of Figure 64A may be implemented using system components and criteria sets such as those illustrated in Figures 63A-63K.

One or more conditions modulated by symptoms of a non-rhythm pulmonary disease/disorder are measured 6410. The conditions may be sensed by a sensing system of a respiratory therapy device, and optionally, by a sensing system of another medical device, such as a cardiac rhythm management device. A diagnosis processor receives the measured conditions and accesses 6420 a criteria library. The diagnostic unit compares 6430 the measured conditions with the one or more criteria sets.

If the measured conditions are consistent 6440 with a particular criteria set, the presence of the non-rhythm pulmonary disease/disorder associated with the particular criteria set is detected 6450. If the If the measured conditions are not consistent 6440 with a particular criteria set, the presence of the non-rhythm pulmonary disease/disorder associated with the particular criteria set is not detected 6460.

According to some embodiments, the system may monitor the non-rhythm pulmonary disease/disorder. Monitoring the progression of the disease/disorder may

include periodically measuring the conditions relevant to the disease/disorder and storing information relevant to the disease/disorder. The periodically measured conditions may be used to monitor the severity of the disease, disease onset, symptoms or physiological changes during the course of the disease, disease regression, disease offset, and/or other aspects of the disease.

Figure 64B is a flowchart illustrating a method of monitoring a presence of a non-rhythm pulmonary disease in accordance with embodiments of the invention. Criteria sets for assessment of the non-rhythm pulmonary diseases are established 6462. A respiratory therapy device such as a CPAP device is used 6464 to sense conditions modulated by disease symptoms. The sensor information may be gathered periodically 6466, e.g., nightly, and stored for evaluation. If a presence of the disease was previously determined 6468, then the progression of the disease may be monitored 6470 based on the conditions used to determine a presence of the disease, or other conditions.

If a presence of the disease was not previously determined 6468, then the levels of the sensed conditions are compared 6472 to a set of criteria associated with the disease. If levels of the conditions are consistent 6474 with the threshold levels, then the presence of the disease is determined 6476. If levels of the conditions are not consistent 6470 with the threshold levels, then the system continues 6464 to sense conditions modulated by disease symptoms.

Coordination of Respiratory and Cardiac Therapies for Disordered Breathing

Aspects of the invention are directed to methods and systems configured to provide coordinated respiratory and cardiac therapies for disordered breathing using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving disordered breathing therapy are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative

operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve an individual system 138 (Figure 1B) for coordinating disordered breathing therapy. The coordinated disordered breathing therapy system 138 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Various embodiments of present invention involve methods and systems for coordinating sleep disordered breathing therapies. In accordance with one embodiment, a method for treating disordered breathing includes controlling a patient-external respiratory therapy delivered to a patient and controlling a cardiac therapy delivered to the patient. The patient-external respiratory therapy and the cardiac therapy are coordinated to treat the disordered breathing.

In accordance with another embodiment of the invention, a medical system includes a respiratory therapy controller configured to control an external respiratory therapy delivered to a patient and a cardiac therapy controller configured to deliver a cardiac therapy to the patient. The system also includes a processor, coupled to the respiratory therapy controller and the cardiac therapy controller. The processor is configured to coordinate delivery of the external respiratory therapy and the cardiac therapy to treat disordered breathing.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes coordination 138 of delivery of disordered breathing therapy. The coordinated system may include, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A

communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy further includes a system 138 configured to coordinate delivery of disordered breathing therapy. The disordered breathing delivery coordination system 138 includes a respiratory therapy controller configured to control an external respiratory therapy delivered to a patient and a cardiac therapy controller configured to control a cardiac therapy delivered to the patient. The system further includes a processor coupled to the respiratory therapy controller and the cardiac therapy controller for coordinating delivery of the external respiratory therapy and the cardiac therapy in order to treat the disordered breathing.

Sleep disordered breathing may be more effectively monitored and/or treated using a coordinated approach. Various embodiments of the invention are implemented using medical systems employing two or more patient-external and/or patient-internal medical devices. The medical devices may communicate or otherwise operate in concert to provide coordinated disordered breathing therapy.

Embodiments of the invention are directed to methods and systems utilizing a plurality of therapies to treat sleep disordered breathing. The therapies include, at least, an external respiratory therapy and cardiac electrical stimulation therapy. Other therapies may also be cooperatively utilized.

Delivery of the plurality of therapies may be coordinated to achieve various therapeutic goals, e.g., to enhance overall therapy efficacy, to reduce impact to the patient, to avoid therapy interactions, among others. According to one example, coordination of therapies may involve shifting the therapy burden from one type of therapy to another type of therapy in response to events or conditions. In one implementation, shifting the burden from one type of therapy to another type of therapy may involve initiating or increasing a first type of disordered breathing therapy and terminating or decreasing a second type of disordered breathing therapy. Another example of coordinating therapy may involve using one type of therapy to treat one type of disordered breathing, and using another type of therapy to treat another type of disordered breathing.

Various types of therapies have been used to treat sleep disordered breathing. Positive airway pressure devices, e.g., continuous positive airway pressure (CPAP) devices

are among the most frequently used mechanical respiration therapy devices employed for treating sleep disordered breathing. Sleep disordered breathing has also been treated using muscle and/or nerve stimulation therapy. For example, a treatment for obstructive sleep apnea involves electrical activation of the tongue muscles. The hypoglossal (HG) nerve innervates the protrusor and retractor tongue muscles. In one approach, an appropriately applied electrical stimulation to the hypoglossal nerve, for example, may prevent backward movement of the tongue, thus preventing the tongue from obstructing the airway.

Central sleep apnea may also be treated by phrenic nerve pacing, also referred to as diaphragmatic pacing. Phrenic nerve pacing uses an electrode implanted in the chest to stimulate the phrenic nerve. The phrenic nerve is generally known as the motor nerve of the diaphragm. It runs through the thorax, along the heart, and then to the diaphragm. Diaphragmatic pacing involves the use of electronic stimulation of the phrenic nerve to control the patient's diaphragm and induce a respiratory cycle. Pacing the phrenic nerve may be accomplished by surgically placing a nerve cuff on the phrenic nerve, and then delivering an electric stimulus. The electric stimulus of the phrenic nerve then causes the diaphragm to induce a respiratory cycle.

Recently, cardiac pacing therapy has been used as a therapy for disordered breathing. Cardiac pacing therapy may be implemented using an implanted electrical pulse generator coupled to endocardiac leads inserted into one or more heart chambers. Cardiac pacing for sleep disordered breathing treatment may include pacing one or more heart chambers, and may involve pacing at a rate above a lower rate limit during sleep and/or during episodes of disordered breathing, for example. Other forms of cardiac pacing such as cardiac resynchronization therapy, biventricular pacing can be delivered to the patient to treat disordered breathing.

Another cardiac therapy that can be adapted to mitigate disordered breathing involves non-excitatory stimulation therapy. In one example, non-excitatory cardiac stimulation therapy involves electrical stimulation of one or more heart chambers, e.g., the left and/or right ventricles, or other cardiac sites, at an energy level below a capture threshold. In another example, non-excitatory cardiac stimulation therapy involves cardiac electrical stimulation delivered to one or more heart chambers during absolute refractory periods of the cardiac tissue. The non-excitatory stimulation may improve cardiac contractility. The non-excitatory cardiac stimulation therapy may be used alone or in combination with cardiac pacing therapy to provide a comprehensive therapy regimen for patients with CHF and disordered breathing such as Cheyne-Stokes respiration.

Cardiac therapy has also been used to mitigate disordered breathing using methods that involve overdrive cardiac pacing of one or more atria or one or more ventricles.

Drug therapy may also be used to treat disordered breathing. Drugs may be delivered to the patient through one or more automatically controllable drug delivery devices, e.g., a drug pump, a controllable nebulizer, or an electrically activated drug patch, for example.

The block diagram of Figure 65 illustrates an example of system 6500 including a fully or partially implantable device 6501 that may be used to monitor patient conditions and to coordinate sleep disordered breathing therapy in accordance with embodiments of the invention. The medical device 6501 may be coupled to an array of data acquisition devices, including patient-internal sensors 6511, patient-external sensors 6512, patient input devices 6513, and/or other information systems 6514 as described in more detail above. Patient conditions monitored by the implantable device 6501 may include both physiological and non-physiological contextual conditions affecting the patient such as those listed in Table 1.

The implantable device 6501 of Figure 65 includes a coordination processor 6537 for processing signals received from the sensors, 6511, 6512, patient input devices 6513, and/or other information system 6514. The coordination processor 6537 may include one or more a detection units 6524, 6526, 6528 that detect the occurrence of various physiological events. For example, the coordination processor 6537 may include one or more of a disordered breathing detector 6524, a sleep detector 6528, and/or a therapy usage detector 6526. Other event detection components may also be included. The coordination processor 6537 may be used to calculate various indices, e.g., AHI, %PB, and/or arousals per unit time, used for evaluating therapy efficacy, and/or therapy impact. The coordination processor 6537 may compare the patient's therapy usage to a prescribed therapy to determine therapy compliance. The coordination processor 6537 can develop control signals for implementing a coordinated therapy based on the monitored conditions, the detected events, and/or the calculated indices.

In one exemplary implementation, the disordered breathing detector 6524 may be coupled to a respiration sensor. The disordered breathing detector 6524 may use the respiration signal developed by the respiration sensor to detect disordered breathing events based on the inspiratory and expiratory phases of the patient's respiration cycles, for example. The sleep detector 6528 may analyze various inputs from the patient-internal sensors 6511, patient-external sensors 6512, patient input devices 6513, other information

systems 6514 to detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and arousals from sleep.

The coordination processor 6537 may include a memory 6536 for storing information derived from signals produced by the patient-internal sensors 6511, patient-external sensors 6512, patient input devices 6513, and/or other information systems 6514. The memory 6536 may also store information about detected events, e.g., sleep and disordered breathing events, and/or information related to calculated indices characterizing various events such as sleep and/or disordered breathing events. The stored data may be used by coordination processor 6537 to develop a coordinated disordered breathing therapy. The stored data may be retrieved by another component of the medical device 6501 for later use, or may be transmitted to a separate device 6540 for storage, further processing, trending, analysis and/or display, for example. In one scenario, the stored data can be downloaded to a separate device periodically or on command. The stored data may be presented to the patient's health care professional on a real-time basis, or as a long-term, e.g., month long or year long, trend of daily measurements.

In the particular embodiment illustrated in Figure 65, the medical device 6501 includes a cardiac therapy unit 6575. This example, the medical device 6501 comprises a cardiac therapy device 6575 configured as a cardiac pulse generator to deliver cardiac electrical stimulation therapy via electrical stimulation electrodes 6552.

The medical device 6501 may further include a communications unit 6506 that controls communications between the medical device 6501 and other devices or systems. For example, the communications unit 6506 may be used to provide wireless or wired communications links between the medical device 6501 and one or more of the patient-internal sensors 6511, patient-external sensors 6512, patient input devices 6513, and information systems 6514.

The communications unit 6506 may also facilitate communications between the medical device 6501 and a remote device 6540 such as another sleep disordered breathing therapy device, a programmer, and/or an APM system. The wireless connections coupling the medical device 6501 to various other devices and systems may utilize a variety of wireless protocols, including, for example, Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol.

Detecting the onset, termination, duration, stages, and quality of sleep experienced by a patient may be employed in connection with constructing a coordinated disordered breathing therapy. Patients suffering from sleep apnea, or other types of sleep disordered

breathing, may be treated for sleep disordered breathing only during periods of sleep. Coordinating disordered breathing therapy may involve determining if the patient is asleep and/or detecting various sleep-related processes, such as arousals from sleep and/or REM or non-REM sleep stages.

In addition, information associated with patient sleep may be used to assess an impact of breathing therapy on the patient. Therapy impact data may be used to develop information to coordinate and adjust the therapy. The implantable monitoring device 6501 may include a sleep detector 6528 for detecting when the patient is asleep and various stages and/or processes of sleep. Various methods of sleep detection implementable in an implanted device involve sensing one or more conditions indicative of sleep. The sleep-related conditions may be compared to one or more thresholds to determine if the patient is asleep.

The sleep-related conditions may be sensed or derived using patient-external or implantable sensors and analyzed by a sleep detector coupled to or incorporated in the implantable therapy coordination device. For example, sleep detection may be implemented in an implantable cardiac rhythm management system configured as a pacemaker/defibrillator and incorporating a coordination processor or an ITCS device.

As illustrated in the flowchart of Figure 66A, embodiments of the invention are directed to an automated method for controlling disordered breathing therapy delivered to a patient. The method involves controlling 6610 delivery of an external respiratory therapy and controlling delivery 6620 of a cardiac therapy. The external respiratory therapy and the cardiac therapy are coordinated 6630 to treat disordered breathing.

In various implementations, one or more conditions affecting the patient and associated with disordered breathing and/or disordered breathing therapy may be sensed. The sensed conditions may be used, for example, to detect and/or predict disordered breathing episodes, determine a severity of disordered breathing, detect sleep, assess sleep quality, evaluate an efficacy of the therapy, evaluate an impact of the therapy on the patient, determine therapy interactions, determine patient usage of the therapies, among other factors. Coordination of the therapies may be performed based on the sensed conditions. The therapies may be adjusted to enhance therapy effectiveness, to reduce an impact of the therapy, to avoid or reduce therapy interactions, and/or to accomplish other therapeutic goals.

According to embodiments presented herein, a coordinating processor unit is used to generate control signals used for controlling disordered breathing therapies delivered to

the patient. In one embodiment, the coordinating unit may transmit control signals directly to an external respiratory therapy device and a cardiac therapy device. The control signals may be used by the respective therapy devices to automatically adjust the therapy delivered to the patient. In another embodiment, both the coordinating unit and the therapy devices may be communicatively coupled to a separate medical device, such as a device programmer or patient management system. The coordinating unit may transmit control information indirectly to the therapy devices through a device programmer or patient management system.

In one embodiment of the invention, a sensor system may sense one or more conditions related to disordered breathing. Disordered breathing events may be detected based on the sensed conditions. Characteristics of the disordered breathing events such as severity, frequency, and/or duration, may be determined. Determination of the one or more characteristics of the sleep disordered breathing events may involve calculation of one or more indices characterizing the disordered breathing events. The indices may include, for example, an apnea/hypopnea index (AHI) and/or a percent time in periodic breathing (%PB), among other indices. The external respiratory therapy and the cardiac therapy maybe coordinated based on the characteristics of the disordered breathing events.

In accordance with an embodiment of the invention, illustrated in the flowchart of Figure 66B, coordination of disordered breathing therapies, including an external respiratory therapy and a cardiac electrical stimulation therapy, may be implemented using circuitry disposed within the housing of an implantable cardiac rhythm management (CRM) device. The therapies delivered to the patient may be coordinated based on a variety of factors, including therapy effectiveness and/or impact of the therapy on the patient. In this embodiment, the external respiratory therapy is delivered by a continuous positive airway pressure (CPAP) device. The cardiac therapy comprises cardiac electrical stimulation therapy for treating disordered breathing delivered by the CRM device.

One or more sensors may be employed to sense conditions related to disordered breathing and/or disordered breathing therapy, including, for example, the effectiveness of the breathing therapy and/or the impact of the therapy on the patient. The sensors may be coupled to the CPAP device, the CRM device, or a first set of sensors may be coupled to the CPAP device and a second set coupled to the CRM device. The coordinating unit within the CRM device receives the signals from the sensors, determines therapy effectiveness and/or impact, and coordinates therapy delivered by the CPAP and CRM devices.

In one example, a condition modulated by patient respiration may be sensed 6674 and a respiration waveform signal generated. Circuitry disposed within the housing of the CRM device may detect 6676 disordered breathing episodes based on the respiration signal. The coordination unit may determine therapy effectiveness based on the severity, frequency and/or duration of sleep disordered breathing episodes experienced by the patient. In one implementation, coordination circuitry disposed within the CRM device may calculate 6678 an apnea/hypopnea index (AHI) indicative of the frequency of disordered breathing episodes. The effectiveness of the sleep disordered breathing therapy may be determined 6680 based on the sleep disordered breathing index. If the AHI is relatively low, the breathing therapy may be determined to be effective. If the AHI is relatively high, then the breathing therapy may be determined to be ineffective.

A CPAP device typically includes a respiratory mask, e.g., a nasal of facial mask, worn by the patient to facilitate delivery or air or other gas to the patient's airway. The respiratory mask may be inconvenient and/or uncomfortable for the patient to wear and may keep the patient awake. Further, delivery of positive airway pressure may inhibit sleep, or cause the patient to arouse frequently. Information about these side effects of the breathing therapy may be helpful in coordinating a therapy regimen for the patient.

Impact of the external breathing therapy and/or cardiac electrical stimulation therapy may be determined based on the patient's sleep quality. Sensors coupled to the coordination processor within the CRM device are configured to sense 6682 one or more conditions related to sleep. The sleep related conditions are used to detect 6684 sleep and/or arousals from sleep. The coordination processor within the CRM device determines 6686 the impact of the therapies on the patient by monitoring the patient's sleep. For example, the coordination processing may monitor the total time the patient spends sleeping, the number of arousals experienced by the patient in one night, the number of arousals correlated to sleep disordered breathing events, the number of arousals correlated to therapy delivery, and/or the depth of the arousals. In various implementations the coordination processor may calculate various indices characterizing sleep and/or one or more composite indices based on indices related to sleep and indices related to sleep disordered breathing. In one example, the monitoring unit calculates the number of arousals experienced by the patient per hour (A/h).

Therapy coordination may be accomplished 6688 based on the therapy effectiveness and impact information. Control signals may be transmitted from the coordinating processor unit to the therapy units of the CRM and CPAP devices. One or

both of the therapies delivered by the CRM and CPAP devices may be adjusted to enhance therapy effectiveness and/or reduce side effects.

In various examples, coordinated disordered breathing therapy may involve adjusting the cardiac electrical stimulation therapy for disordered breathing, adjusting the neurostimulation therapy for disordered breathing and/or adjusting the external respiration therapy for disordered breathing. According to this scenario, a disordered breathing therapy coordination processor may distribute the burden of disordered breathing therapy between one or more therapy devices.

In one implementation, certain types of therapy may be used for predetermined periods of time. For example, a predetermined level of cardiac and/or nerve stimulation therapy may be used prior to the patient falling asleep. The therapy burden may be shifted to the external respiratory therapy device after sleep has been detected. In one implementation, the therapy burden may be distributed based on detected arousals. For example, if the delivery of one type of therapy causes the patient to arouse from sleep, the therapy burden may be shifted to other types of therapy to enhance the patient's sleep quality. Alternatively, rather than shifting to other types of therapy, therapy parameters of a particular therapy may be adjusted to provide more restful sleep. For example, an external respiratory therapy pressure may be adjusted downward to provide a disordered breathing therapy that is more comfortable to the patient and allows the patient to sleep better. In one implementation, the respiratory therapy pressure may be adjusted downward and the pacing rate may be adjusted upward to maintain effectiveness of the therapy while reducing an impact on the patient.

In another implementation, the therapy burden may be distributed based on therapy efficacy. In one scenario, the therapy controller may add therapies to the overall disordered breathing therapy regimen to improve therapy efficacy. For example, if the therapy coordination processor determines that disordered breathing is occurring despite the use of one type of therapy, additional one or more types of therapy may be added to the regimen in order to treat disordered breathing.

In one scenario, the disordered breathing therapy burden may be distributed based on device usage. For example, if the patient does not use the external respiratory therapy device, then the disordered breathing therapy coordination processor may signal a CRM device and/or an external respiratory therapy device to initiate or increase the level of therapy delivered by the CRM device, the external respiratory therapy device, and/or other therapy devices.

In one embodiment, the coordination processor may coordinate the disordered breathing therapy to enhance therapy efficacy while adjusting or avoiding a therapy impact. The coordination processor may acquire information related to the sensed conditions and may evaluate therapy efficacy and/or impact on the patient, i.e., side effects of the therapy, based on the sensed conditions. The coordination processor may modify the therapy delivered by one or more therapy devices to enhance therapy efficacy while reducing or avoiding side effects. The coordination processor may modify the therapy to reduce interactions between the disordered breathing therapy and other types of therapies delivered to the patient, e.g., neurostimulation for anti-hypertensive therapy and/or cardiac pacing for cardiac rhythm management. The coordination processor may modify the therapy to reduce interactions between different types of disordered breathing therapies, for example. The therapy controller may modify a therapy to increase the useable lifetime of an implantable device.

Pulmonary Disease Assessment with Drug Therapy Control

Aspects of the invention that include controlling a drug therapy for treating a non-rhythm pulmonary disease are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving pulmonary disease assessment and drug therapy are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures.

The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve an individual system 134 (Figure 1B) for controlling drug therapy to treat non-rhythm pulmonary disease. The drug therapy control system 134 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Embodiments of the invention involve assessing a presence of a pulmonary disease or disorder that is not a breathing rhythm disorder and controlling the deliver of a drug therapy to treat the pulmonary disease. According to one embodiment, a method for controlling therapy for a non-rhythm related pulmonary disease includes sensing one or more conditions associated with the non-rhythm pulmonary disease using sensors of a patient-external respiratory therapy device. A presence of the non-rhythm pulmonary disease is assessed based on the one or more sensed conditions. A control signal for controlling a drug therapy to treat the non-rhythm pulmonary disease is generated based on the assessment of the non-rhythm pulmonary disease.

According to one aspect, sensing the one or more conditions associated with the non-rhythm pulmonary disease involves performing a pulmonary function test using the sensors of the respiratory therapy device. One or more pulmonary function conditions are determined based on the pulmonary function test.

According to another aspect, the method includes comprising delivering the drug therapy using the generated control signal. In one embodiment, the drug therapy may be delivered using the respiratory therapy device. In other embodiments, the drug therapy may be delivered using a therapy device other than the respiratory therapy device.

One or more additional conditions associated with the non-rhythm pulmonary disease may be sensed using an implantable device. The disease assessment may be based in part on the one or more additional conditions.

Another embodiment of the invention involves a medical system for controlling therapy to treat a non-breathing rhythm related pulmonary disease. The system includes an external respiratory therapy device. The external respiratory therapy device includes a therapy unit configured to deliver respiration therapy to a patient and a sensor system

configured to sense one or more conditions associated with a non-rhythm pulmonary disease. A diagnosis unit is coupled to the sensor system and is configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions. A drug therapy controller is coupled to the diagnosis unit. The drug therapy controller is configured to control a drug therapy delivered to the patient to treat the non-rhythm pulmonary disease.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes a system 134 for controlling a drug therapy to treat non-rhythm pulmonary disease. The coordinated system includes, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy includes a system 134 configured to control drug therapy to treat non-rhythm pulmonary disease. The drug therapy control system 134 includes an external respiratory therapy device with a therapy unit configured to deliver respiration therapy to a patient and a sensor system configured to sense one or more conditions associated with a non-rhythm pulmonary disease. The system further includes a diagnosis unit coupled to the sensor system configured to assess a presence of the non-rhythm pulmonary disease based on one or more sensed conditions. A drug therapy controller is coupled to the diagnosis unit and is configured to control a drug therapy delivered to the patient to treat the non-rhythm pulmonary disease.

The implantable and respiratory therapy devices 181, 184 may operate cooperatively based on system 134 control of drug therapy delivered to a patient. For example, control of drug therapy to treat non-rhythm pulmonary disease may allow the implantable and respiratory therapy devices 181, 184 to operate cooperatively to provide therapies for treating conditions associated with non-rhythm pulmonary disease.

Pulmonary disorders may be organized into broad categories encompassing disorders of breathing rhythm and non-rhythm pulmonary diseases and/or disorders. Breathing rhythm disorders include various syndromes characterized by patterns of disordered breathing that produce insufficient respiration, for example, sleep apnea,

hypopnea, and Cheyne-Stokes Respiration (CSR), among others. Breathing rhythm disorders are not necessarily accompanied by alteration of pulmonary structures.

Non-rhythm pulmonary diseases or disorders typically involve physical changes to lung structures, such as loss of elasticity of the lung tissue, obstruction of airways with mucus, limitation of the expansion of the chest wall during inhalation, fibrous tissue within the lung, excessive pressure in the pulmonary arteries, and/or other characteristics. Pulmonary diseases or disorders that are not rhythm-related are referred to herein as non-rhythm pulmonary diseases and may include various types, for example, obstructive pulmonary diseases, restrictive pulmonary diseases, infectious and non-infectious pulmonary diseases, pulmonary vasculature disorders, and pleural cavity disorders.

Embodiments of the invention are directed to controlling a drug therapy to treat a non-rhythm pulmonary disease. A presence of a non-rhythm pulmonary disease is determined using a sensor system coupled to a respiratory therapy device. If the non-pulmonary disease is present based on the assessment, then a drug therapy to treat the non-pulmonary disease may be delivered. In accordance with embodiments of the invention, a non-rhythm pulmonary disease assessment system may be used to discriminate between types of non-rhythm pulmonary diseases, e.g., between obstructive pulmonary diseases and restrictive pulmonary diseases. The non-rhythm pulmonary disease assessment system may discriminate between non-rhythm pulmonary diseases of a particular type, e.g., between asthma and emphysema, both of which are pulmonary diseases of the obstructive type. Discrimination between pulmonary diseases afflicting the patient facilitates delivery of an effective drug therapy, allowing the system to deliver an appropriate therapy for the particular pulmonary disease detected.

If the presence of a non-rhythm pulmonary disease is determined, then the progression of the disease may be monitored. Monitoring the progression of the non-rhythm pulmonary disease may involve, for example, periodically evaluating one or more physiological changes or symptoms associated with the disease. Evaluation of the one or more physiological changes or symptoms may be accomplished by sensing conditions associated with the symptoms or physiological changes. In a preferred embodiment, information about the sensed conditions is stored and may be trended or otherwise processed to facilitate disease detection.

Typically, a physiological sensor generates a signal modulated by a physiological parameter. In some cases, a physiological condition may be directly measured based on the sensor signal. For example, a blood pressure measurement may directly correlate to the

signal generated by a calibrated blood pressure sensor. In other cases, a condition measurement may be derived from the sensor signal. For example, tidal volume is a respiratory system condition that may be derived based on the signal generated by a transthoracic impedance sensor. In another example, heart rate is a cardiac system condition that may be derived from a cardiac electrogram sensor.

Monitoring a disease may involve, for example, monitoring the severity and/or other characteristics of the disease over time. Monitoring the disease may involve detecting disease onset, monitoring progression and/or regression of the disease and detecting disease offset. Disease monitoring may involve monitoring one or more conditions associated with the physiological changes and/or symptoms of the disease.

In one implementation, the presence of the non-rhythm pulmonary disease is assessed based on one or more patient conditions indicative of symptoms or physiological changes associated with the disease. The one or more conditions are sensed using the sensing system of a patient-external respiratory therapy device. In a preferred embodiment, the respiratory therapy device comprises a positive airway pressure device.

Continuous positive airway pressure (CPAP) devices are frequently used to treat sleep apnea and/or other breathing rhythm disorders. A CPAP device may be used regularly during a patient's sleep time to alleviate symptoms of breathing rhythm related disorders. The sensors of the CPAP device, used nightly to treat disordered breathing disorders, may be employed to detect and/or assess non-rhythm pulmonary diseases. A drug therapy for the non-rhythm pulmonary disease may be controlled based on the assessment of the disease.

In another implementation, the presence of the non-rhythm pulmonary disease may be detected and/or assessed based on conditions sensed using sensors of a patient-external respiratory therapy device in combination with additional conditions sensed using sensors of an implantable device. The implantable device may comprise, for example, an implantable cardiac device, such as a pacemaker, defibrillator, cardioverter, cardiac monitor, and/or cardiac resynchronizer.

Figure 67 is a block diagram of a medical system 6700 that includes components useful in implementing detection and/or assessment of non-rhythm pulmonary diseases and controlling drug therapy in accordance with embodiments of the invention. One or more of the components identified in Figure 67 may be used for assessing pulmonary diseases and controlling delivery of drug therapy.

For example, the medical system 6700 may be implemented to include one or more of the features and/or processes described herein. A system for assessing pulmonary diseases and controlling delivery of drug therapy need not include all of the features and functions described, but may be implemented to include one or more selected features and functions that provide unique structures and/or functionality.

Figure 67 illustrates a patient internal device 6710 and a patient external device 6720. Sensors and/or input devices 6741—6748 coupled to the patient-internal device and the patient-external device may be used to sense patient conditions indicative of symptoms of a pulmonary disease. In addition to the sensing functions performed by the therapy devices 6710, 6720, the devices 6710, 6720 may respectively include therapy units 6716, 6726 providing therapy for disorders other than the detected pulmonary disease, e.g., cardiac therapy for cardiac rhythm disorders and/or CPAP therapy for breathing rhythm disorders. Either of the patient internal device 6710 and/or the patient external device 6720 may include a drug therapy control unit 6750 configured to generate control signals deliverable to a drug therapy device 6727. The drug therapy device provides drug therapy to treat one or more non-rhythm pulmonary diseases. In some embodiments, the components used to generate the drug therapy control signal or signals may be included in both the patient internal device and the patient external device. The patient internal device 6710 and/or the patient external device 6720 may generate control signals that initiate, modify, and/or terminate drug therapy for the non-rhythm pulmonary disease.

The patient-internal device 6710 is typically a fully or partially implantable device that includes circuitry for implantably performing one or more of monitoring 6712, diagnosis 6714, and/or therapy control/delivery functions 6716, 6750. The patient-external device 6720 includes circuitry for performing one or more of monitoring, diagnosis and/or therapy control/delivery functions patient-externally (i.e., not invasively implanted within the patient's body). The patient-external medical device 6720 may be positioned on the patient, near the patient, or in any location external to the patient. It is understood that a portion of a patient-external medical device 6720 may be positioned within an orifice of the body, such as the nasal cavity or mouth, yet can be considered external to the patient (e.g., mouth pieces/appliances, tubes/appliances for nostrils, or temperature sensors positioned in the ear canal).

Each of the patient-internal 6710 and patient-external 6720 devices may include a patient monitoring unit 6712, 6722. The patient-internal and patient-external devices 6710, 6720 may be coupled to one or more sensors 6741, 6742, 6745, 6746, patient input devices

6743, 6747 and/or other information acquisition devices 6744, 6748. The sensors 6741, 6742, 6745, 6746, patient input devices 6744, 6747, and/or other information acquisition devices 6744, 6748 may be employed to detect conditions relevant to the monitoring, diagnostic, and/or therapeutic functions of the patient-internal and patient-external medical devices 6710, 6720. The sensors 6741, 6742, 6745, 6746, patient input devices 6744, 6747, and/or other information acquisition devices 6744, 6748 may be used to detect conditions associated with pulmonary disease.

The medical devices 6710, 6720 may each be coupled to one or more patient-internal sensors 6741, 6745 that are fully or partially implantable within the patient. The medical devices 6710, 6720 may also be coupled to patient-external sensors 6742, 6746 positioned on, near, or in a remote location with respect to the patient. The patient-internal and patient-external sensors are used to sense conditions, such as physiological or environmental conditions.

The patient-internal sensors 6741 may be coupled to the patient-internal medical device 6710 through internal leads. In one example, an internal endocardial lead system is used to couple cardiac electrodes that sense cardiac electrical activity to an implantable pacemaker or other cardiac rhythm management device. In some applications, one or more patient-internal sensors 6741 may be equipped with transceiver circuitry to support wireless communications between the one or more patient-internal sensors 6741 and the patient-internal medical device 6710. Similarly, patient internal sensors 6745 may be coupled to a patient-external device 6720 through wireless communications links.

The patient-external sensors 6742, 6746 may be coupled to the patient-internal medical device 6710 and/or the patient-external medical device 6720 through leads or through wireless connections. Patient-external sensors 6742 preferably communicate with the patient-internal medical device 6710 wirelessly. Patient-external sensors 6746 may be coupled to the patient-external medical device 6720 through leads or through a wireless link.

The medical devices 6710, 6720 may be coupled to one or more patient-input devices 6743, 6747. The patient-input devices are used to allow the patient to manually transfer information to the medical devices 6710, 6720. The patient input devices 6743, 6747 may be particularly useful for inputting information concerning patient perceptions, such as how well the patient feels, and information such as patient smoking, drug use, or other activities that are not automatically sensed or detected by the medical devices 6710, 6720.

The medical devices 6710, 6720 may be connected to one or more information systems 6744, 6748, for example, a database that stores information useful in connection with the monitoring, diagnostic, or therapy functions of the medical devices 6710, 6720. For example, one or more of the medical devices 6710, 6720 may be coupled through a network to a information system server that provides information about environmental conditions affecting the patient, e.g., the pollution index for the patient's location.

The medical devices 6710, 6720 may incorporate therapy units 6716, 6726 for configured to control and deliver therapy to the patient. The therapy units 6716, 6726 may be implemented to provide therapy other than a drug therapy delivered to treat the pulmonary disease. For example, in one embodiment, the patient-internal device 6710 may comprise a cardiac rhythm management (CRM) system configured to deliver cardiac pacing therapy to the patient. The patient-external device 6720 may comprise a positive airway pressure (xPAP) device configured to deliver a respiratory therapy to treat a breathing rhythm disorder. One or both of the patient-internal device 6710 and the patient-external device 6720 may include components that control delivery of a drug therapy to treat the non-rhythm pulmonary disease.

The system 6700 further includes a diagnostics unit 6714 that is configured to detect and/or assess a presence of non-rhythm pulmonary disease. In some embodiments, the diagnostics unit 6714 may be fully incorporated into the patient-external device 6720. In other embodiments, the diagnostics unit 6714 may be fully incorporated into the patient-internal device 6710. In yet other embodiments, components of the diagnostics unit 6714 may be incorporated into both the patient-internal and patient-external devices 6710, 6720. In yet further embodiments, the diagnostics unit may be located remotely from both the patient-internal medical device 6710 and the patient-external medical device 6720. In one scenario, the diagnostics processor may be implemented as a component of an advanced patient management (APM) system 6730, for example.

The monitoring units 6712, 6722 of the patient-internal and patient external medical devices 6710, 6720 collect data based on conditions sensed or detected through the use of the sensors 6741, 6742, 6745, 6746, patient input devices 6743, 6746, and/or information systems 6744, 6748 coupled to the patient-internal and patient-external devices 6710, 6720. The collected data is transferred to a diagnostics unit 6714.

The diagnostics unit 6714 is configured to assess the presence of the non-rhythm pulmonary disease based on the sensed conditions. The diagnostics processor 6714 may also assess and/or monitor the progression, of the medical disease or disorder. Monitoring

the progression of the disease may involve, for example, periodically evaluating one or more conditions indicative of physiological changes or symptoms of the disease. Monitoring disease progression may involve, for example, monitoring the severity of the disease, monitoring disease onset, progression, regression and offset, and/or monitoring other aspects of the disease.

A drug therapy controller 6750 may be configured as a component of the patient-internal device 6710, the patient external device 6720, a device remote from the patient-internal and patient external devices 6710, 6720, or as a stand alone unit. In some configurations, components of the drug therapy controller may be housed in both the patient-internal and patient external devices 6710, 6720. Components of the drug therapy controller and the drug therapy delivery unit may be disposed within a single housing.

The drug therapy controller 6750 generates a control signal for controlling drug therapy delivered to the patient based on the assessment of the non-rhythm pulmonary disease. The drug therapy controller 6750 may generate a control signal to initiate drug therapy if disease onset is detected or if one or more symptoms of the disease are determined to reach a threshold limit, for example. The control signal may indicate termination of the drug therapy if one or more symptoms of the disease subside. Further, during the course of the disease, the control signal may be adjusted based on the assessment of the presence of the non-rhythm pulmonary disease as indicated by sensed conditions indicative of disease symptoms.

The control signal generated by the drug therapy controller 6750 is received by the drug therapy unit 6727. The drug therapy unit 6727, which may comprise an implantable or patient-external device, provides a drug therapy to treat the non-rhythm pulmonary disease. Therapy delivered by the drug therapy unit 6727 is controlled by the control signal generated by the drug therapy controller 6750. In various embodiments, the drug therapy unit may be implemented as an implantable or patient-external drug pump, a gas therapy device, nebulizer, and/or an activatable drug patch.

In various embodiments, the patient-internal device 6710, the patient-external device 6720, drug controller 6750, drug delivery unit 6727, and/or other devices depicted in Figure 67 may communicate through wireless links. For example, two or more devices, such as the patient-internal and patient-external devices 6710, 6720, may be coupled through a short-range radio link, such as Bluetooth or a proprietary wireless link. The wireless communications link may facilitate uni-directional or bi-directional communication between the patient-internal 6710 and patient-external 6720 medical

devices. In one implementation, data and/or control signals may be transmitted between the patient-internal 6710 and patient-external 6720 medical devices to coordinate the functions of the medical devices 6710, 6720.

In an embodiment of the invention, the patient-internal and patient-external medical devices 6710, 6720 may be used within the structure of an advanced patient management system. Advanced patient management systems involve a system of medical devices that are accessible through various communications technologies. For example, patient data may be downloaded from one or more of the medical devices periodically or on command, and stored at a patient information server. The physician and/or the patient may communicate with the medical devices and the patient information server, for example, to acquire patient data or to initiate, terminate or modify therapy.

In the implementation illustrated in Figure 67, the patient-internal device 6710 and the patient-external device 6720 may be coupled through a wireless or wired communications link to a patient information server that is part of an advanced patient management (APM) system 6730. The APM patient information server 6730 may be used to download and store data collected by the patient-internal and patient-external devices 6710, 6720.

The data stored on the APM patient information server 6730 may be accessible by the patient and the patient's physician through terminals, e.g., remote computers located in the patient's home or the physician's office. The APM patient information server 6730 may be used to communicate to one or more of the patient-internal and patient-external medical devices 6710, 6720 to effect remote control of the monitoring, diagnosis, and/or therapy functions of the medical devices 6710, 6720.

In one scenario, the patient's physician may access patient data transmitted from the medical devices 6710, 6720 to the APM patient information server 6730. After evaluation of the patient data, the patient's physician may communicate through one or more of the patient-internal or patient-external devices 6710, 6720 through the APM system 6730 to initiate, terminate, or modify the monitoring, diagnostic, and/or therapy functions of the patient-internal and/or patient-external medical systems 6710, 6720.

The patient-internal and patient-external medical devices 6710, 6720 may not communicate directly, but may communicate indirectly through the APM system 6730. In this embodiment, the APM system 6730 may operate as an intermediary between two or more of the medical devices 6710, 6720. For example, data and/or control information may be transferred from one of the medical devices 6710, 6720 to the APM system 6730.

The APM system 6730 may transfer the data and/or control information to another of the medical devices 6710, 6720.

Figures 68A—68D are block diagrams of systems that may be used for non-rhythm pulmonary disease assessment with drug therapy control in accordance with embodiments of the invention. Figure 68A illustrates an external respiratory therapy device 6810, e.g., a CPAP device, used to sense conditions associated with a non-rhythm pulmonary disease. The sensed conditions are evaluated by the external respiratory therapy device to assess a presence of the non-rhythm pulmonary disease.

The respiratory therapy device 6810 is coupled to one or more sensors or other input devices 6835 configured to sense or detect conditions indicative of physiological changes and/or symptoms associated with the non-rhythm pulmonary disease. A representative set of symptoms and/or physiological changes associated with non-rhythm pulmonary diseases may include, for example, dyspnea (e.g., non-specific dyspnea, orthopnea, exertional dyspnea, paroxysmal nocturnal dyspnea), abnormal concentrations of blood or respiratory gases (e.g., cyanosis, hypoxemia, hypercapnea, low pCO2, arterial acidosis, high alveolar--arterial pO2 differential), respiratory sounds (e.g., wheezing, crackles, rhonchi, fiction rub, attenuated breath sounds, snoring), pulmonary function dysfunction (e.g., low forced expiratory volume (FEV), forced vital capacity (FVC), FEV/FVC, low forced expiratory flow (FEF), high functional residual capacity (FRC), total lung capacity (TLC), high residual volume (RV), high lung compliance, slow exhalation, tachypnea, shallow breathing, high minute ventilation, respiratory failure, reduced diffusion capacity), other pulmonary conditions (e.g., hemoptysis, cough, pleuritic chest pain, local inflammation, excess mucous production, chest pain, respiratory infection, as indicated by a slightly elevated white blood count, pulmonary mucus, overinflated lungs, alveolar wall breakdown, mucosal pulmonary edema, ventilation-perfusion mismatch, subepithelial fibrosis (chronically), respiratory muscle fatigue, high small airway resistance, hoarseness), cardiovascular conditions (e.g., pulmonary hypertension, high pulmonary vascular resistance, tachycardia, circulatory collapse, pulsus paradoxicus, syncope, hypertension, S3 heart sounds, RV hypertrophy, systolic murmur), and general systemic conditions (e.g., fever, weight loss, weight gain, night sweats, peripheral edema, high hemoglobin, fatigue, joint pain, hypersomnolence.

The sensors and/or other input devices 6835 are coupled to signal processor circuitry 6830 which may be configured to energize the sensors, to receive and condition signals generated by the sensors, and/or to facilitate communication between the

respiratory therapy device 6810 and the sensors 6835. The signal processor circuitry 6830 may comprise, for example, driver circuitry, filters, sampling circuitry, A/D converter circuitry. The sensor/input device signals may be averaged, filtered, or otherwise processed by the signal processor circuitry 6830 prior to use by other components of the respiratory therapy device 6810.

The respiratory therapy device 6810, illustrated in Figure 68A as a positive airway pressure (xPAP) device includes a therapy control unit 6820. The therapy control unit 6820 comprises a flow generator 6821 that pulls in air through a filter. The flow generator 6821 is controlled by the pressure control circuitry 6822 to deliver an appropriate air pressure to the patient. Air flows through tubing 6823 coupled to the xPAP device 6810 and is delivered to the patient's airway through a mask 6824. In one example, the mask 6824 may be a nasal mask covering only the patient's nose. In another example, the mask 6824 covers the patient's nose and mouth. Other air delivery systems are also possible.

Continuous positive airway pressure (CPAP) devices deliver a set air pressure to the patient. The pressure level for the individual patient may be determined during a titration study, for example. Such a study may take place in a sleep lab, and involves determination by a sleep physician or other professional of the optimum airway pressure for the patient. The CPAP device pressure control is set to the determined level. When the patient uses the CPAP device, a substantially constant airway pressure level is maintained by the device. The constant air pressure acts a pneumatic splint to keep soft tissue in the patient's throat from collapsing and obstructing the airway.

Autotitration PAP devices are similar to CPAP devices, however, the pressure controller for autotitration devices automatically determines the air pressure delivered to the patient. Instead of maintaining a constant pressure, the autotitration PAP device evaluates sensor signals and the changing needs of the patient to deliver a variable positive airway pressure. Autotitration PAP and CPAP are often used to treat sleep disordered breathing, for example.

Bi-level positive airway pressure (bi-PAP) devices provide two levels of positive airway pressure. A higher pressure is maintained while the patient inhales. The device switches to a lower pressure during expiration. Bi-PAP devices are used to treat a variety of respiratory dysfunctions, including chronic obstructive pulmonary disease (COPD), respiratory insufficiency, and ALS or Lou Gehrig's disease, among others.

Some positive airway pressure devices may also be configured to provide both positive and negative pressure, such that negative pressure is selectively used (and de-

activated) when necessary, such as when treating Cheyne-Stokes breathing, for example. The term xPAP will be used herein as a generic term for any such device, including devices using forms of positive airway pressure (and negative pressure when necessary), whether continuous or otherwise.

In accordance with various embodiments of the invention, the xPAP device 6810 may include a diagnostic unit 6810. The diagnostic unit 6810 evaluates patient conditions sensed or input directly by the sensors/input devices 6835 or derived from the sensor signals to assess a presence of a non-rhythm pulmonary disease.

In some embodiments, the therapy control unit 6820 of the respiratory therapy unit 6810 includes circuitry for drug therapy control 6823. The drug therapy controller 6823 generates a control signal to initiate, terminate, or modify drug therapy based on the assessment of the non-rhythm pulmonary disease. In one embodiment, the drug therapy comprises a gas that is delivered to the patient through the xPAP tubing 6823 and mask 6824. A gas therapy delivery unit is incorporated within the xPAP device 6810. The drug therapy controller 6823 generates a signal that controls and modulates the release of a gas by the gas therapy delivery unit 6827.

The xPAP device 6810 may include a communications unit 6840 for communicating with one or more separate devices 6870, such as a device programmer, APM system, and/or other patient-external or patient-internal monitoring, diagnostic and/or therapeutic devices. Communication between cooperating devices allows the xPAP device 6810 to provide or obtain information to/from the cooperating devices or to control therapy delivered by the cooperating devices, for example.

In one implementation, illustrated in Figure 68B, one or both of the diagnostics unit and the drug therapy controller may be positioned remotely with respect to the patient-external respiratory therapy device 6810. The xPAP device 6810 may include a monitoring unit 6850 including a memory for storing data related to the non-rhythm pulmonary disease or other data. In one scenario, monitoring unit 6850 may sense the one or more patient conditions and may store data related to the sensed conditions. The monitoring unit may collect and store data hourly, nightly, weekly, randomly or according to a time schedule that corresponds to the patient's usage times of the respiratory therapy device 6810. Typically an xPAP device is used nightly for treatment of sleep apnea and/or other breathing rhythm disorders. The xPAP device 6810 may collect data from the sensors/input devices 6835 during one or more periods of time that the device is used. The presence of the non-rhythm pulmonary disease may be assessed based on the collected

data. Assessment of the non-rhythm pulmonary disease may involve assessment of the onset, progression, regression and/or offset of the disease.

In the implementation illustrated in Figure 68B, the respiratory therapy device 6810 may transmit information about conditions sensed by the respiratory therapy device 6810 to the diagnosis unit 6860 of a remotely located device 6870. The diagnosis unit 6860 assesses the non-rhythm pulmonary disease presence based on the transmitted information. The drug therapy controller develops a control signal for controlling drug therapy delivery. The remotely located device 6870 transmits the control signal to a drug delivery unit. In one embodiment, the drug delivery unit may be activated to release a gas, e.g., albuterol, into the airflow of the respiratory therapy device. In other embodiments, other types of drug delivery methodologies, such as a drug pump, an electrically activated drug patch, and/or other types of drug delivery devices may be employed.

The remote device 6870 may comprise a patient-external or patient-internal medical device. The remote device 6870 may be configured, for example, as a cardiac diagnostic and/or therapeutic device. In one configuration, for example, the remote device 6870 may comprise a cardiac rhythm management system, such as a pacemaker, defibrillator, or cardiac resynchronizer.

In some embodiments, as illustrated in Figures 68C and 68D, an external respiratory therapy device may be used in combination with an implantable device, such as an implantable cardiac rhythm management device, to detect and/or monitor a presence of a non-rhythm pulmonary disease. The system illustrated in Figure 68C includes an external respiratory therapy device 6810 and a cardiac device 6892, such as an implantable pacemaker, defibrillator, cardioverter, cardiac resynchronizer or cardiac monitor. Both the respiratory therapy device 6810 and the cardiac device 6892 are equipped with sensors/input devices 6835, 6836 for sensing conditions associated with symptoms of one or more non-rhythm pulmonary diseases.

The respiratory therapy device 6810 may transmit its sensed condition information to the cardiac device 6892, e.g., over a wireless communications link. The cardiac device 6892 includes a diagnostic unit 6860 configured to assess a presence of one or more non-rhythm pulmonary diseases by evaluating the conditions sensed by the respiratory device and/or by evaluating additional conditions sensed by the cardiac device.

The diagnostic unit 6860 may assess the one or more non-rhythm pulmonary diseases, for example, by comparing sensed conditions to corresponding sets of criteria indicative of the non-rhythm pulmonary diseases. In this system depicted in Figure 68C,

the cardiac device 6892 includes a drug therapy controller 6893 that develops control signals to control a drug therapy delivered to the patient. The cardiac device 6892 transmits signals to the drug delivery device 6895 to initiate, modify or terminate drug therapy delivered to the patient based on the assessment of the pulmonary disease.

In an alternate implementation one or both of the diagnostics processor 6860 and the drug therapy controller 6893 may be disposed in the respiratory therapy device housing.

The block diagram of Figure 68D illustrates another arrangement of a pulmonary disease assessment and drug therapy delivery system. In this example, the system includes a respiratory therapy device 6810 and a cardiac device 6892. The respiratory therapy device 6810 and the cardiac device 6892 communicate with a remote diagnostic unit 6860, such as may be incorporated in an APM system. The respiratory therapy device 6810 and the cardiac device 6892 are each equipped with sensors/input devices 6835, 6836 for sensing conditions associated with one or more non-rhythm pulmonary diseases. The respiratory therapy device 6810 and the cardiac device 6892 may transmit sensed condition information to the diagnostic unit 6860 through a wireless or wired communication links. The pulmonary disease diagnostic unit 6860 is configured to use the information transmitted by the respiration therapy device 6810 and the cardiac device 6892 to assess the presence of one or more non-rhythm pulmonary diseases.

A drug therapy controller 6893 uses the assessment of the non-rhythm pulmonary disease to develop signals from controlling the drug therapy delivered to the patient. In one configuration, the diagnostic unit 6860 and the drug therapy controller 6893 may be configured as components of an APM system 6830. A control signal developed by the drug therapy controller may be used to activate, modify, terminate or otherwise control therapy delivered by a drug therapy device 6895.

Assessment of conditions indicative of non-rhythm pulmonary diseases/disorders may include assessing the patient's pulmonary function as previously described. The charts provided in Figures 62A—62G illustrate conditions and sensors that may be used to determine physiological changes associated with various non-rhythm pulmonary diseases and disorders. The charts depicted in Figures 62A—62G illustrate relationships between various physiological changes and/or disease symptoms associated with non-rhythm pulmonary diseases. Figure 62A lists representative sets of non-rhythm pulmonary diseases that may be assessed in accordance with embodiments of the invention. The representative set of non-rhythm pulmonary diseases that may be assessed includes, for example, obstructive pulmonary diseases (e.g., chronic bronchitis, emphysema, asthma),

restrictive pulmonary diseases (e.g., sarcoidosis, pulmonary fibrosis, pneumoconiosis), infections pulmonary diseases (e.g., bronchitis, pneumonia, bronchiolitis, tuberculosis, and bronchiectasis), pulmonary vasculature diseases (e.g., pulmonary hypertension, pulmonary edema, pulmonary embolism, atalectasis), and diseases of the pleural cavity (e.g., pleural effusion, pneumothorax, and hemothorax).

The non-rhythm pulmonary diseases listed in Figure 62A are cross-referenced with the physiological changes and/or symptoms associated with the non-rhythm pulmonary disease. The physiological changes and/or symptoms are cross referenced with conditions indicative of the physiological changes and/or symptoms. Sensors used to sense the conditions indicative of the physiological changes or symptoms are provided in Figure 62A. Sensors of the respiratory therapy device may include, for example, ventilation gas, ventilation flow and/or ventilation pressure sensors, or other sensors for example.

Figure 69 is a flowchart illustrating various optional methods for controlling drug therapy in accordance with embodiments of the invention. In some embodiments, the system generates a control system for controlling the drug therapy. In other embodiments, the system includes a drug delivery unit that is controlled by the control signal.

One method involves using 6902 an external respiratory therapy device to sense conditions associated with the non-rhythm related pulmonary disease. A presence of the non-rhythm pulmonary disease is assessed 6904 based on the sensed conditions. A control signal for controlling drug therapy used to treat the detected pulmonary disease is generated 6905.

Optionally, the external respiratory therapy device may sense 6902 one set of conditions and an implantable device may be used to sense 6903 another set of conditions. The disease presence may be assessed based on the conditions sensed by the external respiratory therapy device and the conditions sensed by the implantable device. In one implementation, the external respiratory therapy device and the implantable device may be used cooperatively to sense conditions affecting the patient and to detect and/or assess a disease presence.

In some embodiments the system includes a drug delivery device. The drug delivery device delivers a drug therapy that is controlled by the control signal. The drug delivery device may be a component of the external respiratory therapy device, the implanted device, or a device separate from the external respiratory therapy device and the implanted device. The drug delivery device may comprise a drug pump, an activatable drug patch, and/or a gas therapy delivery device, for example.

In one scenario, the respiratory device is a CPAP device that has drug delivery functionality. Upon detection and/or assessment of a non-rhythm pulmonary disease, such as asthma, the CPAP device can activate a drug delivery unit to deliver a mist, e.g., an albuterol mist, into the air stream supplied by the CPAP device.

In another scenario, drug therapy may be accomplished using an implantable drug delivery device such as an implantable drug pump. In one implementation, the implantable drug delivery device is configured as a component of an implantable cardiac rhythm management (CRM) system. In another implementation, the implantable drug delivery device is separate from the CRM or other implantable device used for sensing.

Assessing the presence of pulmonary disease may be enhanced by the performance of pulmonary function tests. Pulmonary function testing evaluates lung mechanics, gas exchange, pulmonary blood flow, and blood gases and pH. These tests may be used to evaluate patients in the diagnosis of pulmonary disease and assessment of disease development. According to various aspects of the invention, pulmonary function testing may be implemented using the sensors of the respiratory therapy device, and/or using the sensors of the implantable device.

Various parameters related to pulmonary performance, some of which may be measured using sensors of a respiratory therapy device and/or sensors of an implantable device include, for example, tidal volume, minute ventilation, inspiratory reserve volume, forced expiratory volume, residual volume, and forced vital capacity, among other parameters. According to one embodiment, testing of some pulmonary function parameters may be performed using the ventilation pressure and ventilation flow sensors of a CPAP device or other patient-external respiratory therapy device. The pulmonary function testing may be used, for example, to assess a presence of restrictive and/or obstructive pulmonary disorders.

Pulmonary performance may be evaluated based on data acquired by the respiratory therapy device during normal and forced inspiration and expiration. From such data, pulmonary parameters including tidal volume, minute ventilation, forced expiratory volume, forced vital capacity, among other parameters may be determined.

Because the results of pulmonary function tests vary with size and age, the normal values are calculated using prediction equations or nomograms, which give the normal value for a specific age, height, and sex. The prediction equations are derived using linear regression on the data from a population of normal subjects. The observed values are

usually reported as a percentage of the predicted value. Abnormal test results may show either an obstructive or restrictive pattern. Sometimes, both patterns are present.

Figure 70 is a flowchart illustrating a method in accordance with embodiments of the invention. Criteria sets for assessment of the non-rhythm pulmonary diseases are established 7010. A respiratory therapy device such as a CPAP device is used to sense conditions modulated by disease symptoms. The sensor information may be collected 7012 periodically, e.g., nightly, and stored for evaluation. If a presence of the disease was not previously determined 7015, then the levels of the sensed conditions are compared 7020 to a set of criteria associated with the disease. If levels of the conditions are consistent 7025 with the threshold criteria levels, then a presence of the disease is determined 7030. Drug therapy is initiated 7035 to treat the respiratory disease.

If levels of the conditions are not consistent 7025 with the threshold criteria levels, then the system continues to sense conditions modulated by disease symptoms and collect 7012 and store data based on the sensed conditions.

If the presence of the disease was previously determined 7015, then the progression of the disease may be monitored 7040 based on the conditions and/or criteria used to determine a presence of the disease, or using other conditions and/or criteria. If the disease presence is still detected 7045 based on the conditions and criteria used for monitoring, then therapy is maintained or modified 7050 based on the disease progression. Disease progression may be determined, for example, by trending one or more conditions used for monitoring the disease presence over a period of time. Modifications to the drug therapy may be made based on the condition trends. If the disease presence is no longer detected 7045, then the drug therapy may be terminated.

Therapy Control Based on Cardiopulmonary Status

Aspects of the invention that include therapy control based on cardiopulmonary status are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two

or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving therapy control based on cardiopulmonary status are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve an individual system 137 (Figure 1B) for controlling patient therapy based on cardiopulmonary status. The patient therapy control system 137 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Various embodiments of present invention involve methods and systems for controlling therapy based on the cardiopulmonary status of the patient. One embodiment of the invention involves a method for controlling a therapy delivered to a patient based on cardiopulmonary status. One or more physiological conditions are sensed using an external respiratory therapy device. The patient's cardiopulmonary status is assessed based on the sensed physiological conditions. Therapy delivered to the patient is controlled based on the patient's cardiopulmonary status. At least one of assessing the patient's cardiopulmonary status and controlling the therapy is performed at least in part implantably.

According to various aspects of the invention, the physiological conditions are sensed using the sensors of a disordered breathing therapy device. The sensed physiological conditions may include, for example, sensing respiratory pressure, flow, and/or exhaled gas concentration.

In accordance with another aspect of the invention, the sensor system of an additional medical device, different from the respiratory therapy device may be used to sense additional physiological conditions used to assess cardiopulmonary status. In one implementation, the additional medical device comprises an implantable cardiac therapy device.

In accordance with another embodiment of the invention, a medical therapy control system controls therapy based on a patient's cardiopulmonary status. The control system includes an external respiratory device including a sensor system configured to sense one or more physiological conditions. A cardiopulmonary status processor is coupled to the sensor system. The cardiopulmonary status processor is configured to determine a cardiopulmonary status of a patient based on the sensed physiological conditions. A therapy controller is configured to control a therapy delivered to the patient based on the patient's cardiopulmonary status. At least one of the cardiopulmonary status processor and the therapy controller include an implantable component.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes therapy control system 137. The coordinated system includes, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy includes a system 137 configured control patient therapy based on cardiopulmonary status The therapy control system 137 includes an external respiratory device having a sensor system configured to sense one or more physiological conditions. A cardiopulmonary status processor is coupled to the sensor system and is configured to determine a patient's cardiopulmonary status using sensed physiological conditions. The system further includes a therapy controller coupled to the cardiopulmonary status processor that is configured to control patient therapy using the patient's cardiopulmonary status. At least one of the cardiopulmonary status processor and the therapy controller are at least in part implantable

The implantable and respiratory therapy devices 181, 184 may operate cooperatively based therapies delivered according to a patient's cardiopulmonary status.

For example, control of patient therapy based on cardiopulmonary status may allow the implantable and respiratory therapy devices 181, 184 to operate cooperatively to provide external and implantable sensing capabilities and external and implantable therapy controlling capabilities.

Figures 71A and 71Bare block diagrams of medical systems that may be used to implement therapy control based on cardiopulmonary status assessment in accordance with embodiments of the invention. In these embodiments, the system utilizes a sensor system 7110 of a respiratory therapy device 7120 to sense one or more physiological conditions. For example, the sensor system 7110 may sense conditions associated with patient respiration, including breathing cycles, respiratory pressure, concentration of respiratory gases, respiratory airflow, and/or other physiological conditions. The respiratory therapy device 7110 includes a respiratory therapy delivery system 7115, such as a positive airway pressure delivery system in the case of a CPAP device, for example.

The system includes a cardiopulmonary status processor 7130 coupled to the respiratory therapy sensor system 7110. The cardiopulmonary status processor assesses the patient's cardiopulmonary status. Assessment of cardiopulmonary status may include evaluating the patient's pulmonary function as previously described. In some implementations, the cardiopulmonary status processor may work in cooperation with the respiratory therapy device, and/or other therapy or diagnostic devices to perform the pulmonary function testing required or desired. Cardiopulmonary status evaluation may comprise determining and/or assessing a presence of cardiac and/or pulmonary disease.

As illustrated in Figure 71A, the system include a therapy controller 7140, that develops control signals that may be used to control one or more therapy devices 7160.

Figure 71B illustrates another embodiment of the invention. The embodiment illustrated in Figure 71B includes a cardiac therapy device 7150 including a cardiac therapy sensor system 7154 that is used in combination with the respiratory therapy sensor system 7110 to assess the patient's cardiopulmonary status. Signals from the cardiac therapy sensor system 7154 and the respiratory therapy system 7115 are utilized by the cardiopulmonary status processor 7130 to determine the cardiopulmonary status of the patient. Assessment of the patient's cardiopulmonary status may involve sensing a presence of a cardiac and/or pulmonary disease. The sensor systems 7110, 7154, of one or both of the respiratory therapy device 7120, the cardiac therapy device 7154, and/or other sensor systems (not shown), may be used for cardiopulmonary status assessment.

The sensor systems 7110, 7154, may be used in connection with performing pulmonary function testing as described above. Cardiopulmonary status assessment may comprise determining and/or assessing a presence of cardiac and/or pulmonary disease. According to one aspect of the invention, the cardiopulmonary status processor may assess a presence of a cardiac disease/disorder. The cardiac disease/disorder assessment may involve, for example, cardiac rhythm related disorders, arterial diseases, heart failure, and/or hypertension.

The cardiopulmonary status processor may be used to detect a presence of one or more rhythm-related and/or non-rhythm related pulmonary diseases/disorders. Rhythm-related breathing disorders involve disruption of the normal respiratory cycle. Although disordered breathing often occurs during sleep, the condition may also occur while the patient is awake. Disordered breathing may be detected by sensing and analyzing various conditions associated with disordered breathing. Table 1 above provides examples of how a representative subset of physiological and non-physiological, contextual conditions may be used in connection with disordered breathing detection.

Detection of apnea and severe apnea may utilize information related to the patient's sleep state. Because disordered breathing occurs more frequently during sleep, assessment of rhythm-related breathing disorders may involve determination of whether the patient is asleep. Other types of cardiopulmonary disorders may be modified by the patient's sleep state. The cardiopulmonary status processor may use sleep state information in connection with the assessment of the patient's cardiopulmonary status.

The cardiopulmonary status processor 7130 develops signals related to the patient's cardiopulmonary status. These signals are transmitted to a therapy controller 7140 that utilizes signals to control therapy delivered to the patient. The controlled therapy may comprise a respiratory therapy delivered to the patient by a respiratory therapy delivery system 7115, a cardiac therapy delivered to the patient by a cardiac therapy delivery system 7152, or a therapy delivered by another therapy system 7160, e.g., internal or external nerve or muscle stimulator and/or internal or external drug pump.

Figure 72 illustrates a block diagram of a therapy system including a respiratory therapy device 7210, e.g., CPAP device or other respiratory therapy device, which may be used to provide external respiratory therapy for disordered breathing. The respiratory therapy device 7210 includes one or more sensors 7235, e.g., flow, pressure and/or exhaled gas concentration sensors used to sense respiratory conditions and/or other conditions useful in the assessment of the patient's cardiopulmonary status. Signals generated by the

sensors 7235 are processed by signal processing circuitry 7230 within the respiratory therapy device 7210.

The respiratory therapy device 7210 may include a device that provides positive and negative airflow pressure to the patient. The breathing therapy delivery unit 7220 includes a flow generator 7221 that pulls in air through a filter. The flow generator 7221 is controlled by the pressure control circuitry 7222 to deliver an appropriate air pressure to the patient. Air flows through tubing 7223 and is delivered to the patient's airway through a mask 7224. In one example, the mask 7224 may be a nasal mask covering only the patient's nose. In another example, the mask 7224 covers the patient's nose and mouth.

The respiratory therapy device 7210 may include a communications unit 7240 for communicating with a compatible communications unit 7241 of one or more separate devices, such as an implantable device 7270. In one example, the respiratory therapy device 7210 sends information about sensed respiratory flow, pressure, and expired gas to the implantable device. The respiratory therapy device receives therapy control information controlling the therapy delivered by the respiratory therapy device 7210 from the implantable device 7270.

The implantable device 7270, which may comprise an implantable cardiac device, includes a cardiopulmonary status processor 7250 used to assess the cardiopulmonary status of the patient. The cardiopulmonary status processor 7250 uses the sensor information transferred to the implantable device 7270 from the respiratory therapy device 7210 to determine the status of the patient's cardiopulmonary system. Information from the respiratory therapy device sensors 7235 may be transferred from the respiratory therapy device 7210 to the implantable device 7270 through communications units 7240, 7241 of the respective devices 7210, 7270. In some embodiments, the cardiopulmonary assessment processor 7250 may use information acquired by the respiratory therapy device sensors 7235 in addition to other information received from other devices and/or sensors in performing the cardiopulmonary status assessment.

The implantable device 7270 may additionally or alternatively include a therapy controller 7260 that develops therapy control signals based on the patient's assessed cardiopulmonary status. Therapy control signals developed by the therapy controller 7260 may be transmitted to the respiratory therapy device 7210 through the communications units 7241, 7240. The therapy control signals are used to control the therapy delivered by the respiratory therapy device. For example, if the cardiopulmonary assessment processor 7250 detects a presence of a cardiopulmonary disease, the delivery of respiratory therapy to

the patient may be controlled to treat the detected cardiopulmonary disease presence. In other examples, delivery of the respiratory therapy may be controlled to improve patient comfort based on the assessed cardiopulmonary status, or to meet other therapeutic goals.

The therapy controller 7260 may control the respiratory therapy by initiating, terminating or modifying the respiratory therapy. Controlling the respiratory therapy may involve initiating, terminating or modifying one or more therapy parameters. For example, the therapy controller 7260 may be used to modify gas pressure or gas flow delivered by the respiratory therapy device 7210. The therapy controller 7260 may initiate or terminate a gas flow or modify a gas concentration of the respiratory therapy, for example.

Additionally or alternatively, the therapy controller 7260 may develop control signals used to control therapy delivered by the implantable device 7270. The implantable device therapy may be controlled to treat a detected cardiopulmonary disease or disorder, to improve patient comfort, or for other purposes. In one embodiment, the implantable device comprises a cardiac therapy device that delivers cardiac electrical stimulation therapy to the patient. The therapy controller initiate or terminate the cardiac electrical stimulation therapy and/or control various parameters of the cardiac electrical stimulation, e.g., stimulation energy, stimulation timing. The cardiac electrical stimulation therapy may involve non-excitatory electrical stimulation involving sub-capture threshold stimulation or stimulation during a refractory period, for example. The therapy controller may modify one or more parameters of the non-excitatory electrical stimulation therapy.

The cardiac electrical stimulation may involve cardiac pacing therapy. The therapy controller may initiate or terminate the pacing therapy. The therapy controller may modify the cardiac pacing therapy by alter a pacing rate (e.g., change from a normal sleep rate to an overdrive pacing rate), pacing timing (e.g., modify the AV delay or other pacing timing parameter), pacing mode, (e.g., switch from DDD to VVI pacing or from a tracking mode to a non-tracking pacing mode) and/or pacing type (e.g., switch from dual chamber to biventricular pacing or from single chamber to dual chamber).

Embodiments of the invention involve methods of controlling a therapy delivered to the patient, as illustrated in the flowchart of Figure 73. One or more physiological conditions are sensed 7302 using the sensing system of an external respiratory therapy device. In various implementations, the external respiratory therapy device may comprise, for example, a gas therapy device, nebulizer, ventilator, positive airway pressure device, or other type of respiration therapy device. The patient's cardiopulmonary status is assessed 7304 based on the sensed physiological conditions. Therapy delivered to the patient is

controlled 7306 based on the patient's cardiopulmonary status. The therapy may be used to treat breathing rhythm disorders, non-rhythm related pulmonary diseases/disorders, cardiac disorders, and/or other diseases or disorders affecting the patient.

In one embodiment, an implantable device may be used to sense 7303 additional physiological conditions. The patient's cardiopulmonary status is assessed 7304 based on the physiological conditions sensed by the external respiratory device and the additional physiological conditions sensed by the implantable device. At least one of assessing the patient's cardiopulmonary status and controlling the therapy is performed at least in part implantably.

In one implementation, the presence of a cardiac and/or pulmonary disease or disorder is detected and therapy to treat the disease or disorder is delivered to the patient. The therapy may be modified to improve therapy effectiveness based on the assessment of the cardiac and/or pulmonary disease or disorder. In another embodiment of the invention, the patient's cardiopulmonary status is assessed and the therapy delivered to the patient is modified to enhance patient comfort or to achieve another result.

For example, the patient's cardiopulmonary status may be assessed based on sensed physiological conditions indicative of symptoms or physiological changes associated with a particular disease or disorder. A respiratory therapy device used to sense the physiological conditions may comprise, for example, a gas therapy device, nebulizer, ventilator, positive airway pressure device, or other type of respiration therapy device. In a preferred embodiment, the respiratory therapy device comprises a positive airway pressure device. Continuous positive airway pressure (CPAP) devices are frequently used to treat sleep apnea and/or other breathing rhythm disorders. A CPAP device may be used regularly during a patient's sleep time to prevent or treat sleep disordered breathing events. Use of a CPAP device for treatment of breathing rhythm disorders facilitates detection of rhythm-related and non-rhythm related pulmonary diseases. The CPAP device provides sensors available on a periodic basis, e.g., nightly, that may be used to sense conditions indicative of cardiopulmonary status.

In another implementation, assessment of the cardiopulmonary status of the patient is based on one or more physiological conditions sensed using a patient-external respiratory therapy device and on one or more additional physiological conditions sensed using a cardiac device. The cardiac device may comprise, for example, an implantable cardiac therapy device, such as a pacemaker, defibrillator, cardioverter, cardiac monitor, and/or cardiac resynchronizer.

In yet another implementation, assessment of the cardiopulmonary status of the patient is based on one or more physiological conditions sensed using a patient-external respiratory therapy device and one or more additional conditions sensed or detected using an additional patient-external device. The patient-external device may comprise, for example, a patient operated input device, a patient information database, or a network-connected server, for example.

According to one aspect of the invention, pulmonary function testing may be employed to detect physiological changes associated with the presence of cardiac and/or pulmonary disease. Pulmonary function tests may be used to evaluate lung mechanics, gas exchange, pulmonary blood flow, and blood gases and pH. They are used to evaluate patients in the diagnosis of pulmonary disease, assessment of disease development, or evaluation of the risk of pulmonary complications.

Various parameters related to pulmonary performance, some of which may be measured using sensors of a respiratory therapy device include, for example, tidal volume, minute ventilation, inspiratory reserve volume, forced expiratory volume, residual volume, and forced vital capacity, among other parameters. According to one embodiment, testing of some pulmonary function parameters may be performed using the ventilation pressure and ventilation flow sensors of a CPAP device or other patient-external respiratory therapy device. The pulmonary function testing may be used, for example, to assess a presence of restrictive and/or obstructive pulmonary disorders.

In some embodiments, pulmonary function testing may be performed using a cardiac rhythm management system (CRM) or other implantable device. In one implementation, the pulmonary function testing is performed using an implanted transthoracic impedance sensor. Transthoracic impedance sensing has been used in connection with rate-adaptive pacemakers to measure respiration cycles. An impedance sensor may be used to measure the variation in transthoracic impedance, which increases during the inspiratory and decreases during the expiratory phase of a respiration cycle. The sensor injects a sub-threshold stimulating current between the pacemaker case and an electrode on an intracardiac or subcutaneous lead, and measures the voltage across the case and another electrode on the same or another lead. Clinical investigations have shown that the impedance sensor can measure respiratory rate tidal volume, and minute ventilation accurately.

In accordance with various embodiments of the invention, a properly calibrated impedance sensor, implemented in cooperation with a pacemaker or other implantable

device, may be used to measure FVC and FEV during forced expiration. From these two parameters, FEV/FVC can be derived to differentiate obstructive versus restrictive respiratory patterns as shown in the Figures 1C and 1D, respectively.

In addition, the forced expiratory flow ($FEF_{25-75\%}$) may be measured. The middle half by volume of the total expiration is marked, and its duration is measured. The $FEF_{25-75\%}$ is the volume in liters divided by the time in seconds. In patients with obstructive diseases, the $FEF_{25-75\%}$ is generally greater than their expected values.

The implantable device may be used to compare measured FVC, FEV and $FEF_{25-75\%}$ values derived from the implanted impedance sensor with predicted values from normal subjects in accordance with various embodiments. The comparison provides diagnostic information of lung mechanics.

Data acquired using the above-described techniques may be transmitted from the implantable device to an advanced patient management system or other remote device. Assessment of the patient's cardiopulmonary status or control of the therapy may be performed by the advanced patient management system.

Assessment of cardiopulmonary status may include assessing the patient's pulmonary function as previously described. In some implementations, the cardiopulmonary status processor may use sensed conditions acquired by the respiratory therapy device, and/or other therapy or diagnostic devices to assess patient's cardiopulmonary status. Cardiopulmonary status assessment may comprise evaluating a presence of cardiac and/or pulmonary disease. The charts provided in Figures 6A—6N illustrate conditions and sensors that may be used to determine physiological changes associated with various cardiac and/or pulmonary diseases and disorders.

The left section 6202 of Figure 62A illustrates various conditions that may be sensed using sensors of a respiratory therapy device (CPAP), a cardiac device (CRM), or an external non-CPAP, non-CRM device. The top section 6201 lists various conditions that may be sensed and provides information about sensors used to sense the conditions. The center section 6204 of Figure 62A provides physiological changes and/or symptoms that may be evaluated using the conditions listed in the left section 6202. The right section 603 of Figure 6A provides pulmonary diseases/disorders. The presence of the pulmonary diseases/disorders of the right section 6203 may be assessed based on the physiological changes and/or symptoms of the center section 6204.

For legibility, the left and right sections 6202, 6203 of Figure 62A are divided into six portions, Figures 62B—62G. Figure 62B represents the upper left portion 6210 of the

left section 6202 of Figure 62A. Figure 62C represents the upper right portion 6212 of the left section 6222 of Figure 62A. Figure 62D represents the lower left portion 6214 of the left section 6202 of Figure 62A. Figure 62E represents the lower right portion 6216 of the left section 6202 of Figure 62A. Figure 62F represents the upper portion 6220 of the right section 6204 of Figure 62A. Figure 62G represents the lower portion 6222 of the right section 6204 of Figure 62A. Relevant portions of the center section 6204 and the top section 6201 of Figure 62A appear in each of the Figures 62B—62G for convenience.

The charts provided in Figures 62H—62N illustrate conditions and sensors that may be used to determine physiological changes associated with various cardiac diseases and disorders. The left section 6232 of Figure 62H illustrates various conditions that may be sensed using sensors of a respiratory therapy device (CPAP), a cardiac device (CRM), or an external non-CPAP, non-CRM device. The center section 6234 of Figure 6H provides physiological changes and/or symptoms that may be evaluated using the conditions listed in the left section 6232. The right section 6236 of Figure 62H lists cardiac diseases/disorders. The presence of the cardiac diseases/disorders of the right section 6236 may be assessed based on the physiological changes and/or symptoms of the center section 6234.

For legibility, the chart of Figure 6H is divided into six portions, Figures 62I—62N. Figure 62I represents the upper left portion 6240 of the left section 6232 of Figure 62H. Figure 62J represents the upper right portion 6242 of the left section 6232 of Figure 62H. Figure 62K represents the lower left portion 6244 of the left section 6232 of Figure 62H. Figure 62L represents the lower right portion 6246 of the left section 6232 of Figure 62H. Figure 62M represents the upper portion 6250 of the right section 6236 of Figure 62H. Figure 62N represents the lower portion 6252 of the right section 6236 of Figure 62H. Relevant portions of the center section 6204 and the top section 6201 of Figure 62H appear in each of the Figures 62I—62N for convenience.

An example of how Figures 62A—62N may be used follows. Referring to Figures 62 and 62G, the restrictive pulmonary disorder pneumoconiosis produces the physiological changes non-specific dyspnea (Figure 62F) and cough (Figure 62G). Non-specific dyspnea (Figure 62F) and cough (Figure 62G) are indicated by X or D marks in the column denoted pneumoconiosis in Figures 6F and 6G, respectively. An "X" mark indicates that the symptom or physiological change may be derived from the sensed condition. A "D" mark indicates that the symptom or physiological change may be directly determined from the sensed condition. Non-specific dyspnea may be detected based on one or more of the

conditions listed in the row for non-specific dyspnea illustrated in Figures 62B and 62C. The conditions include duration of symptoms, abnormal breathing/coughing, blood pO2, inspiratory flow, expiratory flow, exhaled % CO2 and exhaled % O2, illustrated in Figure 62C. The conditions also include arterial/venous pO2, blood pCO2, blood pO2, exhalation time, inspiration time, minute ventilation, tidal volume, respiration rate, and/or respiration sounds illustrated in Figure 62B.

Figure 74 is a flowchart illustrating a method in accordance with embodiments of the invention. One or more threshold criteria sets for assessment of cardiopulmonary status based on the disease/disorder presence are established 7410. A respiratory therapy device such as a CPAP device may be used to sense 7412 conditions modulated by disease symptoms. The sensor information may be collected periodically, e.g., nightly, and stored for evaluation. If a presence of the disease has not been previously determined 7415, then the levels of the sensed conditions are compared 7420 to a set of criteria associated with the disease. If levels of the conditions are consistent 7425 with the threshold criteria levels, then a presence of the disease is determined 7430. Therapy may be modified based on the presence of the disease/disorder. In one implementation, therapy may be initiated 7435 to treat the disease.

If levels of the conditions are not consistent 7425 with the threshold criteria levels, then the system continues to sense conditions modulated by disease symptoms and collect 7412 data based on the sensed conditions.

If the presence of the disease was previously determined 7415, then the progression of the disease may be monitored 7440 based on the conditions and/or criteria used to determine a presence of the disease, or using other conditions and/or criteria. If the disease presence is still detected 7445 based on the conditions and criteria used for monitoring, then therapy may be maintained or modified 7450 based on the disease progression. Disease progression may be determined, for example, by trending one or more conditions used for monitoring the disease presence over a period of time. Modifications to the therapy may be made based on the condition trends.

Methods and Systems for Control of Gas Therapy

Aspects of the invention that include control of gas therapy are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or

therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include control of gas therapy are directed methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve adapting gas therapy based on blood gas concentration. Methods may involve sensing concentration of a blood gas and adapting a gas therapy for a patient. Methods may further involve delivering the adapted gas therapy to the patient. At least one of sensing the blood gas concentration and adapting the gas therapy is performed at least in part implantably.

Other embodiments of methods involve both sensing the blood gas concentration and adapting the therapy being performed at least in part implantably. Adapting a therapy may involve comparing the sensed blood gas concentration to a threshold and modifying the therapy if the blood gas concentration is beyond the threshold. Modifying the therapy may involve increasing or decreasing a gas pressure of a positive airway pressure device. Adapting a therapy may involve comparing the sensed blood gas concentration to a predetermined range and modifying the therapy if the blood gas concentration is beyond the predetermined range.

Some embodiments may involve adapting oxygen therapy delivered to a patient, wherein adapting the therapy involves comparing a blood oxygen level to a predetermined range and modifying the therapy if the blood oxygen level is beyond a predetermined range, such as by increasing oxygen gas pressure in response to the blood oxygen level falling below a threshold. Alternatively, or additionally, adding or increasing a vasodilator or a bronchodilator in response to the blood oxygen level falling below a threshold may also be performed.

In other embodiments, a therapy system includes a sensor unit configured to sense blood gas concentration. A therapy controller is coupled to the sensor unit and is configured to adapt a gas therapy. The system further includes a gas therapy delivery unit coupled to the therapy controller and configured to deliver the adapted gas therapy to the patient. At least one of the sensor unit and the controller includes an implantable component.

Other embodiments include each of a sensor unit and a therapy controller having an implantable component. The sensor unit may be a component of an implantable cardiac therapy device or a component of a patient-external respiratory therapy device. The sensor unit may include a blood oxygen sensor and/or carbon dioxide sensor, and may be coupled to an implantable cardiac therapy device, directly or wirelessly. In further embodiments, the sensor unit is coupled to the controller through the gas therapy delivery unit, which may deliver a vasodilating or a bronchodilator agent.

According to additional embodiments, a sensor may be configured to detect disordered breathing, and, in response to detecting disordered breathing, gas therapy may be modified (e.g., initiated, modified, terminated) to suppress the disordered breathing. In addition, the type of disordered breathing may be discerned, such as discerning central apnea from obstructive apnea. If, for example, central apnea is detected, small amounts of carbon dioxide may be applied to the patient's air supply (e.g., via a positive airway pressure device) to mitigate the carbon dioxide instability that is leading to central apnea.

Embodiments of the invention may involve an individual system 135 (Figure 1B) for sensing concentration of a blood gas and adapting a gas therapy for a patient. Sensing concentration of a blood gas and adapting a gas therapy for a patient may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D. For example, embodiments of the invention may involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes sensing 135 concentration of a blood gas and adapting a gas therapy.

The coordinated system may include, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

Various embodiments of the present invention are implemented using medical systems employing one or a number of patient-external and/or patient-internal medical devices. Medical devices may communicate or otherwise operate in concert or in a stand-alone manner to provide more comprehensive patient monitoring, diagnosis, and therapy. For example, a system of the present invention may control gas therapy using one or more patient-internal sensors, one or more patient-external sensors, and/or an implanted device.

Gas therapy devices may be used to provide a variety of respiration therapies, including, for example, providing vasodilating or bronchodilator agents, continuous positive airway pressure (CPAP), bi-level positive airway pressure (bi-level PAP), proportional positive airway pressure (PPAP), auto-titrating positive airway pressure, ventilation, oxygen, carbon dioxide or other gas therapies. All types of gas therapy and positive airway pressure devices are referred to generically herein as xTherapy devices.

The following discussion, with reference to Figures 75 through 78, describes embodiments of the invention involving modulation of external gas therapy. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

In accordance with embodiments of the invention, a system controls gas therapy, such as oxygen or carbon dioxide therapy, using one or more patient-internal sensors, one or more patient-external sensors and/or an implanted device. The gas therapy may be delivered to the patient, and measurement of exhaled gas concentration may be implemented using a respiratory mask, such as a CPAP mask, for example. The one or more sensors may include, for example, a gas saturation sensor or other implanted sensor for determining the patient's blood gas saturation. Other sensors, such as a disordered breathing detector (internal or external) may be used to determine the presence of disordered breathing, and then deliver gas therapy as needed to resolve or treat the

disordered breathing. The patient's blood gas saturation may be determined externally, e.g., using pulse oximetry techniques, and/or external sensors positioned on a respiratory mask or nasal cannulae.

One illustrative approach involves sensing the patient's blood gas saturation and controlling the delivery of gas by a patient-external therapy device based on the blood gas saturation. At least one of sensing the blood gas saturation and controlling the delivery of gas is performed at least in part implantably. Another approach involves sensing the body's need for gas, as manifested, for example, as apnea, hypopnea, hypoxia, hypocapnia, or myocardial ischemia, and then providing appropriate gas therapy to remedy the physiological need. Sensing of the body's need for gas may be effected either internally or externally of the patient.

Figure 75 illustrates a block diagram of a system 7550 for providing coordinated cardiac and respiratory therapy in accordance with embodiments of the invention. The system utilizes an xTherapy device 7582 to provide respiratory therapy to the patient. A controlled flow of air, oxygen, carbon dioxide or other gas is developed by the xTherapy device 7582 and delivered to the patient's airway through tubing and a mask 7584, such as a nasal mask.

The system 7550 provides electrical stimulation therapy using an implantable cardiac rhythm management (CRM) device 7581. The CRM device 7581 provides electrical stimulation to the heart 7585 through an implanted lead system 7586 with electrodes 7587 positioned in, on, or about the heart 7585 to electrically couple the heart 7585 to the CRM device 7581. The CRM device 7581 may be used to sense symptoms of a disease or disorder, such as hypoxemia and ischemia. The CRM device 7581 may also be used to improve cardiac output by atrial pacing, bi-ventricular pacing, atrial or ventricular overdrive pacing, pacing above a programmed pacing rate, and/or other therapies, which may, in turn, improve blood gas transport.

One or both of the xTherapy device 7582 and the CRM device 7581 have one or more sensors 7588, 7589 for sensing conditions associated with disordered breathing. For example, the CRM sensors 7589 may include, for example, cardiac signal electrodes, a minute ventilation (MV) sensor, and an accelerometer. The xTherapy device sensors 7588 may include a microphone and respiratory flow sensor.

The sensor signals are analyzed by the xTherapy device 7582, the CRM device 7581, or both devices 7582, 7581, to determine the presence and/or severity of a disorders such as ischemia, hypoxemia, pulmonary, and/or disordered breathing. The xTherapy and

CRM devices 7582, 7581 may have bi-directional or uni-directional communication capability for communicating information about the disordered breathing to the other device 7581, 7582. In one scenario, the xTherapy 7582 and the CRM 7581 have the ability to communicate directly, e.g., through a wireless link. In another scenario, the xTherapy 7582 and the CRM 7581 do not have the ability to communicate directly, but communicate through an intermediate device 7580, such as a programmer or an information server 7580 used in connection with an advanced patient management system. The intermediary device 7580 may receive information from the xTherapy device 7582 and transmit the information to the CRM device 7581. Similarly, the intermediary device 7580 may receive information from the CRM device 7581 and transmit the information to the xTherapy device 7582.

In one example, either the CRM device 7581 or the xTherapy device 7582 may sense a set of patient conditions and transmit the patient conditions to the other device 7582, 7581. For example, the CRM device 7581 may sense a set of patient conditions using the sensors 7589 coupled to the CRM device 7581. The CRM device 7581 may then transmit the sensor information to the xTherapy device 7582. Each device 7581, 7582 may individually detect a disorder such as ischemia, hypoxemia, pulmonary, and/or disordered breathing and determine the severity of the disorder based on the sensor information. Each device 7581, 7582 may adjust the therapy provided by the device based on the detection and/or severity of the detected disorder.

In another example, the xTherapy device 7582 may sense a set of patient conditions and transmit the patient conditions to the CRM device 7581. The xTherapy device 7582 and the CRM device 7581 may individually modify their therapies based on the sensed conditions.

In yet another example the xTherapy device 7582 may sense a first set of patient conditions and transmit the first set of patient conditions to the CRM device 7581. The CRM device 7581 may detect a second set of patient conditions and transmit the second set of patient conditions to the xTherapy device 7582. The xTherapy and CRM devices 7582, 7581 may then individually modify their therapies based on the first and the second sets of conditions.

In another example, the detection and/or determination of the severity of a disorder, such as ischemia, hypoxemia, pulmonary, and/or disordered breathing, may be performed in one device and the information transmitted to the other device. For example, the CRM device 7581 may sense a first set of patient conditions from sensors 7589 coupled to the CRM device 7581 and receive a second set of patient conditions from the xTherapy device

7582. The CRM device 7581 may detect a disorder such as ischemia, hypoxemia, pulmonary, and/or disordered breathing and determine the severity of the disorder based on the first and the second set of conditions. The CRM device 7581 may transmit information about the detection/severity of a condition such as ischemia, hypoxemia, pulmonary, and/or disordered breathing to the xTherapy device 7582. The CRM device 7581 may modify its therapy based on the detection/severity of the disorder. The xTherapy device 7582 may also modify its therapy based on the detection/severity of the disorder. In an alternate embodiment, the detection and severity determination may be performed by the xTherapy device 7582 and transmitted to the CRM device 7581.

Therapy provided by the xTherapy device 7582 may include, for example, therapy delivery at a variable pressure, e.g., autotitration PAP, gas therapy, among others. Therapy provided by the CRM device 7581 may include, for example, cardiac resynchronization therapy, bi-ventricular pacing, atrial or ventricular overdrive pacing, and/or pacing above a programmed sleep rate.

The detection of a disorder such as ischemia, hypoxemia, pulmonary, and/or disordered breathing and determination of the severity of the disorder may be used to implement an adaptive therapy utilizing both the xTherapy device 7582 and the CRM device 7581. The adaptive therapy techniques described above may be used in connection with the xTherapy device 7582 alone or with the CRM and xTherapy devices 7581, 7582 together. Thus, the therapy provided by either or both devices 7581, 7582 may be initiated, terminated, or modified based on the effectiveness of the therapy, the impact of the therapy on the patient, or both effectiveness and impact.

Figure 76 illustrates the use of one or more external sensors with the patient-internal device operating as the gas therapy control unit in accordance with embodiments of the invention. A patient-external therapy device 7620 provides gas therapy to a patient, for example, through a nasal or facial mask 7601. In this example, the therapy control unit 7615, located in a patient-internal device 7610, such as a CRM device, receives blood gas information from an external sensor 7605, such as, but not limited to, a sensor positioned on a respiratory mask. It is understood that other sensors may be used which are not positioned on a respiratory mask, such as a finger oximetry sensor. The sensor 7605 may communicate with the patient-internal device 7610 through, for example, a wireless communication link.

Alternatively, the sensor signals may be received by the patient-external therapy device 7620, e.g., CPAP device or other xTherapy device, and transmitted from the patient-

external device 7620 to the patient-internal device 7610, for example. The therapy control unit 7615 compares the sensed gas saturation level to a predetermined threshold or range. When the gas saturation is beyond the threshold or range, the patient-internal device 7610 may transmit control signals to the patient-external therapy delivery device 7620 to initiate, terminate, or modify the gas therapy.

Figure 77A illustrates another implementation of gas therapy control in accordance with an embodiment of the invention. In the example depicted in Figure 77A, gas saturation is sensed using one or more patient-internal sensors 7706 positioned on an endocardial lead. In this implementation, the patient-internal sensors 7706 may include a gas saturation sensing lead used with an implantable CRM device. The gas sensing device need not be positioned on a lead, but may alternatively be located on the CRM device housing or header, or on a sensor lead independent from the pacing leads. The patient-internal device 7610 includes a gas therapy control unit 7615. In this example, the therapy control unit 7615 receives blood gas information from the blood gas sensor 7706. The therapy control unit 7615 compares the sensed gas saturation level to a predetermined threshold or range. When the gas saturation is beyond the threshold or range, the patient-internal device 7610 may transmit control signals to the patient-external therapy delivery device 7620 to initiate, terminate, or modify the gas therapy.

Figure 77B illustrates another implementation of gas therapy control in accordance with an embodiment of the invention. In the example depicted in Figure 77B, gas saturation is sensed using one or more patient-internal sensors 7706 positioned in or on the patient-internal device 7610, such as the can of a cardiac monitoring and/or stimulation device. In this implementation, the patient-internal sensors 7706 may include a gas saturation sensing lead used with an implantable CRM device. The patient-external device 7620 includes a gas therapy control unit 7615. In this example, the therapy control unit 7615 receives blood gas information from the blood gas sensor 7706 via, for example, wireless link. The therapy control unit 7615 compares the sensed gas saturation level to a predetermined threshold or range. When the gas saturation is beyond the threshold or range, the patient-external device 7620 may initiate, terminate, or modify the gas therapy.

Figure 78 is a flow chart illustrating a method 7800 of gas therapy control based on signals from a patient-internal device in accordance with embodiments of the present invention. The method 7800 may be useful for controlling any gas therapy system, such as those illustrated with reference to Figures 75 through 77. For clarity of understanding, and

not by way of limitation, the sensing of blood oxygen level will be used as an example of one particular use of the method 7800.

Block 7802 provides for the sensing of blood gas, such as blood oxygen level. A disorder is detected 7804 using the sensed blood gas information. For example, a blood oxygen level may be compared to a range of acceptable blood oxygen levels to detect whether the blood gas is within an acceptable range, or whether some disorder is indicated. If no disorder is detected at block 7804, blood gas sensing continues at block 7802. Sensing may occur continuously, intermittently, by-request, periodically, or as otherwise desired or needed.

If a disorder is detected at detection block 7804, a determination of one or more possible actions and/or interventions is made at block 7806, relative to the detected disorder. For example, detecting a blood oxygen level below a lower threshold may suggest that more oxygen is needed by the patient. A decision is made at block 7808, based on the determination from block 7806, as to whether therapy initiation or therapy modification is desired to increase the patient's blood oxygen level. For example, if a patient is receiving oxygen therapy, the oxygen level administered to the patient may be increased. In another embodiment, if the patient is sleeping and wearing a CPAP device, the air pressure may be increased.

In a further embodiment, the patient may be administered a vasodilating or bronchodilator agent, or have a level of vasodilating or bronchodilator agent therapy modified. Combined therapies may also be performed, such as increasing gas pressure and adding a vasodilating or bronchodilator agent, increasing the heart rate of a patient using a pacemaker and increasing oxygen therapy, or other desired combined therapies.

If no therapy change is desired, the disorder may be recorded, monitored, or alerted, for example, before returning to the sense block 7802. If a therapy change is desired, the therapy is modified at block 7810 before again returning to the blood sense block 7802. For example, if a patient is receiving oxygen therapy, the oxygen level administered to the patient is increased, and the method 7800 may be performed again after an appropriate time to determine if the change was effective, or whether other action is necessary.

Synergistic Use of Medical Devices for Detecting Medical Disorders

Aspects of the invention that include synergistic use of medical devices for detecting medical disorders are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures.

Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhanced patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving synergistic use of medical devices to detect disorders are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve a system providing synergistic use of medical devices for detecting medical disorders 126 (Figure 1B). The medical disorder detection system may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

A system for assessing a disease presence includes a plurality of medical devices, each medical device comprising a sensing system configured to sense one or more physiological conditions. A selection processor is coupled to the plurality of medical devices. The selection processor is configured to select one or more medical devices to sense one or more physiological conditions. A diagnosis processor is coupled to the sensing systems of the plurality of medical devices. The diagnosis processor is configured to assess a presence of a medical disorder based on the one or more physiological conditions.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes a disease assessment system 126. The coordinated system may include, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy involves a disease assessment system. The implantable device and the respiratory therapy device work cooperatively to implement the disease assessment system and/or to perform a function involving the assessment of disease presence.

Embodiments of the invention are directed to synergistic use of medical devices for detecting the presence of a medical disease or disorder. Processes described herein involve automatically selecting one or more medical devices to sense one or more physiological conditions. A monitoring unit, which may be distributed among the selected medical devices, for example, collects data based on the one or more sensed conditions. A diagnostics unit detects a presence of a medical disorder based on the collected data and may assess the progression of the disorder.

Figure 1A illustrates an implantable device 110 and a patient-external medical device 220. The medical devices 110, 120 may comprise circuitry for implementing synergistic use of medical devices for disease assessment.

In accordance with embodiments of the invention, the medical system 100 includes a selection processor and a diagnostics processor. The selection and diagnostics processors may be implemented as components of the patient-internal medical device 110, the patient-external medical device 120, or as a unit separate from the patient-internal medical device 110 and the patient-external medical device 120. The selection and diagnostics processors 114, 124 may be implemented as components of an advanced patient management (APM) system 170, for example.

The selection processor is configured to select one or more medical devices to sense patient conditions. The selection of the medical devices may be based, for example, on patient usage and/or on the proficiency or accuracy of the sensing system associated with a

particular medical device. In one implementation, if the selection processor determines that the patient is not using the patient-external device, then the sensing function may be transferred to the patient-internal device.

The block diagram of Figure 79 provides an example of a coordinated monitoring, diagnosis and/or therapeutic system 7900 in accordance with embodiments of the invention. The system 7900 employs a medical device 7901 that may be fully or partially implantable, or may be positioned on, near, or at a remote location external to the patient. The medical device 7901 may be coupled to an array of data acquisition devices, including patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, and/or other information systems 7914 as described herein. The patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, and/or other information systems 7914 are used to input a variety of conditions affecting the patient and useful for the monitoring, diagnostic, and/or therapeutic functions of the medical device 7901. One or more patient conditions may also be sensed using a remote system 7940.

The medical device 7901 of Figure 79 includes a medical disease/disorder assessment unit 7920 that processes data collected from one or more of the patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, information systems 7914, and/or data collected from the remote system 7940 to assess the presence of various medical diseases and/or disorders. The assessment unit 7920 may include detection circuitry for detecting the occurrence of various physiological events. For example, the assessment unit 7920 may include one or more of a cardiovascular system event/condition detector 7922, a respiratory event/condition detector 7924, a muscle system event/condition detector 7926 and/or a sleep stage detector 7928. Other event detection components may also be included in the assessment unit 7920. The event/condition detectors 7922, 7924, 7926, 7928 may be used to detect normal and/or abnormal physiological system events or conditions. For example, the cardiovascular system event/condition detector 7922 may used to detect abnormal or unusual events of the cardiovascular system such as ventricular tachycardia or fibrillation. The cardiovascular system event/condition detector 7922 may also be used to detect normal cardiac beats or other events or conditions associated with the usual functioning of the heart.
The respiratory system event detector 7924 may be used to detect events or conditions associated with various respiratory system disorders, such as a disordered breathing event or a pulmonary congestion condition. The respiratory system event/condition detector

7924 may also be used to detect the inspiratory and expiratory phases of normal respiration cycles, for example.

The muscle system event/condition detector 7926 may be used to detect normal or abnormal conditions, such as normal muscle atonia associated with REM sleep or abnormal muscle tone of the upper airway associated with obstructive sleep apnea events. The muscle system event/condition detector 7926 may also be used, for example, to detect the level of patient activity. Patient activity information may be useful, for example, in assessing the overall activity level of the patient, or determining if the patient is asleep.

The assessment unit 7920 may also include a sleep stage detector 7928. The sleep stage detector 7928 may analyze various inputs from the patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, other information systems 7914 and/or events/conditions detected by the event/condition detectors 7922, 7924, 7926, to detect sleep-related events, including, for example, sleep onset, sleep offset, sleep stages, and arousals from sleep.

Components of the detection unit 7920 may cooperate with a monitoring unit 7902. The monitoring unit 7902 may incorporate a memory to store data derived from signals produced by the patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, and/or other information systems 7914 and information derived from the event/condition detectors 7922, 7924, 7926, 7928. The stored data may be transmitted to another component of the medical device 7901 or to a separate device for storage, further processing, trending, analysis and/or display, for example. In one scenario, the stored data can be downloaded to a separate device periodically or on command. The stored data may be presented to the patient's health care professional on a real-time basis, or as a long-term, e.g., month long or year long, trend of daily measurements.

The assessment unit 7920 includes a selection processor 7980 for selecting one or more medical devices used for sensing various conditions used for the detection and/or assessment of the medical disease/disorder. Data collected from the one or more medical devices is evaluated in a diagnostics processor 7904. The diagnostics unit 7904 may evaluate events or conditions detected by the selected medical devices to provide diagnostic information related to various medical disorders or diseases affecting the patient. The diagnostics processor 7904 may detect a presence of a medical disease or disorder based on the data collected by the selected medical devices. The diagnostics processor 7904 may also assess the onset, progression, regression, and/or offset of the medical disease or disorder. Information related to the sensed conditions and/or disease or disorder

diagnostics may be stored, analyzed, trended, transmitted to a separate device, printed and/or displayed, for example. In some implementations, the information may be transmitted to a device not used to sensed physiological conditions for medical disease diagnosis, for example. In some implementations, an alert may be activated based on detection or assessment of one or more medical diseases/disorders, for example a visual or audible alert.

The medical device 7901 may also include a therapy control unit 7930 that controls one or more types of therapy delivered to the patient. For example, the medical device may include a cardiac therapy control unit 7952 for controlling cardiac electrical stimulation delivered to the heart through one or more cardiac electrodes 7958. The therapy control unit 7930 may also include respiration therapy control unit 7934 that provides control signals to a respiratory therapy device 7954 and a drug control unit 7936 that provides control signals to a drug delivery device 7956. In one configuration, the medical device 7901 may control the therapy delivered by a separate therapy delivery device 7954, 7956 by communicating directly with the separate therapy delivery device 7954, 7956. In another configuration, the medical device 7901 may communicate with another medical device, e.g., APM system or programmer, to indirectly affect or control the therapy delivery device 7954, 7956.

The medical device 7901 may further include a communications unit 7906 that controls communications between the medical device 7901 and other devices or systems. For example, the communications unit 7906 may be used to provide wireless or wired communications links between the medical device 7901 and one or more of the patient-internal sensors 7911, patient-external sensors 7912, patient input devices 7913, and information systems 7914. The communications unit 7906 may also facilitate communication between the medical device 7901 and the therapy delivery devices 7954, 7956 through wireless or wired connections. The communications unit 7906 may also facilitate communications between the medical device 7901 and a remote device 7940 such as another medical device, a remote programmer and/or an APM system as described previously in connection with Figure 1. The wireless connections coupling the medical device 7901 to various other devices and systems may utilize a variety of wireless protocols, including, for example, Bluetooth, IEEE 802.11, and/or a proprietary wireless protocol.

Embodiments of the invention are directed to the synergistic use of patient external and patient internal devices to detect a presence of and/or assess a variety of medical

disorders, including cardiac disorders and/or pulmonary disorders. Figures 62A—62N list various cardiac and/or pulmonary diseases/disorders that may be detected using the approaches of the present invention.

As referenced in Figures 62A—62N, the term "condition," denotes an parameter that may be sensed and/or measured based on a signal generated by a sensor or other input device of the one or more medical devices. Typically, a physiological sensor generates a signal modulated by a physiological parameter. In some cases, a physiological condition may be directly measured based on the sensor signal. For example, a blood pressure measurement may directly correlate to the signal generated by a blood pressure sensor. In other cases, a condition may be derived from the sensor signal. For example, tidal volume is a respiratory system condition that may be derived from the signal generated by a transthoracic impedance sensor. In another example, heart rate is a cardiac system condition that may be derived from a cardiac electrogram sensor.

The terms "symptom" and "physiological change" refer to a manifestation of a medical disease or disorder. Symptoms and/or physiological changes may be detectable based on a sensed presence of one or more physiological conditions and/or measured values associated with the one or more sensed physiological conditions. The terms "disease" and/or "disorder" are used to refer to a medical dysfunction that is characterizable by a collection of symptoms or physiological changes.

The chart depicted in Figures 62A—62N illustrates relationships between various physiological changes and/or disease symptoms with medical disorders. The chart lists a representative set of medical disorders that may be evaluated in accordance with embodiments of the invention.

The presence of a disorder/disease, such as those listed in Figures 6A—6N, may be assessed by based on physiological changes and/or symptoms associated with the disorder/disease. The physiological changes and/or symptoms may be detected using conditions sensed by a sensor system of a respiratory therapy alone or in combination with the sensor systems of other therapeutic or diagnostic medical devices. If the sensed conditions indicate that the physiological changes or symptoms of a disease or disorder are consistent with a threshold level, the presence of the disease or disorder may be determined.

In another example, assessment of disease presence may be based on relative changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. For example, assessment of a presence of a disease or disorder may be

accomplished by evaluating the changes in conditions indicative of physiological changes or symptoms caused by the disease. The changes in the one or more conditions may be compared to threshold criteria. If changes in the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold levels, a presence of the disease or disorder may be determined.

In a further example, the threshold criteria may involve relationships between the conditions indicative of physiological changes or symptoms caused by the disease. The presence of a disease may be assessed by evaluating relationships between conditions indicative of physiological changes or symptoms caused by the disease. For example, assessment of a disease may involve the determination that levels or amounts of two or more conditions have a certain relationship with one another. If relationships between the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold relationship criteria, the disease or disorder may be present.

Figure 80 is a flowchart of a method of detecting the presence of medical disorders in accordance with embodiments of the inventions. The method involves selecting 8002 one or more medical devices to sense one or more patient conditions associated with symptoms of the medical disorder. The medical devices selected may comprise for example, one or more implantable devices, one or more patient-external devices, or a combination of implantable and patient-external devices. The medical devices selected may comprise any number of therapeutic and/or diagnostic devices, including, for example, various therapeutic or diagnostic devices, including cardiac devices (pacemakers, cardioverter/defibrillators, cardiac resynchronizers, cardiac monitors), muscle stimulators, neurostimulators, implantable or patient-external drug delivery devices (drug pumps, electrically activate drug patches), patient-external respiratory devices (respiratory monitors, nebulizers, oxygen or gas therapy devices, ventilators, respirators, respiratory therapy devices providing positive and/or negative airway pressure), and the like.

The selection of the medical devices may be based, for example, on patient usage and/or on the proficiency or accuracy of the sensing system associated with a particular medical device. The one or more patient conditions are sensed 8004 using the selected devices. Data may be collected based on the one or more sensed physiological conditions. The presence of a medical disorder is detected 8008 based on the one or more sensed physiological conditions. Data pertaining to the sensed physiological conditions may be collected and stored, for example, continuously, or periodically, or according to some other time basis.

In some embodiments of the invention, portions of the data collection may be initiated upon detection of a medical event. For example, data collection may be initiated upon detection of an arousal event, a respiratory event, such as a sleep apnea event, and/or a cardiac event, such as a cardiac arrhythmia event.

In an embodiment of the invention, data collection may occur periodically, e.g., daily or hourly. In some implementations, the data collection may occur continuously or according to a random schedule. In some scenarios, it may be desirable to collect data only when the patient is asleep or only when the patient is awake. The system may detect sleep events to implement nocturnal and/or diurnal data collection, for example. The system may select one set of medical devices for sensing conditions during the day and alter the selection to include a second set of medical devices for sensing conditions at night.

In one example, a patient may have an implanted cardiac pacemaker and may also use, on a periodic basis, e.g., nightly, an external respiratory therapy device, such as a CPAP device. One or more conditions, including respiration may be sensed each night using the cardiac pacemaker and the CPAP device. The airflow sensor of the CPAP device may be automatically selected to sense patient respiration due to the higher accuracy of the airflow measurement in the CPAP device compared to the cardiac pacemaker. However, on some nights the patient may not use the CPAP device. If the patient does not use the CPAP device during a particular period, then patient respiration may be sensed using a surrogate measure, such as the transthoracic impedance sensor of the cardiac pacemaker. The cardiac pacemaker may be automatically selected as the medical device used for sensing patient respiration.

The medical devices used for sensing may be selected based on the proficiency of the sensing system associated with a particular medical device. For example, respiration sounds may be detectable using the accelerometer of a CRM or a patient-external microphone. If patient movements or other interference degrades respiration sound detection acquired by the CRM accelerometer, then the system may select the microphone as the preferred method of sensing respiration sounds.

Assessment of disease presence may be based on relative changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. For example, detection of a presence of a medical disorder may be accomplished by evaluating the changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. The changes in the one or more conditions may be compared to threshold criteria. If changes in the conditions indicative of physiological changes or

symptoms caused by the disease are consistent with threshold levels, the non-rhythm pulmonary disease or disorder may be present. For example, if the levels of one or more conditions increase or decrease by a threshold amount of change, then a determination that the medical disorder is present may be made.

The threshold criteria may involve relationships between the conditions indicative of physiological changes or symptoms caused by the disease or disorder. The presence of a medical disorder may be assessed by evaluating relationships between conditions indicative of physiological changes or symptoms caused by the disease. For example, detection of the presence of a medical disorder may involve the determination that levels or amounts of two or more conditions have a certain relationship with one another. If relationships between the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold relationship criteria, the system may determine that a particular medical disorder is present.

If the presence of a medical disease/disorder is determined, then the progression of the disease may be monitored. Monitoring the progression of the disease or disorder may involve, for example, collecting data and periodically evaluating one or more physiological changes or symptoms of the disease. Evaluating the one or more physiological changes or symptoms may be accomplished by comparing patient conditions to thresholds or other quantifiable indices. Monitoring the medical disorder may involve, for example, monitoring the progression and/or regression of the medical disorder, determining a severity of the disease, detecting disease onset and offset, and/or monitoring other aspects and/or events associated with the disorder.

As illustrated in Figures 62H—62N, cardiac disorders may be organized into disorders of cardiac rhythm, such as bradycardia, ventricular tachyarrhythmia, ventricular fibrillation, paroxymal atrial tachyarrhythmia/fibrillation and chronic atrial tachyarrhythmia/fibrillation). Heart failure may cause contractions of the ventricles to become uncoordinated. Non-rhythm cardiac disorders include coronary artery disease (acute myocardial infarction, ischemia), and hypertension, which may be associated with systolic or diastolic types.

According to one aspect of the invention, pulmonary function testing may be employed to detect physiological changes associated with the presence of cardiac and/or pulmonary disease. Pulmonary function tests may be used to evaluate lung mechanics, gas exchange, pulmonary blood flow, and blood gases and pH. They are used to evaluate

patients in the diagnosis of pulmonary disease, assessment of disease development, or evaluation of the risk of pulmonary complications.

Data acquired using the above-described techniques may be transmitted from the implantable device to an advanced patient management system or other remote device. Assessment of the patient's cardiopulmonary status or control of the therapy may be performed by the advanced patient management system.

In accordance with various embodiments of the invention, the presence of a medical disease or disorder, such as those listed in Figures 62A—62N, may be assessed by evaluating sensed conditions indicative of the a medical disease or disorder. Sensing the conditions may be accomplished using a synergistic process involving selection of one or more medical devices based on various parameters, including, for example, usage of the medical device, quality of the available sensed signals and/or other factors.

In one implementation, the presence of medical disease or disorder may be assessed by comparing levels or values associated with conditions indicative of physiological changes or symptoms caused by the medical disease/disorder to threshold criteria. If the condition levels or values are determined to be beyond threshold criteria levels, the system may determine that the non-rhythm pulmonary disease or disorder is present. The system may use the comparison of condition levels or values to threshold criteria to detect a presence of the medical disease/disorder, the progression of the medical disease/disorder, the regression of the medical disease/disorder and/or the offset of the medical disease/disorder, for example.

The system may initially determine the threshold criteria for one or more medical diseases or disorders by establishing baseline conditions for an individual patient. The baseline conditions may be established using data collected from the patient over a period of time. Clinical data acquired from a number of patients may alternatively or additionally used for establishing the threshold criteria.

In one implementation, assessment of disease presence may be based on relative changes in one or more conditions indicative of physiological changes or symptoms caused by the disease. In this implementation, the threshold criteria may involve a rate of change. For example, diagnosis of a medical disease or disorder may be accomplished by evaluating the rate of change in conditions indicative of physiological changes or symptoms caused by the disease. The changes in the one or more conditions may be compared to threshold criteria involving rate of change. If changes in the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold criteria, then the medical disease or disorder may be present.

In a further example, the threshold criteria may involve relationships between the conditions indicative of physiological changes or symptoms caused by the medical disease/disorder. The presence of a medical disease or disorder may be assessed by evaluating relationships between conditions indicative of physiological changes or symptoms caused by the disease. For example, assessment of a medical disease or disorder may involve the determination that levels or amounts of two or more conditions have a certain relationship with one another. If relationships between the conditions indicative of physiological changes or symptoms caused by the disease are consistent with threshold relationship criteria, the medical disease or disorder may be present.

The system may establish a number of thresholds used for monitoring the progress of the disease. Following detection of the presence of the medical disease or disorder, the system may track the progression, regression and/or offset of the disease by comparing the sensed conditions to the established thresholds.

Figure 81 is a flowchart illustrating a method of assessing a presence of a medical disease in accordance with embodiments of the invention. Criteria sets for assessment of the non-rhythm pulmonary diseases are established 8110. The usage of one or more medical devices is determined 8112. Usage of a medical device may be implemented, for example, by determining a proximity of the patient to the medical device.

In one implementation, the proximity of the patient to an external breathing therapy device may be determined using a transmitter coupled to the external breathing therapy device and a receiver in the selection processor. If the patient is near the external breathing therapy device, the receiver receives a signal broadcast by the transmitter. The transmitter may be located on a bedside unit of the external breathing therapy device, or on the respiratory mask of the external breathing therapy device, for example.

Further, usage of an external device may be implemented in other ways, involving, for example, notification by the patient that the external device is in use, or by examining one or more sensed signals to determine if the sensed signals correspond to nominal signal values when the medical device is in use by the patient.

One or more medical devices are selected 8114 to sense one or more conditions associated with a medical disorder. The selected medical devices are used to sense 8116 the one or more conditions. The system may select the medical devices based on at least one of a sensing parameter of the medical devices. For example, the system may select the medical devices based on sensing characteristics including the type, quality, reliability, repeatability, efficiency, availability, accuracy, resolution, dynamic range, specificity, sensitivity or predictive value of the sensing or measurement provided by the medical device. In one implementation, a medical device may be selected based on patient usage. For example, if first and second medical devices are available to sense patient conditions, the first medical device may be selected to sense a first condition and a second medical device may be selected to sense a second condition. However, if only the first medical device is in use, then both conditions may be sensed using the first medical device.

In another implementation, medical device selection may depend on the sleep/wake cycle of the patient. A first medical device may be selected to monitor a physiological condition while the patient is awake, and a second medical device may be selected to monitor the physiological condition while the patient is asleep.

Data is collected 8118 based on the sensed information. In some implementations, data collection may be initiated based on the detection of a triggering event. For example, data collection may be initiated and/or terminated based on the detection of a respiratory system event, a cardiac event, a sleep event, and/or other types of events.

If a presence of the medical disorder was previously determined 8120, marking an onset of the medical disorder, then the progression, regression, and/or offset of the medical disorder is monitored 8122.

If the presence of the disease was not previously determined 8122, then the levels of the sensed conditions are compared 8124 to a set of criteria associated with the disease. If levels of the conditions are consistent 8126 with the threshold levels, then a presence of the medical disorder is detected 8128.

The system may continue to collect data based on the sensed conditions to monitor the progression, regression and/or offset of the medical disorder. The system may modify the selection of the medical devices used to sense patient conditions before the disorder presence is detected and/or during the time that the system monitors the disorder. For example, the system may check nightly to determine the usage of a CPAP device. If the CPAP device is in use on a particular night, the CPAP device may be used to sense conditions associated with the medical disorder. However, on a different night, the patient may not use the CPAP. In this situation, the system may automatically shift the sensing function previously performed by the CPAP to another medical device.

Therapy Control Based on Physiologic Cycle

Aspects of the invention that include therapy control based on physiologic cycle are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention involving therapy control based on physiologic cycle are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures.

The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention involve an individual system 140 (Figure 1B) for controlling respiratory therapy based on a patient's cardiac cycle. The respiratory therapy control system 140 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Various embodiments of present invention involve methods and systems for matching intrathoracic pressure with cardiac cycle phase. One embodiment of the invention involves a method for delivering airway pressure to a patient. The method includes determining the cardiac cycle phase and controlling the airway pressure based on the cardiac cycle phase. Controlling the airway pressure is performed at least in part implantably.

In accordance with another embodiment of the invention, a therapy control system includes a detector system configured to determine cardiac cycle phase and control unit coupled to the detector system. The control unit is configured to control airway pressure based on the cardiac cycle phase. The control unit includes at least one implantable component.

In yet another embodiment of the invention, a method for controlling airway pressure comprises delivering cardiac pacing pulses to a patient and controlling airway pressure delivered to the patient based on the delivery of the cardiac pacing pulses.

A further embodiment of the invention involves a medical system is configured to control airway pressure delivered to a patient. The medical system includes a pulse generator configured to deliver cardiac pacing pulses to a patient's heart and control circuitry coupled to the pulse generator. The control unit configured to control airway pressure delivered to the patient based on the delivery of the cardiac pacing pulses.

Yet a further embodiment involves a method of delivering and external respiratory therapy to a patient. The external respiratory therapy is delivered to a patient to treat disordered breathing. The cardiac cycle phase of the patient is determined. The delivery of the external respiratory therapy is controlled based on the cardiac cycle phase.

In another embodiment of the invention, a medical system controls delivery of a patient-external respiratory therapy based on cardiac cycle phase. The medical system includes a respiratory therapy unit configured to deliver a patient-external respiratory therapy to a patient to treat disordered breathing. The system also includes detector circuitry configured to determine cardiac cycle phase. A control unit is coupled to the detector system and the respiratory therapy unit. The control unit is configured to control delivery of the respiratory therapy based on the cardiac cycle phase.

Various embodiments of present invention involve methods and systems for matching intrathoracic pressure with cardiac cycle phase. One embodiment of the invention involves a medical system configured to control cardiac pacing via a respiratory therapy device. The respiratory therapy device includes a sensor system and a therapy delivery unit. The system is configured to sense respiration cycles. The therapy delivery unit is configured to deliver an external respiratory therapy to the patient.

The system also includes a pulse generator configured to deliver cardiac pacing pulses to the patient. A controller is coupled to the sensing system and the pulse generator. The control unit configured to adjust a cardiac pacing rate based on the respiration cycles.

Another embodiment of the invention involves a method for controlling cardiac pacing therapy. Respiration cycles are sensed using one or more sensors of an external respiratory therapy device. The cardiac pacing is adjusted based on the respiration cycles.

Another embodiment of the invention involves a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes the system 140 control of respiratory therapy based on cardiac cycle. The coordinated system includes, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

According to this embodiment, the system providing coordinated patient monitoring, diagnosis and/or therapy further includes a system 140 configured to control respiratory therapy based on cardiac cycle. The respiratory therapy control system 140 includes a detector system configured to determine cardiac cycle phase, and a control unit coupled to the detector system. The control unit is configured to control airway pressure based on the cardiac cycle phase and includes at least one implantable component.

Alternatively this embodiment can include a system for delivering respiratory therapy based on cardiac cycle using a system 140 that includes a pulse generator configured to deliver cardiac pacing pulses to a patient's heart; and a control unit coupled to the pulse generator. The control unit configured to control airway pressure delivered to the patient based on the delivery of the cardiac pacing pulses.

Another alternative embodiment can include a system for delivering respiratory therapy based on cardiac cycle using a system 140 that includes a respiratory therapy unit configured to deliver a patient-external respiratory therapy to a patient to treat disordered breathing, detector circuitry configured to determine cardiac cycle phase, and a control unit coupled to the detector system and the respiratory therapy unit. The control unit configured to control delivery of the respiratory therapy based on the cardiac cycle phase

Under healthy conditions, heart rate and blood pressure vary with respiration. The heart rate varies in response to autonomic as well as other regulatory inputs to the sinoatrial node (SA). Figure 82 is a graph comparing respiration 8202, blood pressure 8206, and heart rate 8204 in a healthy individual. Modulation of heart rate with respiration is known as respiratory sinus arrhythmia (RSA). The rate variations of RSA have been found to be important to survival. Individuals without RSA have higher rates of overall mortality than those with RSA.

Respiratory sinus arrhythmia has a role in increasing the efficiency of the cardiovascular system. In many patients with cardiovascular disease or heart failure, RSA is attenuated or absent. Studies have shown that RSA improves pulmonary gas exchange and circulatory efficiency. Mimicking RSA behavior using a cardiac pacemaker enhances cardiac function over fixed pacing.

Some patients suffer from multiple disorders affecting the cardiac and pulmonary systems. For example, patients suffering from congestive heart failure (CHF) may experience disordered breathing as well as a decrease in the pumping action of the heart. In some cases, patients receive therapy from multiple units to improve cardiac and respiratory functioning. For example, a patient may receive treatment for disordered breathing from a patient-external respiratory therapy unit and the patient may receive cardiac resynchronization pacing therapy from a patient-internal cardiac rhythm management (CRM) system.

Various aspects of the invention are directed to coordinated use of multiple therapy devices to increase cardiopulmonary functioning. Some embodiments of the invention utilize information acquired by sensors of a respiratory therapy device to control cardiac

pacing based on the interactions of cardiac and pulmonary systems associated with RSA. The cardiac pacing rate may be modulated by respiration to mimic RSA.

Other embodiments of the invention modulate intrathoracic pressure based on cardiac cycle phase. In these embodiments, although the cause/effect relationship of RSA is reversed, the cardiovascular system may benefit from similar efficiencies as RSA because intrathoracic pressure is matched to cardiac cycle.

Methods, devices, and systems in accordance with the present invention may incorporate one or more of the features, structures, methods, or combinations thereof described herein below. For example, a medical system may be implemented to include one or more of the features and/or processes described below. It is intended that such a method, device, or system need not include all of the features and functions described herein, but may be implemented to include one or more selected features and functions that provide unique structures and/or functionality.

Figures 83A—83C are diagrams of systems employing a therapy controller that controls airway pressure delivered by the respiratory therapy device based on cardiac cycle phase. Figure 83A is a block diagram illustrating a system 8300 that may be used to modulate intrathoracic pressure based on cardiac cycle phase in accordance with embodiments of the invention. In this example, intrathoracic pressure is modulated by a positive airway pressure therapy system 8300 comprising a positive airway pressure therapy controller unit 8330 and airway pressure delivery components 8348, 8346. Respiratory therapy devices, including positive airway pressure (xPAP) devices may be used to treat disordered breathing, heart failure and/or other pulmonary disorders.

Positive airway pressure therapy is particularly useful in the treatment of disordered breathing. Disordered breathing may be caused by an obstructed airway or by derangement of the signals controlling respiration from the brain. Disordered breathing typically occurs while the patient is asleep, and is associated with excessive daytime sleepiness, systemic hypertension, increased risk of stroke, angina and myocardial infarction. Disordered breathing is related to congestive heart failure and can be particularly serious for patients concurrently suffering from cardiovascular deficiencies. Treatment for disordered breathing and/or heart failure may involve the used of an xPAP therapy system. An xPAP therapy system develops a positive air pressure that is delivered to the patient's airway, keeping the patient's airway open and reducing the severity and/or number of occurrences of disordered breathing due to airway obstruction. Reducing the number of occurrences of disordered breathing lessens the strain on the heart, thus providing therapy for heart failure.

The positive airway pressure (xPAP) device 8310 of Figure 83A, which is typically a bedside unit, delivers air or other gas through tubing 8346 to a facial or nasal mask 8348 worn by the patient. The airway pressure supplied by the xPAP device 8310 acts as a pneumatic splint keeping the patient's airway open and reducing the severity and/or number of occurrences of disordered breathing due to airway obstruction.

The xPAP device 8310 includes a flow generator 8342 that pulls in air through a filter. The flow generator 8342 is controlled by the pressure control circuitry 8344 to deliver an appropriate air pressure to the patient. Air flows through tubing 8346 coupled to the xPAP device 8310 and is delivered to the patient's airway through a mask 8348. In one example, the mask 8348 may be a nasal mask covering only the patient's nose. In another example, the mask 8348 covers the patient's nose and mouth.

The xPAP device 8310 may include a communications unit for communicating with one or more separate devices, including patient-external and/or patient-internal monitoring, diagnostic and/or therapeutic devices. In one example, the xPAP device 8310 may receive control signals for controlling delivery of the respiratory therapy from an implantable therapy or monitoring device. In another example, the xPAP device 8310 may receive control signals for controlling delivery of the respiratory therapy from a patient management server or other computing device.

In one configuration, the xPAP unit 8310 includes a control unit 8330 that further contains a cardiac cycle sensor 8322. The cardiac cycle sensor 8322 measures a physiological parameter associated with the patient's cardiac cycle and sends cardiac cycle information to a phase detector 8332. The phase detector 8332 detects cardiac cycle phase based on the monitored physiological parameter. In one implementation, the cardiac cycle information may be determined from cardiac electrical activity detected using implantable electrogram (EGM) sensors or patient-external electrocardiogram (ECG) sensors. In other implementations the cardiac cycle information may be detected, for example, based on various parameters that may be sensed by the cardiac cycle sensor 8322, including one or more of blood pressure, blood oxygen saturation, e.g., via pulse oximetry, thoracic motion, e.g., via thoracic electrical impedance, heart sounds, airway pressure modulation, and/or atrial tonometry.

Cardiac cycle phase may be determined by the timing of cardiac paces delivered to the patient. In one embodiment, illustrated in Figure 83B, the phase detector determines cardiac cycle phase based on cardiac pacing information received from a pacemaker control unit 8321. Cardiac pacing information may be used to determine cardiac cycle

phase alternatively or in addition to sensed physiological parameters acquired by sensors as described in connection with Figure 83A.

Figure 83C illustrates a medical system for controlling respiratory therapy in accordance with embodiments of the invention. The system includes an external respiratory therapy controller unit 8310 that delivers airway pressure through tubing 8346 and mask 8348. An implantable or patient-external cardiac cycle sensor is coupled a therapy controller 8330 disposed within a housing of an implantable cardiac device 8390. The implantable cardiac device 8390 may comprise, for example, a cardiac therapy device, cardiac rhythm management (CRM) system, pacemaker, defibrillator, bi-ventricular pacemaker, intrathoracic cardiac sensing and/or stimulation (ITCS) system, cardiac resynchronizer, cardiac monitor, or other implantable cardiac device.

In one example, cardiac electrodes may be positioned in, on or about the heart in appropriate locations to sense the cardiac electrical activity of one or more heart chambers and/or to deliver pacing pulses to the heart. The cardiac electrodes may be coupled to the implantable cardiac device 8390 through an intracardiac, intrathoracic, or subcutaneous lead system.

In one configuration, cardiac electrical activity is sensed by intracardiac EGM electrodes. Signals corresponding to the cardiac electrical activity are transmitted to a control unit 8330 disposed within the implantable housing of the cardiac therapy or monitoring device 8390. The control unit 8330 evaluates the cardiac electrical signals to determine cardiac cycle phase. Control signals for controlling the airway pressure therapy are developed by the control unit 8330 based on the sensed cardiac electrical activity. The control signals direct the respiratory therapy controller unit 8310 to modulate therapy based on cardiac cycle phase.

In another configuration, the implantable cardiac device 8390 comprises a cardiac rhythm management (CRM) system including a pacemaker that delivers cardiac pacing pulses to one or more heart chambers. The cardiac pacing pulses may be delivered to treat bradycardia, tachycardia and/or cardiac mechanical dysynchrony.

The pacing pulses produce contractions of the heart chambers that may be used to regulate and/or synchronize the heart contractions to enhance the pumping action of the heart. In this configuration, the cardiac cycle phase information may be determined from the timing of the cardiac paces. Cardiac pacing information, e.g., the timing of pacing pulses delivered to the heart chambers, may be provided to the therapy control unit 8330 by the pacemaker of the CRM system 8390. The cardiac pacing information is used by the

therapy control unit 8330 to develop control signals for controlling the respiratory therapy based on cardiac phase.

Figures 84A and 84B illustrate systems employing a therapy controller that develops a signal to control cardiac pacing based on respiration information acquired from sensors of a respiratory therapy system. In the block diagram of Figure 84A, the control processor 8434 is implemented as a component of the xPAP controller unit 8310. The control processor 8434 receives respiration information from a sensor 8422 that senses a parameter modulated by respiration. In one example, the sensor 8422 may comprise an airflow sensor of the respiratory therapy device. In other examples, the sensor 8422 may comprise a motion sensor, such as a thoracic or abdominal motion sensor.

The control processor 8434 utilizes the respiration information to develop a signal for controlling cardiac pacing. The control information is transmitted to the cardiac pulse generator 8420 through a wireless communications link 8407. Cardiac pacing pulses, delivered to the heart via the pacemaker 8430 of the cardiac pulse generator 8420, are modulated with respiration based on the control signals provided by the control processor 8434.

Figure 84B illustrates an embodiment wherein the control processor 8434 is disposed within the implantable housing of the cardiac pulse generator 8420. The control processor 8434 receives respiration information acquired by the respiration sensor 8422 of the respiratory therapy device. Respiration information is transmitted to the cardiac pulse generator 8420 through a wireless communications link 8407. The control processor develops a signal for controlling cardiac pacing based on the respiration information. Cardiac pacing pulses, delivered to the heart 8490 via the pacemaker 8430 of the cardiac pulse generator 8420, are modulated by respiration.

Figures 85A and 85B are flowcharts of methods that may be implemented by the systems depicted herein to adjust intrathoracic pressure based on cardiac cycle phase in accordance with embodiments of the invention. As illustrated in Figure 85A, a method involves determining 8510 cardiac cycle phase by sensing a physiological parameter associated with a cardiac cycle. Control of airway pressure is based on 8520 the cardiac cycle phase. In one embodiment, the physiological parameter used to determine cardiac cycle comprises cardiac electrical activity which may be sensed using an EGM sensor. In other implementations, the cardiac cycle phase may be determined based on a cardiac stroke signal acquired via a transthoracic impedance sensor or a heart sound signal acquired via a microphone or an accelerometer.

The method depicted by the flowchart of Figure 85B involves sensing 8530 a physiological parameter indicative of cardiac phase. During systole 8540, the therapy pressure is increased 8550, e.g., above a baseline pressure. During diastole 8560, the therapy pressure is decreased 8570.

Figure 85C illustrates a method of controlling cardiac pacing in accordance with embodiments of the invention. A parameter associated with respiration is sensed 8580 using a sensor of a respiratory therapy device. For example, the respiratory therapy device may comprise a positive airway pressure device, gas therapy device, nebulizer, ventilator, or other device that delivers respiratory therapy to the patient and includes a sensing system configured to sense a parameter that is modulated by respiration. In one example, the respiratory therapy device may include or be coupled to a blood pressure sensor. In another example, the respiratory therapy device may include or be coupled to an air flow sensor.

According to some aspects of the invention, the therapy controller may control the cardiac device to adjust cardiac pacing based on respiration information acquired from sensors of the respiratory therapy system. The therapy controller may modulate cardiac pacing rate based on respiration cycle information acquired from the sensors of the respiratory therapy unit. Cardiac pacing is controlled based on the sensed parameter associated with respiration. For example, the cardiac pacing rate may be modulated above and below a base rate to mimic RSA. Modulating the cardiac pacing rate with respiration restores normal respiratory sinus arrhythmia in patients who have lost this functionality. Such therapy is particularly useful for patient's suffering from cardiopulmonary diseases such as congestive heart failure. In one embodiment a phase shift is imposed between the respiratory phase and the cardiac phase produced by the cardiac pacing to more closely mimic RSA.

Figure 86 graphically illustrates modulation of respiratory therapy pressure based on cardiac phase in accordance with embodiments of the invention. Figure 86 compares graphs of an ECG signal 8610, cardiac stroke signal from an implanted impedance sensor 8620, therapy pressure 8630, and net respiration flow 8640 (as measured into the patient). The net respiration flow 8640 illustrates the patient's respiration cycle modulated by the therapy pressure delivered to the patient. As shown in Figure 86, the therapy pressure 8630 delivered by the respiratory therapy device is modulated by the phase of the cardiac cycle. The phase of the cardiac cycle may be determined based on the ECG signal 8610 and/or the cardiac impedance stroke signal 8620. Thus, the therapy pressure is increased above its

otherwise static positive value 8632 during cardiac systole. The increased thoracic pressure reinforces the cardiac contraction and thus reduces cardiac afterload. During cardiac diastole, the respiratory therapy pressure is decreased from its otherwise static positive value 8632. Although reduced, the therapy pressure is still positive in this embodiment. However, in other embodiments the applied pressure may be zero or negative during cardiac diastole. The reduced ventilation pressure during cardiac diastole assists the heart in filling and thereby increases preload. The control unit may anticipate the cardiac cycle phase based on recent cardiac cycle history.

System and Method for Moderating a Therapy Delivered during Sleep using Physiologic Data Acquired during Non-Sleep

Aspects of the invention that include moderating a therapy delivered during sleep using physiologic data acquired during non-sleep are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include moderating a therapy delivered during sleep using physiologic data acquired during non-sleep are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may

implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

System and method embodiments provide for gathering patient related data during non-sleep periods and modulating a therapy delivered to the patient during sleep using the gathered data. According to one approach, data associated with a patient is gathered while the patient is awake. A therapy delivered to the patient during patient sleep is adjusted using the acquired data. The therapy includes one or both of a respiratory therapy and a therapy to treat a sleep-related disorder.

For example, the therapy delivered to the patient may include one or more of a respiratory therapy, such as a positive airway pressure (xPAP) therapy, a sleep disordered breathing therapy, a cardiac rhythm management therapy, such as a cardiac overdrive pacing therapy, a medication therapy, or a drug delivery therapy. The therapy delivered to the patient may be enhanced or optimized using the acquired data. For example, therapy adjustment and/or optimization may involve performing therapy titration using the acquired data.

A pathological disorder may also be detected using the acquired data. A rate of change in the pathological condition may be computed and evaluated. In one approach, a pathological condition may be detected using the acquired data, and a therapy delivered to the patient may be adjusted in response to the detected pathological condition.

The acquired data may include one or more of the following: respiratory data, breathing pattern data, breathing rate data, transthoracic impedance data, heart rate data, heart rate variability (HRV) data, PR interval data, cardiac arrhythmia data, patient activity data, cardiac sound data or pulmonary sound data, contextual data impacting the patient, glucose level data, autonomic nervous system activity data, medication use data, blood pressure data, blood oxygen level data, and/or symptom-based data. Contextual data may include environmental parameters, examples of which include temperature, humidity, pollution, barometric pressure, and body related parameters such as posture and location.

Embodiments of the invention involve an individual system 129 (Figure 1B) for moderating a therapy delivered during sleep using physiologic data acquired during non-sleep. The system 129 for moderating a therapy delivered during sleep using physiologic data acquired during non-sleep may be implemented as a stand alone system or in

combination with other individual medical systems, such as those described in Figures 1B—1D.

Embodiments of the invention involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes moderation 129 of a therapy delivered during sleep using physiologic data acquired during non-sleep. The coordinated system may include, for example, an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

The following discussion, with reference to Figures 87A-87C, describes embodiments of the invention involving use of diurnal data to aid nocturnal therapy and diagnosis of sleep disorders. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

In accordance with embodiments of the invention, many types of data acquired during non-sleep periods may be used to adjust or enhance therapy during periods of sleep. The data acquired during non-sleep may also be used to provide enhanced diagnostic capabilities for sleep-related disorders. The data acquired during non-sleep may be used, for example, to determine the existence of a condition that occurs during non-sleep periods and is caused, or results from, a sleep-related disorder. The data acquired during non-sleep may determine the extent of the condition, the rate of change of the condition, the amount of change of the condition relative to a baseline, and/or the effect of nocturnal therapy for the condition.

Examples of data acquired during non-sleep that may aid in nocturnal therapy and diagnosis include: transthoracic impedance or other arrangement to assess pathological breathing patterns or conditions such as Cheyne-Stokes breathing, periodic breathing, rapid breathing, respiratory rates, inspiration/expiration intervals, pulmonary function parameters, including for example, forced expiratory volume (FEV) and forced vital capacity (FVC); heart rates, postventricular (PV) intervals and cardiac arrhythmias; activity level; cardiac and pulmonary sounds, (e.g., S3, rales, coughs); environmental data, (e.g., air pollution, humidity); glucose levels; autonomic nervous system activity; medication use,

particularly for patients whose use is aperiodic and patient determined (e.g., albuterol for asthma); blood pressure (e.g., average arterial, left atrial end diastolic); blood oxygen level; posture; and symptom-based data (e.g., dyspnea, daytime sleepiness, fatigue, restless leg syndrome (RLS) symptoms).

A variety of sleep-time therapy may be modulated using the data acquired during non-sleep. In one implementation, data acquired during non-sleep may be used to modulate respiration therapy for disordered breathing, e.g., xPAP therapy. In another implementation, data acquired during non-sleep may be used to adjust cardiac overdrive pacing for sleep disordered breathing. In yet another implementation, data acquired during non-sleep may be used to adjust medications used for sleep disorders, e.g., benzodiazepine, tricyclic antidepressants, and theophylline, among others. In another implementation, data acquired during non-sleep may be provided to the patient for behavior modification (e.g., excessive activity too close to sleep time).

Referring to Figure 87A, a system 8700 in accordance with an embodiment of the present invention includes a data acquisition unit 8704 configured to acquire data associated with a patient while the patient is awake. The data acquisition unit 8704 is coupled to a therapy delivery system 8706 configured to adjust a therapy delivered to the patient, during patient sleep, using the acquired data. One or more sensor(s) 8702 are used to sense physiological signals useful to the data acquisition unit 8704.

As illustrated in Figure 87B, a system, in accordance with an embodiment of the invention, includes one or more patient-internal and/or patient-external sensors 8720 for sensing non-sleep conditions related to disordered breathing. Signals from the one or more sensors 8720 may be acquired by a disordered breathing detector 8712 in a patient-internal or patient-external medical device 8710 and used to detect non-sleep episodes of disordered breathing. In one implementation, respiratory signals, sensed using the sensor 8720, such as a transthoracic impedance sensor, are detected during non-sleep periods.

The respiration signals may be stored in the memory of a monitoring unit 8714 within the medical device 8710. The respiration signals may be trended, displayed, and/or transmitted to another device, such as an advanced patient management (APM) system 8730 or a programmer 8740 periodically or on command.

The non-sleep respiration signals may be used to modify therapy for sleep disordered breathing. In one example, the APM system 8730 analyzes the non-sleep respiration signals to determine the presence and/or severity of non-sleep time periodic breathing. The APM system 8730 may use information about disordered breathing, such as

the onset or extent of periodic and/or Cheyne-Stokes breathing during non-sleep periods, to determine the optimal sleep time xPAP therapy for Cheyne-Stokes breathing and/or central sleep apnea therapy. The APM system 8730 determines a modified therapy based on the non-sleep respiration signals.

In one example, when periodic and/or Cheyne-Stokes breathing increases or decreases, the pressure delivered by an xPAP therapy unit may be increased or decreased, respectively. In another example, non-sleep time breathing information may be used to modify the initial pressures for an auto-titrating PAP device. The APM system 8730 may transmit control signals to a therapy device 8750, e.g., a respiration therapy device such as an xPAP device, to modify therapy delivered to the patient during sleep.

Although the example provided in Figure 87B contemplates the use of the APM system 8730 to analyze the non-sleep signals and modify the sleep time delivered therapy, the medical device 8710 may perform one or both of these functions.

In another embodiment of the invention, illustrated in Figure 87C, cardiac information is used to adjust cardiac overdrive pacing prescribed for the treatment of sleep disordered breathing. In this embodiment, a cardiac signal detector unit 8716 within an implanted or external device 8780 detects cardiac signal information from cardiac electrodes 8760, e.g., implanted, subcutaneous, surface electrodes or combinations thereof, during non-sleep periods. The cardiac information may be saved in the memory of a monitoring unit 8712 within the medical device 8780. The cardiac information may be trended, displayed, or transmitted to another device, such as a programmer 8740 or an APM system 8730.

The non-sleep period cardiac information may be analyzed to determine an enhanced or optimum cardiac electrical stimulation therapy for sleep disordered breathing. In this example, the non-sleep cardiac information is analyzed in a data analysis unit 8790 within the medical device 8780. In another implementation, the cardiac information may be analyzed by the APM 8730 or other device.

In this example configuration, the medical device 8780 uses the cardiac information to adjust timing parameters in an implanted therapy device 8770, such as a CRM device. For example, the data analysis unit 8790 may determine an average intrinsic heart rate and/or an average PR interval during non-sleep periods. These values may be used to enhance the rate and AV delay used by the cardiac overdrive pacing therapy prescribed to treat sleep disordered breathing in subsequent sleep periods.

In one illustrative configuration, the functions of the medical device 8780, including the cardiac signal detector 8716, the monitoring unit 8712 and/or the data analysis unit 8790, and the implanted therapy device 8770 are located within an implantable CRM device 181. In this configuration, the data analysis unit 8790 receives cardiac signals from implanted cardiac electrodes during non-sleep times. The data analysis unit 8790 analyzes the cardiac signals to adjust therapy delivered by the CRM device 181 to treat sleep disordered breathing.

Figure 88 illustrates a method 8800 of moderating sleep therapy using physiologic data acquired during non-sleep. A sensor (internal or external to the patient, such as an EEG sensor) is used at block 8802 to sense a patient's non-sleep state physiologic condition. The data, trends, or selected parameters may then be stored in memory of an implantable device and/or a patient-external device such as an APM device or server system.

A determination 8804 is made that the patient is asleep. If the patient is sleeping, the information stored during the non-sleep period is used at block 8806 to, for example, compare the current paced heart rate to the non-sleep intrinsic heart rate. A decision 8808 is then made to select continuation of the current therapy or to modify patient therapy based at least in part on physiologic data acquired during non-sleep. If treatment modification is desired, the modification is performed at block 8810 before re-starting the method 8800.

In certain embodiments, sounds, such as hearts sounds and pulmonary sounds, are used to aid in moderating sleep therapy using physiologic information acquired during non-sleep. Because heart sounds are time correlated with respect to the cardiac electrophysiological signals, the non-electrophysiologic signal may provide information about a patient's rhythm state even in the presence of electrical noise and/or electrocardiographic artifacts. A subcutaneous sensor, such as an accelerometer or acoustic transducer, may be used to detect heart sounds. It should also be noted that other sensor derived signals could replace heart sounds. For example, impedance, pulse pressure, blood volume/flow, or cardiac accelerations could be used.

Various types of acoustic sensors may be used to detect heart sounds. Examples of such acoustic sensors include diaphragm based acoustic sensors, MEMS-based acoustic sensors such as a MEMS-based acoustic transducer, fiber optic acoustic sensors, piezoelectric sensors, and accelerometer based acoustic sensors and arrays. These sensors may be used to detect audio frequency (and/or subsonic frequency) pressure waves

associated with the heart sounds, and may also be used to detect other non-electrophysiologic cardiac related signals.

The presence of cardiac pulse, or heartbeat, in a patient is generally detected by palpating the patient's neck and sensing changes in the volume of the patient's carotid artery due to blood pumped from the patient's heart. A graph of a carotid pulse signal 8910, representative of the physical expansion and contraction of a patient's carotid artery during two consecutive pulses, or heartbeats, is shown at the top of Figure 89. When the heart's ventricles contract during a heartbeat, a pressure wave is sent throughout the patient's peripheral circulation system. The carotid pulse signal 8910 shown in Figure 89 rises with the ventricular ejection of blood at systole and peaks when the pressure wave from the heart reaches a maximum. The carotid pulse signal 8910 falls off again as the pressure subsides toward the end of each pulse.

The opening and closing of the patient's heart valves during a heartbeat causes high-frequency vibrations in the adjacent heart wall and blood vessels. These vibrations may be heard in the patient's body as heart sounds, and may be detected by sensors, as described earlier. A conventional phonocardiogram (PCG) transducer placed on a patient converts the acoustical energy of the heart sounds to electrical energy, resulting in a PCG waveform 8920 that may be recorded and displayed, as shown by the graph in the upper middle portion of Figure 89.

As indicated by the PCG waveform 8920 shown in Figure 89, a typical heartbeat produces two main heart sounds and may produce other sounds depending on pathology. A first heart sound 8930, denoted S1, is generated by vibration generally associated with the closure of the tricuspid and mitral valves at the beginning of systole. Typically, the heart sound 8930 is about 14 milliseconds long and contains frequencies up to approximately 500 Hz. A second heart sound 8940, denoted S2, is generally associated with vibrations resulting from the closure of the aortic and pulmonary valves at the end of systole. While the duration of the second heart sound 8940 is typically shorter than the first heart sound 8930, the spectral bandwidth of the second heart sound 8940 is typically larger than that of the first heart sound 8930. A third heart sound 8942, denoted S3, is also seen in the PCG waveform 8920. The S3 heart sound 8942 is created when the ventricles relax and pressure from the filling blood rapidly distends the ventricle. When the stiff, non-compliant ventricular wall reaches its physical limits, it suddenly tenses, and the S3 sound is created. In children an S3 is common and normal. After age 40, it almost always indicates the failing heart in congestive heart failure. As stated earlier, an accelerometer or

acoustic transducer may also detect pulmonary sounds, such as rales and/or coughs, to provide physiologic data.

An electrocardiogram (ECG) waveform 8950 describes the electrical activity of a patient's heart. The graph in the lower middle portion of Figure 89 illustrates an example of the ECG waveform 8950 for two heartbeats and corresponds in time with the carotid pulse signal 8910 and PCG waveform 8920 also shown in Figure 89. Referring to the first shown heartbeat, the portion of the ECG waveform 8950 representing depolarization of the atrial muscle fibers is referred to as the "P" wave. Depolarization of the ventricular muscle fibers is collectively represented by the "Q." "R," and "S" waves of the ECG waveform, referred to as the QRS complex. Finally, the portion of the waveform representing repolarization of the ventricular muscle fibers is known as the "T" wave. Between heartbeats, the ECG waveform 8950 returns to an isopotential level.

Fluctuations in a patient's transthoracic impedance signal 8960 also correlate with blood flow that occurs with each cardiac pulse wave as well as provide breathing information. The bottom graph of Figure 89 illustrates an example of a filtered transthoracic impedance signal 8960 for a patient in which fluctuations in impedance correspond in time with the carotid pulse signal 8910, the PCG waveform 8920, and ECG waveform 8950, also shown in Figure 89.

Automatic Activation of Medical Processes

Aspects of the invention that include automatic activation of medical processes are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include automatic activation of medical processes are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180.

Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention may involve automatic control of therapies or other medical processes based on sleep stage, such as is determined by brain activity. Automatic control may involve automatic activation, de-activation and/or modification of such therapies and processes. In various embodiments, a system includes a sensor system having one or more sensors configured to sense signals related to the brain activity of the patient. A brain activity analyzer detects various brain states, including, for example, sleep state/stage and/or brain seizures. The brain activity detector may also be configured to discriminate between sleep and wakefulness. A controller uses the brain state detection information to control a medical system configured to perform at least one respiratory or cardiac process.

Other embodiments include at least one of an EEG sensor and an EMG sensor configured for one or more of detecting brain state. One or more sensors may be positioned on a respiratory mask of a respiratory device, such as a positive airway pressure therapy device. Further embodiments include a cardiac rhythm management device, wherein the cardiac process may involve one or both of a cardiac therapy process and a breathing therapy process. The cardiac process may further involve a diagnostic process and/or a monitoring process.

According to other embodiments, a method involves sensing signals related to brain state and determining the brain state of a patient based on the sensed signals. At least one respiratory or cardiac medical process is activated, de-activated, modified or otherwise controlled based on the patient's brain state.

Further embodiments involve sensing the signals related to brain state using EEG signals and/or EMG signals. Sensing signals related to brain state may further involve

sensing signals related to sleep stage. Sensing signals related to brain state may involve sensing seizure, and activating the medical process may involve activating, de-activating, modifying or otherwise controlling arrhythmia therapy based on seizure detection.

Embodiments of the invention involve an individual system 132 (Figure 1B) for automatic activation of medical processes based on brain state. A system employing automatic activation of medical processes 132 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D.

Other embodiments involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that employ automatic activation of medical processes 132. A coordinated system may include, for example, one or both of an implantable cardiac device 181 and a patient-external respiratory therapy device 184. The system may further include an external processor 183 providing a coordination function. A communication channel couples the implantable device 181 and the respiratory therapy device 184. The implantable 181 and respiratory therapy devices 184 operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

Two or more of the implantable device 181, respiratory therapy device 184, and external processor 183 may operate cooperatively based on brain state for employing automatic activation of medical processes 132. For example, detection of brain state may allow two or more of the implantable device 181, respiratory therapy device 184, and external processor 183 to operate cooperatively to provide a therapy to treat a cardiac, respiratory, or other condition.

The following discussion, with reference to Figures 90A-91, describes embodiments of the invention involving automatic activation, de-activation, modification and/or control of therapy based on sleep stage. Sleep staging may be detected using various approaches, including, for example, by detecting brain activity, skeletal muscle movement, heart rate or other cardiac timing or intervals (e.g., PR interval), respiratory patterns, and/or other activity/signal that can be used as a surrogate measurement of sleep. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

Although disordered breathing may occur while the patient is awake, the disorder is much more prevalent while the patient is sleeping. In various embodiments of the invention, sleep stage information is used to enhance sleep disordered breathing therapy and/or diagnosis of a variety of sleep related disorders.

In accordance with various embodiments, sleep stage detection may be used to trigger therapy for disordered breathing. Using this approach, administration of disordered breathing therapy may be coordinated with a particular sleep stage. For example, disordered breathing episodes are typically more frequent during stage 1 or stage 2 sleep. The system may use sleep stage detection to deliver the therapy during these sleep stages. REM sleep and sleep stages 3 and 4 are the most restful sleep stages, therefore it is desirable to avoid interruption of sleep during these stages. The system may terminate or reduce the level of therapy during REM sleep and sleep stages 3 and 4 when avoidance of sleep interruptions are most desirable.

Sleep stage detection may be accomplished using a number of techniques, including, for example, a technique using muscle atonia sensors. Sleep stage detection may also be effected using patient-internal or patient-external sensors, including, for example EEG sensors and/or EMG sensors. In one configuration, the sensors, e.g., EEG and/or EMG sensors, used in combination with a respiratory therapy device, such as an xPAP device, may be positioned on the xPAP mask. Sleep stage detection may also be derived from heart rate, cardiac PR intervals (or other cardiac timing), tidal volume, respiratory rate, minute ventilation, body core temperature, or other physiological measurements that are affected by autonomic control.

Sleep stage information may also be valuable in the context of diagnosing various disorders, including sleep-related disorders. In accordance with one embodiment, sleep information, including sleep onset, offset, sleep stages, sleep efficiency, sleep latency, and the number and degree of arousals may be collected by the system for storage, display, or transmission to a remote device. The sleep-related information may be evaluated along with information about detected disordered breathing episodes to more fully understand how sleep disordered breathing affects a particular patient. The use of EEG sensors also allows detection of abnormal brain activity, including seizures. The EEG sensor information may be collected and used for a variety of diagnostic and therapeutic purposes.

Figure 90A is a flow chart illustrating a system 9001 useful for activating, de-activating or modifying a medical process using brain state information in accordance with embodiments of the invention. The system 9001 involves sensing brain activity with a

sensor 9002, either directly, such as by using an EEG sensor to measure brain-waves, or indirectly, such as by using an EMG sensor to measure muscular response to neurostimulation. An EMG sensor may be implemented, for example, using an electromyogram (EMG) electrode or force responsive sensor positioned on the housing of an implantable medical device. An EMG sensor may, for example, be positioned on the header of the implantable medical device. Alternatively, an EMG sensor (e.g., EMG electrode or strain gauge) may be positioned on a lead system or may be coupled to the housing through a catheter or lead system.

A brain activity detector 9003 receives information from the sensor 9002 and determines a brain state, which is used by a controller 9004. The controller 9004 may control one or both of an implantable medical device 9005 and a respiratory therapy unit 9006. The implantable medical device 9005 and/or the respiratory therapy unit 9006 provides therapy based on information about the sensed brain activity.

A system utilizing sleep stage sensors in connection with the control of diagnostic and/or therapeutic functions of a disordered breathing system in accordance with an embodiment of the invention is illustrated in Figure 90B. In this embodiment, patient-internal or patient-external sensors 9014, for example EEG and/or EMG sensors, are coupled to a therapy device 9011. The therapy device 9011 includes a sleep stage processor 9012 that analyzes the sensor signals to detect the patient's sleep state, including sleep offset, onset, and stages of sleep.

The sleep stage processor 9012 is coupled to a therapy control unit 9013. The therapy control unit 9013 may control various types of therapy, including, for example, disordered breathing therapy, cardiac pacing therapy, respiratory therapy, electrical stimulation therapy, muscle stimulation therapy, nerve stimulation therapy, and/or pharmacological therapy, among other therapy types. The therapy control unit 9013 uses the sleep information to initiate, terminate or adjust therapy to the patient based on the patient's sleep stage.

The therapy device 9011 may further include a memory 9014 that receives and stores information from the sleep stage processor 9012, the sensors 9014 and/or other components. The information stored in the memory 9015 may be displayed and/or downloaded to a remote device, or used for a variety of diagnostic purposes.

Another embodiment of the invention is illustrated in Figure 90C. In accordance with this embodiment, a first therapy device 9070 is used to control therapy delivery of a second therapy device 9090. The first therapy device 9070 includes a sleep stage processor

9072 coupled to sensors 9080, e.g., EEG and/or EMG sensors. The sleep stage processor receives signals from the sensors 9080 and analyzes the sensor signals to determine sleep onset, offset, and stages of sleep.

Sleep stage information is transferred from the sleep stage processor 9072 to a first therapy control unit 9074 and a second therapy control unit 9076. The therapy control units 9074, 9076 use the sleep stage information to initiate, terminate or modify the therapy delivered by the first and the second therapy devices 9070, 9090, respectively, based on the patient's sleep state.

The first therapy device 9070 may also include a memory 9077 that receives and stores information from the sleep stage processor 9072, the sensors 9080 and/or other components. The information stored in the memory 9077 may be displayed and/or downloaded to a remote device, or used for a variety of diagnostic purposes.

A further embodiment of the invention is illustrated in Figure 90D. According to this embodiment, first and second therapy devices 9010, 9030 deliver first and second therapies to a patient. The first therapy device 9010 may be implemented as a CRM device, providing cardiac pacing and/or defibrillation therapies to treat various arrhythmias and/or to provide resynchronization therapy, for example. The CRM device 9010 may also deliver electrical stimulation therapy to the heart to treat disordered breathing.

The second therapy device 9030 may be implemented as respiratory therapy device, such as an xPAP device. The xPAP device 9030 delivers air or other gas therapy at a controlled pressure to the patient's airway.

EEG sensors 9020 are coupled to a sleep stage processor 9060 located in the CRM device 9010. Other sensors, such as EMG sensors, may also be included. Signals from the EEG and/or other sensors 9020 are analyzed by the sleep stage processor 9060 to determine various stages of sleep, including sleep onset, offset, sleep stage, the number and frequency of arousals, and the degree of arousal.

Information from the sleep stage processor 9060 is provided to the respiratory therapy controller 9050 located in the CRM device 9010. The respiratory therapy controller 9050 uses the sleep stage information to initiate, terminate, or modify the respiratory therapy based on the sleep stage.

Information from the sleep stage processor 9060 and a brain wave analyzer 9062 is provided to the CRM therapy controller 9040. The CRM therapy controller140 includes a disordered breathing (DB) therapy control unit 9042 that uses the sleep stage information

to initiate, terminate, or modify electrical stimulation DB therapy delivered by the CRM device 9010 based on the patient's sleep state.

The CRM therapy controller 9040 may further include an arrhythmia therapy control unit 9044. Information from the sleep stage processor 9060 and the brain wave analyzer 9062 may be used by the arrhythmia therapy control unit to 9044 initiate, terminate, or modify arrhythmia therapy delivered to the patient.

For example, the CRM therapy controller 9040 may decrease the cardiac pacing rate to a sleep rate upon sleep onset and raise the pacing rate at sleep offset. Further, the CRM therapy controller 9040 may adjust the pacing therapy delivered to the patient during proarrhythmic sleep periods, such as REM sleep or the during morning arousal. In one example, the arrhythmia therapy control unit 9044 may deliver atrial overdrive pacing during proarrhythmic sleep periods to prevent the occurrence of arrhythmia.

The EEG sensor signals may also be used by a brain wave analyzer 9062 to evaluate brain activity. The brain wave analyzer 9062 detects abnormal brain activity, such as seizures. Patients may have seizures during the night and not realize that the seizures have occurred. Some seizures are accompanied by cardiac rhythm disturbances. The brain wave analyzer 9062 may detect the occurrence of seizures and provide information about the seizures to the arrhythmia therapy control unit 9044. The arrhythmia therapy control unit 9044 may modify the CRM therapy to treat cardiac rhythm disturbances cause by, or associated with, seizures. The arrhythmia therapy control unit 9044 may also withhold therapy for rhythm disturbances that are associated with seizures.

The CRM device 9010 may include a memory 9064 for storing information from the sleep stage processor 9060, the brain wave analyzer 9062 and other components of the CRM device 9010. Stored information may be transferred to a display or other device.

Autonomic arousal responses, as detected using EEG sensors and EMG sensors, are indicative of brain state. Arousal may be detected from changes in the sympathetic or parasympathetic nervous system. These changes may be either short-term (i.e., changes associated with individual arousals) or long-term (i.e., aggregate effect of multiple arousals). A short-term effect of arousal includes, for example, the activation of sympathetic nerve activities. Sympathetic or parasympathetic changes, or the changes of autonomic balance, may be assessed, for example, by heart rate variability (HRV), which may be readily detected using a CRM device.

Arousal information may be also used by the sleep stage processor 9060 to augment disordered breathing detection. For example, arousal information may be used to confirm

occurrences of disordered breathing. Arousal information may be used to distinguish between correctly and incorrectly identified disordered breathing occurrences indicated by the disordered breathing detector. Further, information from arousal detection may be used to separate disordered breathing episodes, e.g., apnea and/or hypopnea, followed by arousal versus those terminated without arousal. The disordered breathing events that are followed by arousal are considered to be the most disruptive, as these arousals interrupt the normal course of sleep and prevent the patient from receiving a full sleep cycle each night. Detecting these types of disordered breathing events may enhance the specificity of disordered breathing detection.

Figure 91 illustrates a method 9100 for implantably sensing and detecting brain state. A brain state sense signal is sensed at a block 9102. Brain state may be sensed, for example, directly using EEG sensors, and/or indirectly using ECG sensors, EEG sensors, EMG sensors, transthoracic impedance sensors, or other sensors suitable for determining patient brain state. If the patient is sleeping, brain state may be detected using the brain state sense signal illustrated by determination block 9104.

The brain state detected at determination block 9104 provides various types of information recorded at block 9106. For example, date, time, sensor data, sense signal amplitudes and/or cycle lengths. This and other information may be useful for updating, developing, and/or determining an arousal index, an apnea/hypopnea index, a composite index and other parameters useful for patient diagnosis and treatment, such as the automatic activation, de-activation or modification of medical processes. This information may be useful for detecting abnormal brain activity, such as seizures. The information recorded at block 9106 may be useful, for example, to predict, verify, classify, and/or determine the severity of a disordered breathing episode and abnormal brain activity.

If intervention and/or treatment is desired at determination block 9108, the intervention and/or treatment may be performed at block 9110 before re-starting the method 9100. For example, the intervention at block 9110 may be the automatic activation of a medical process, modification of a patient's CRM stimulation, modification of a disordered breathing therapy, or other desirable action.

Implantable Device Employing Movement Sensing for Detecting Sleep-Related Disorders

Aspects of the invention that include movement sensing for detecting sleep-related disorders are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include movement sensing for detecting sleep-related disorders are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

Embodiments of the invention are directed to systems and methods for detecting sleep-related disorders involving sensing physiological signals including at least muscle movement signals. Sleep-related disorders are detected using the sensed physiological signals. The sleep-related disorders include at least an involuntary muscle movement disorder and sleep-disordered breathing. The physiological signals may include movement signals, such as electromyogram signals, at least some of which may be sensed from one or

more intramuscular and/or skin/surface locations. The physiological signals may include transthoracic impedance signals, which may be sensed implantably.

Embodiments of methods of detecting sleep-related disorders may involve detecting one or more sleep stages using muscle movement signals. Methods may also involve delivering and/or controlling a therapy to treat one or more of the detected sleep-related disorders, such as a respiratory therapy, a cardiac pacing therapy, a nerve stimulation therapy, and/or a drug therapy.

Embodiments may involve detecting the sleep-related disorders patient-externally and/or patient-internally. Detecting the sleep-related disorders may involve detecting a first sleep-related disorder patient-internally and detecting a second sleep-related disorder patient-externally. Methods may further involve detecting one or more sleep stages using the muscle movement signals.

Sleep-disordered breathing may include sleep apnea, hypopnea, and/or Cheyne-Stokes respiration, and sleep-related disorders may include bruxism, periodic limb movement disorder, and/or restless leg syndrome. One or both of the physiological signals and information associated with the detected sleep-related disorders may be communicated to a patient-external processing system or an implantable medical device. Methods may further involve delivering and/or controlling a therapy to treat one or more of the detected sleep-related disorders, such as by delivering a respiratory therapy, a cardiac pacing therapy, a nerve stimulation therapy, and/or a drug therapy.

According to other embodiments, systems for detecting sleep-related disorders include one or more movement sensors, such as electromyogram (EMG) sensors, configured for sensing (internally and/or externally) movement of skeletal musculature and a sensor configured to sense a parameter associated with sleep-disordered breathing (SDB). A processor may be communicatively coupled to the movement sensors and the SDB sensor for detecting sleep-disordered breathing based on the sensed parameter and detecting an involuntary muscle movement disorder using signals produced by the movement sensors. The processor may be disposed in an implantable housing.

The processor may be disposed in a patient-external and/or patient-internal processing system. For example, the processor may be a networked processor, a component of a cardiac rhythm management system, a component of a respiratory therapy system, and/or a component of a positive airway pressure device.

The SDB sensor and/or sleep detector may include a transthoracic impedance sensor. The sleep detector may be communicatively coupled to the processor. Conditions

detected by the processor include hypopnea, bruxism, involuntary muscle movement disorder, periodic limb movement disorder, and/or restless leg syndrome. A therapy delivery system may be configured to treat the sleep-disordered breathing and involuntary muscle movement disorder. A cardiac rhythm management system, a drug delivery device, a nerve stimulation device, and/or a positive airway pressure device may be configured to treat the sleep-related disorder.

Movement sensors may include one or more accelerometers, one or more electromyogram (EMG) sensors, or a combination of these sensors. The system may include a communications interface for communicating acquired movement data and/or detection information to a patient-external and/or patient-internal processing system. Control signals may also be communicated unidirectionally or bidirectionally between the system and a remote processing system.

Embodiments of the invention involve an individual system 127 (Figure 1C) that provides movement sensing for detecting sleep-related disorders. The 127 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D and in Figure 92.

Other embodiments of the invention involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes movement sensing for detecting sleep-related disorders 127. The coordinated system may include, for example, an implantable cardiac device 181, a patient-external respiratory therapy device 184, and/or other devices, such as a drug therapy device and/or a nerve stimulation therapy device. The system may further include an external processor 183 providing a coordination function. A communication channel couples the various devices. The devices (e.g., implantable device 181, respiratory therapy device 184, drug therapy device, nerve stimulation therapy device, and/or external processing device) operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

The devices may operate cooperatively based on sensed movement indicative of sleep-related disorders 127. For example, sensing movement indicative of sleep-related disorders 127 may allow the various implantable and/or external devices to operate cooperatively to provide an appropriate therapy to treat a detected sleep-related disorder.

A number of disorders, for example, sleep-disordered breathing and movement disorders such as PLMD, occur primarily while the patient is asleep. Information about the patient's sleep stage may be used to enhance sleep monitoring and/or diagnosis of a variety

of disorders. In addition, it may be useful to provide a first therapy while the patient is awake and a second therapy while the patient is asleep. Detection of muscle movement, such as indicated by EMG, may be used to diagnose disorders as well as trigger the sleep-time therapy in a respiratory and/or cardiac device. Data acquired during sleep may assist in diagnosing various sleep-related disorders. The collected data may be stored, displayed, printed, or transmitted to a separate device.

Systems and methods may acquire and process electromyogram signals in an implantable or partially implantable device. Information acquired from electromyogram sensors may be used in connection with patient monitoring, diagnosis, and therapy. An implantable system may incorporate EMG and SDB detection for various purposes, including disease/disorder diagnosis, sleep detection, and therapy control, among other functions. The system may include one or more EMG sensors, which may be implemented as one or more patient-internal and/or one or more patient external EMG sensors.

An electromyogram sensor detects the electrical activity of muscles during muscle activity. When muscles are active, they produce an electrical current that is proportional to the level of the muscle activity. The use of EMG sensing devices is helpful in the diagnosis of many pathological conditions.

Electromyogram sensing devices may facilitate diagnosis of many pathological conditions. These conditions include, for example, muscular dystrophy, inflammation of muscles, pinched nerves, peripheral nerve damage (damage to nerves in the arms and legs), amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig disease), myasthenia gravis, disc herniation, sleep-disordered breathing, and movement disorders such as periodic limb movement, restless limb movement, and bruxism.

Embodiments are directed to systems and methods for screening and/or diagnosing and subsequently treating an involuntary limb movement condition, such as RLS or PLMD. PLMD, RLS, and/or other movement disorders such as bruxism, for example, may be diagnosed using a system that is fully or partially implantable. A partially or fully implantable device, such as a cardiac rhythm management system, may incorporate a movement detector. One or more movement sensors are coupled to the movement detector within the implantable device. The movement sensors may include any sensor or any combination of sensors capable of detecting motion and/or muscle activity associated with motion, such as accelerometers, electromyogram (EMG) sensors, and/or a combination of one or more accelerometers and one or more EMG sensors.

Signals from the movement sensors may be received and processed by the movement detector in the implantable device. The movement data may be stored in the implantable device or communicated to an external processing system, either of which may process the sensed movement information. Movement information may be processed, trended, displayed, etc. locally or remotely to detect presence of an involuntary limb movement condition.

Various therapies have been used to treat central and/or obstructive disordered breathing episodes, and may further be used to treat sleep-related muscle disorders. Obstructive sleep apnea has been associated with prolapse of the tongue and its surrounding structure into the pharynx, thus occluding the respiratory pathway. A commonly prescribed treatment for obstructive apnea is continuous positive airway pressure (CPAP). The application of continuous positive airway pressure keeps the patient's throat open, reducing or eliminating the obstruction causing apnea.

The following discussion, with reference to Figure 92, describes embodiments of the invention involving disease/disorder diagnosis using an EMG detector and SDB detector in an implanted or partially implanted device. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy. Information acquired from EMG detector and the SDB detector may be used in connection with patient monitoring, diagnosis, and therapy.

Figure 92 illustrates an implantable system 9200 incorporating EMG and SDB detection that may be used for sleep-related disease/disorder diagnosis, sleep detection, and therapy control, among other functions. In accordance with various embodiments, the system 9200 includes one or more EMG sensors 9220, which may be implemented as one or more patient-internal and/or one or more patient external EMG sensors.

The EMG sensor or sensors 9220 may be positioned in or on the patient's body at one or more selected locations to sense electrical muscular activity at the one or more selected locations. The location of the EMG sensor or sensors 9220 depends on the specific application. For example, one or more EMG sensors 9220 may be positioned intramuscularly or on the surface of the skin above the muscle to detect the electrical activity of the muscle.

Intramuscular placement of EMG sensors involves inserting a needle electrode through the skin into the muscle whose electrical activity is to be measured. Because

skeletal muscles are often large, several needle electrodes may need to be placed at various locations to obtain an accurate reading of muscle activity.

Signals from EMG sensor or sensors 9220 may be transmitted to an EMG detector 9212 of the implanted device 9210 through leads or using a wireless communications link. The EMG detector 9212 receives signals from the EMG sensor or sensors 9220 and processes the signals for use by a diagnosis processor 9216 and/or a sleep detector 9214, for example.

The sleep detector 9214 may use EMG information to determine various sleep stages, including REM sleep. The sleep detector 9214 may also provide information from the EMG detector 9212 to a sleep disordered breathing detector 9213, which may use the EMG sensors 9220 to detect sleep disordered breathing episodes, and/or may be coupled to one or more SDB sensors 9215. It is understood that other component connection/communication architectures are possible in addition to those shown in Figure 92. In one implementation, one or more EMG sensors 9220 may be placed on the patient's face to facilitate the detection of REM sleep. For example, one or more surface EMG sensors 9220 may be placed on the patient's chin or jaw, e.g., on the mentalis muscle and/or submentalis muscle, to detect muscle atonia associated with rapid eye movement sleep.

In another implementation, one or more EMG sensors 9220 and/or SDB sensors 9215 may be placed on the housing, header, or lead of an implanted device 9210 positioned in the pectoral region of the patient. In one configuration, the EMG sensors 9220 may be used to detect atonia of the pectoral muscles during REM sleep. A sleep detector 9214 may use information from the EMG detector 9212 to facilitate the detection of sleep onset and offset, and to determine the various stages of sleep. Detection of sleep stages may be used, for example, in patient monitoring, diagnosis and/or therapy for various disorders, including sleep-disordered breathing.

The diagnosis processor 9216 may use EMG-related information and SDB detection to diagnose a variety of diseases or disorders such as those listed above. Disease/disorder diagnosis may be facilitated using information acquired from the EMG detector 9212 associated with the patient's muscle activity, limb movements, and respiratory motions, for example. The diagnosis processor 9216 may also use information about the patient's sleep stages to aid in diagnosis.

In various embodiments, the diagnosis processor 9216 may use EMG-related information and SDB detection to diagnose disorders and diseases involving muscle

dysfunction, such as those caused by muscle inflammation and/or muscular dystrophy for example. The EMG information may be used to diagnose muscle weakness due to nerve disorders, including pinched nerves, peripheral nerve damage, amyotrophic lateral sclerosis (ALS), myasthenia gravis, and disc herniation, for example. The EMG- and SDB-related information may be used to diagnose a variety of movement disorders, such as periodic limb movement disorders and/or restless legs syndrome.

In other embodiments, the diagnosis processor may use information from the EMG detector 9212 to diagnose disordered breathing. For example, EMG sensor or sensors 9220 may be used to sense activity of the intercostal muscles produced by expansion of the chest during respiration. As previously described, the absence or presence of chest motion may be used to discriminate between central or obstructive apnea.

Alternatively, or additionally, an EMG sensor 9220 may be used to detect obstructive apnea based on the degree of patency of the upper airway. Obstructive apnea is caused by upper airway occlusion due to the collapse of soft tissue in the rear of the throat. One or more EMG sensors 9220 placed on the patient's chin or jaw may be used to detect muscle activity associated with tongue movement opening the upper airway.

A majority of disordered breathing episodes occur while the patient is sleeping. Sleep-related disorders such as sleep-disordered breathing may be more prevalent during particular sleep stages. Information about sleep stages, and about the frequency, number, and degree of arousals from sleep may be useful in the diagnosis of disordered breathing. Thus, a diagnosis of disordered breathing may be enhanced using sleep information from the sleep detector 9214.

In other embodiments, diagnosis of various movement disorders, such as periodic limb movement disorder (PLMD), restless leg syndrome (RLS), and bruxism (nighttime teeth grinding) may be facilitated using one or more EMG sensors 9220 coupled to an implantable device 9210. Periodic limb movement disorder and restless leg syndrome are disorders that involve undesirable movements of the limbs as described in more detail below.

One or more EMG sensors 9220 may be placed in or on the muscles of the limbs or other muscles to detect limb movements. For example, EMG sensors 9220 placed on or in the anterior tibialis muscles may be used to identify leg movements associated with PLMD and/or RLS. EMG sensors 9220 placed on the jaw may be used to identify tempomanidibular disorders such as nighttime teeth grinding or other involuntary jaw movements.

EMG-related information may be trended, stored, displayed, or transmitted from the implantable device 9210 to another device. In one embodiment, information from the EMG detector 9212, the sleep detector 9214, and/or the diagnosis processor 9216 is downloaded to a remote device, such as a programmer 9260 or advanced patient management system 9230 for further analysis by the remote device 9230, 9260 and/or the patient's physician.

Information from the EMG detector, 9212 the sleep detector 9214,the SDB detector 9213, and/or the diagnosis processor 9216 may optionally be used to adjust therapy provided to a patient. Therapy provided by the implanted device 9210 may be adjusted by the patient's physician or by a remote device, such as an APM 9230 device or programmer 9260. In one example, the patient's physician may send a command through the programmer 9260 or APM device 9230 to a therapy control unit 9218 in the implanted device 9210 to initiate, terminate, or modify therapy. In another example, the APM device 9230, 9260 may automatically command the implanted device 9210 to adjust therapy based on analysis performed in the remote device 9230, 9260. In another embodiment, the therapy control unit 9218 of the implanted device 9210 may use information from the EMG detector 9212, the sleep detector 9214, and/or the diagnosis processor 9216, to automatically adjust therapy provided to a patient.

The EMG-related information and SDB detection information acquired by the implantable device 9210 may be transferred to other therapy devices, such as drug delivery devices 9250, respiration therapy devices 9240, and/or nerve stimulation therapy devices 9255, such as devices that deliver a transcutaneous electric nerve stimulation therapy.

The EMG-related information acquired by the implantable device 9210 may be transferred to other therapy devices (internal or external), such as drug delivery devices 9250 and/or nerve stimulation therapy devices 9255. For example, transcutaneous electric nerve stimulation may improve symptoms in some RLS sufferers who also have PLMD. Electrical stimulation may be applied to an area of the legs or feet, usually before bedtime, for about 15 to 30 minutes. Transcutaneous electric nerve stimulation therapy has been found to be helpful in reducing nighttime leg jerking.

The transferred information may be used to adjust the therapy delivered by one or more of the therapy devices 9240, 9250, 9255, or used in further diagnosis and/or monitoring functions, for example. Examples of drugs useful with the drug therapy device 9250 include dopamine agents (muscle relaxers), benzodiazepines (sedatives), anti-convulsants (to reduce muscle activity), and opioids (narcotics to reduce motor activity).

Although the sleep detector 9214, the diagnosis processor 9216, and the therapy control unit 9218 are illustrated internal to the implantable device 9210, it is contemplated that any or all of these components may be patient-external in alternate embodiments, and may be incorporated into other components such as the APM 9230, for example. Similarly, the respiration therapy devices 9240, drug delivery devices 9250, and/or nerve stimulation therapy devices 9255 illustrated as patient-external in Figure 92, may be included in the implantable device 9210 in alternate embodiments. Moreover, all or particular component(s) of these devices 9240, 9250, 9255 may be configured for patient-internal placement, patient-external placement, or both patient-internal and patient-external placement.

The following discussion, with reference to Figures 93-95, describes embodiments involving detection of movement disorders. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

In accordance with embodiments of the invention, PLMD, RLS, and/or other movement disorders such as bruxism, for example, may be diagnosed using a system that is fully or partially implantable. Figure 93 illustrates an implantable medical device, e.g., a CRM that incorporates a movement/SDB detector 9312. One or more movement/SDB sensor(s) 9320 are coupled to the movement/SDB detector 9312 within an implantable device 9310. Although illustrated as a single block 9312 in Figure 93 (and in Figure 94) for simplicity, it is understood that the movement detector and SDB detector may be represented as separate blocks. Similarly, it is understood that the movement sensor(s) and SDB sensors(s) of block 9320 may be represented as separate blocks.

The movement/SDB sensor(s) 9320 may include any sensor or any combination of sensors capable of detecting motion and/or muscle activity associated with motion. For example, the patient's movements may be detected using one or more accelerometers, one or more EMG sensors, and/or a combination of one or more accelerometers and one or more EMG sensors.

In various embodiments, one or more movement sensors (e.g., accelerometers and/or EMG sensors) are coupled to the patient at appropriate locations to detect movements of the extremities, e.g., limb movements, or other movements. Signals from the movement/SDB sensor(s) 9320 are received and processed by a movement/SDB detector 9312 in the implantable device 9310. The movement/SDB detector 9312 may

cooperate with a memory in a monitoring unit 9314 to store information about the detected movements. Movement information may be stored, trended, displayed, and/or transmitted to a separate device, such as an APM system 9330 or a programmer 9340 for further operations.

In other embodiments, as illustrated in Figure 94, one or more movement/SDB sensor(s) 9320 are coupled to a movement/SDB detector 9312 within the implantable device 9310, as previously discussed. The implantable device 9310 also includes a movement disorder diagnosis processor 9415 that receives movement information from the movement/SDB detector 9312. The movement disorder diagnosis processor 9415 evaluates the movement information to determine if the movements are consistent with various movement disorders such as RLS and/or PLMD.

In one example, the movement/SDB sensor(s) 9320 may include one or more EMG sensors placed on or in the anterior tibialis. Typical EMG bursts due to PLMD movements may last between 0.5-5 seconds and may recur every 20-40 seconds, for example. The movement disorder diagnosis processor 9415 may make a diagnosis of PLMD if at least about 40 EMG bursts are detected within an 8-hour sleep period, for example. Sleep disruption caused by the PLMD movements may be determined by any or a combination of the sleep detection techniques described herein, including, for example, brain wave (EEG) sensing and/or a combination of respiration (MV) and activity sensing, among others. Movement disorder diagnosis may be downloaded to a programmer 9340, an APM system 9330, or other therapeutic or diagnostic device.

In accordance with another embodiment, RLS diagnosis may involve patient input regarding their symptoms. For example, as illustrated in Figures 93 and 94, a patient input device 9350 may be used to acquire information from the patient regarding the patient's perception of symptoms. The patient may be prompted to rate their symptoms on a scale of 0 to 4, or some other scale, for example with a lower number representing fewer RLS symptoms and higher number representing greater RLS symptoms, for example. The patient input may be acquired using the patient input device 9350 over a period of days, for example, about three days to about nine days to establish a diagnosis. Patient input through the patient input device 9350 may also be acquired after diagnosis and/or treatment, for example to assess status of the disorder or the efficacy of treatment.

For example, if the patient input is acquired over a period of six days, the maximum score is 24, i.e., a score of four for each or six days. In this scenario, a score greater than

about 12 suggests a diagnosis of severe RLS. A score of about six to about twelve suggests a diagnosis of moderate RLS.

In the embodiment illustrated in Figure 93, information about SDB and RLS symptoms may be acquired by the patient input device 9350 and transmitted to an APM device 9330, the programmer 9340, or other device for monitoring, display, storage, evaluation, and/or diagnosis. In the embodiment illustrated in Figure 94, the information acquired by the patient input device 9350, along with the movement information, may be used by the movement disorder diagnosis processor 9415 in the implantable device 9310 to make a diagnosis of RLS.

Embodiments of the present invention are directed to methods and systems for diagnosis of SDB and movement disorders such as PLMD and RLS. RLS diagnosis may be complicated due to the symptom based nature of the RLS diagnosis. The use of patient input through a patient-input device provides a system for collection of symptom based information. Because PLMD and RLS are related disorders, the diagnosis of PLMD through movement detection techniques described herein may be used to enhance the RLS diagnosis.

Use of such methods and systems may reduce the need for in-clinic sleep studies typically used for movement disorder diagnosis. Further, daily measurements may be made over a number of days, which is not practical for in-clinic studies. Earlier and more frequent diagnosis of movement disorders may be enabled using the systems and methods of the invention.

Figure 95 illustrates a method 9500 of implantably sensing and detecting movement useful for diagnosing sleep-related muscle disorders and sleep disordered breathing. A muscle activity signal is sensed at a block 9502. Muscle activity may be sensed, for example, using EMG sensors, accelerometers, or other sensors suitable for determining patient movement. A determination block 9504 is used to decide if the patient is sleeping. If determination 9504 concludes that the patient is not sleeping, the method 9500 loops back to the beginning.

If the patient is determined to be sleeping at block 9504, the muscle activity sensed at block 9502 provides information recorded at block 9506. For example, date, time, sensor data, sense signal amplitudes or other information may be useful for updating, developing, and/or determining an muscle disorder index, a diagnosis, a sleep-related muscle activity history, and other parameters useful for patient diagnosis and treatment. The information recorded at block 9506 may be useful, for example, to predict, verify,

classify, and/or determine the existence of a sleep-related muscle disorder and sleep disordered breathing.

If intervention and/or treatment is desired at determination block 9508, the intervention and/or treatment may be performed at block 9510 before re-starting the method 9500. For example, the intervention at block 9510 may be the automatic activation of a medical process, modification of a disordered breathing therapy, notification to a patient-external device and/or a physician, or other desirable action.

System and Method for Detecting an Involuntary Muscle Movement Disorder

Aspects of the invention that include involuntary muscle movement disorder detection are directed to methods and systems configured to monitor, diagnose, and/or provide patient therapy using one or more individual medical procedures. Each of the circles 180 illustrated in Figures 1B—1D represents an individual medical procedure providing a specific monitoring, diagnosis or therapeutic function or set of functions. Each individual medical procedure may be implemented as a stand-alone system. Two or more of the individual medical procedures 180 may be used in combination to provide more comprehensive patient monitoring, diagnosis and/or therapy. One or more functions of two or more individual medical procedures 180 may be used in combination to enhance patient monitoring, diagnosis and/or therapy.

Other aspects of the invention that include involuntary muscle movement disorder detection are directed to methods and systems configured to monitor, diagnose, and/or provide therapy using coordinated medical procedures. Coordinated medical procedures may involve cooperative operation of two or more of the individual processes 180. Coordinated medical procedures may also involve cooperative operation of one or more functions of two or more of the individual processes 180.

Coordinated use of two or more medical procedures typically involves transfer of some form of information, such as data and/or control signals, that is used by, or influences the behavior of the medical procedures or devices implementing such medical procedures. The transfer of information may implicate one of the medical procedures, some of the medical procedures, or all of the medical procedures. The transfer of information may implicate other processes that interact with one or more medical procedures, such as processes implemented by a patient-external processing system. The transfer of information may be unidirectional or bi-directional with respect to medical procedures and/or other processes.

System and method embodiments provide for evaluating pathological conditions associated with an involuntary limb movement disorder. According various embodiments, evaluating a pathological condition involves sensing muscle movement signals, and implantably detecting presence of an involuntary muscle movement disorder using the muscle movement signals. Sensing the muscle movement signals may be preformed implantably and externally. Detecting presence of the involuntary muscle movement disorder may involve detecting a sleep-related involuntary muscle movement disorder and/or a non sleep-related involuntary muscle movement disorder using the sensed muscle movement signals.

Detecting presence of the involuntary muscle movement disorder may involve detecting a disease or pathological syndrome using the muscle movement signals. Detecting presence of the involuntary muscle movement disorder may involve detecting conditions associated with bruxism, periodic limb movement disorder, restless leg syndrome, muscular dystrophy, muscle inflammation, pinched nerves, peripheral nerve damage, amyotrophic lateral sclerosis, myasthenia gravis, and disc herniation, for example.

Sensing muscle movement signals may involve acquiring data from a sensor directly detecting physical movement, such as an accelerometer. Sensing muscle movement signals may involve acquiring data from a sensor detecting bio-electrical changes associated with movement, such as an electromyogram sensor. Sensing muscle movement signals may involve acquiring data from sensors detecting physical movement and bio-electrical changes.

Onset and offset of sleep may be detected, for purposes of discriminating between sleep-related and non sleep-related involuntary limb movement conditions, for example. Sensed muscle movement signals and/or information associated with the detected involuntary muscle movement disorder may be communicated to a patient-external processing system, such as a network, or to a patient-internal processing system.

A therapy based on one or both of the muscle movement signals and the detected involuntary muscle movement disorder may be delivered to the patient. For example, a drug therapy, nerve stimulation therapy, or other therapy may be delivered to treat the detected involuntary muscle movement disorder.

According other embodiments, systems for evaluating a pathological condition include a sensor configured to sense movement of skeletal musculature, a detector coupled to the sensor, and an implantable processor coupled to the detector. The processor is

configured to determine presence of an involuntary muscle movement disorder, such as those discussed above.

In one configuration, one of the sensor and detector includes an implantable component. In another configuration, each of the sensor and detector includes an implantable component. The sensor may include one or both of electromyogram (EMG) sensors and an accelerometer. A sleep detector may be coupled to the processor, and the processor may detect a sleep-related involuntary muscle movement disorder and/or a non sleep-related involuntary muscle movement disorder.

Systems may include a communication interface coupled to the processor. The communication interface may be configured to effect connectivity between the processor and a patient-external processing system, such as an external network. Systems may also include a therapy delivery system configured to deliver a therapy to treat the involuntary muscle movement disorder, such as a drug therapy device, nerve stimulation therapy, or other therapy device.

Embodiments of the invention involve an individual system 141 (Figure 1D) for detecting involuntary muscle movement disorder detection. The involuntary muscle movement disorder detection system 141 may be implemented as a stand alone system or in combination with other individual medical systems, such as those described in Figures 1B—1D and in Figure 96.

Other embodiments of the invention involve a system for providing coordinated patient monitoring, diagnosis and/or therapy that utilizes involuntary muscle movement disorder detection 141. The coordinated system may include, for example, an implantable cardiac device 181, a patient-external respiratory therapy device 184, and/or other devices, such as a drug therapy device and/or a nerve stimulation therapy device. The system may further include an external processor 183 providing a coordination function. A communication channel couples the various devices. The devices (e.g., implantable device 181, respiratory therapy device 184, drug therapy device, nerve stimulation therapy device, and/or external processing device) operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy. The devices may operate cooperatively based on detection of an involuntary muscle movement disorder 141. For example, involuntary muscle movement disorder detection 141 may allow the various implantable and/or external devices to operate cooperatively to provide an appropriate therapy to treat the involuntary muscle movement disorder or other associated disorder.

Systems and methods provide for acquisition and processing of muscle movement signals in an implantable or partially implantable device. Information acquired from muscle movement sensors may be used in connection with patient monitoring, diagnosis, and therapy. An implantable system may incorporate muscle movement detection for various purposes, including disease diagnosis, sleep detection, and therapy control, among other functions. Systems may include one or more movement sensors, which may be implemented as one or more patient-internal and/or one or more patient external movement sensors. For example, systems may include one or more electromyogram (EMG) sensors, which may be implemented as one or more patient-internal and/or one or more patient external EMG sensors. Systems may alternatively, or additionally, include one or more accelerometers to detect muscle movement, and may further be used to detect patient sleep and non sleep.

An EMG sensor detects the electrical activity of muscles during muscle activity. When muscles are active, they produce an electrical current that is proportional to the level of the muscle activity. Electromyogram sensing devices of the present invention may facilitate diagnosis of many pathological conditions. These conditions include, for example, muscular dystrophy, inflammation of muscles, pinched nerves, peripheral nerve damage (damage to nerves in the arms and legs), amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig disease), myasthenia gravis, disc herniation, and movement disorders such as periodic limb movement, restless limb movement, and bruxism.

Various embodiments are directed to systems and methods for screening and/or diagnosing an involuntary limb movement condition, such as Restless Leg Syndrome (RLS) or Periodic Limb Movement Disorder (PLMD). PLMD, RLS, and/or other movement disorders such as bruxism, for example, may be diagnosed using a system that is fully or partially implantable. A partially or fully implantable system, such as a cardiac rhythm management system, may incorporate a movement detector. One or more movement sensors are coupled to the movement detector within the implantable device. The movement sensors may include any sensor or any combination of sensors capable of detecting motion and/or muscle activity associated with motion, such as accelerometers, electromyogram (EMG) sensors, and/or a combination of one or more accelerometers and one or more EMG sensors.

Signals from the movement sensors may be received and processed by the movement detector in the implantable device. The movement data may be stored in the implantable device or communicated to an external processing system, either of which may

process the sensed movement information. Movement information may be processed, trended, displayed, etc. locally or remotely to detect presence of an involuntary limb movement condition.

Embodiments of the present invention are directed to implementing components and/or functions of an electromyogram sensor in an implanted or partially implanted medical device. Information acquired from the electromyogram sensor(s) may be used in connection with patient monitoring, diagnosis, and therapy.

The following discussion, with reference to Figure 96, describes embodiments of the invention involving disease diagnosis using an EMG in an implanted device. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described or incorporated herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

Figure 96 illustrates an implantable system 9600 incorporating EMG detection that may be used for disease diagnosis, sleep detection, and therapy control, among other functions. In accordance with various embodiments, the system 9600 includes one or more EMG sensors 9620, which may be implemented as one or more patient-internal and/or one or more patient external EMG sensors.

The EMG sensor or sensors 9620 may be positioned in or on the patient's body at one or more selected locations to sense electrical muscular activity at the one or more selected locations. The location of the EMG sensor or sensors 9620 depends on the specific application. For example, one or more EMG sensors 9620 may be positioned intramuscularly or on the surface of the skin above the muscle to detect the electrical activity of the muscle.

Intramuscular placement of EMG sensors involves inserting a needle electrode through the skin into the muscle whose electrical activity is to be measured. Because skeletal muscles are often large, several needle electrodes may need to be placed at various locations to obtain an accurate reading of muscle activity.

Signals from EMG sensor or sensors 9620 may be transmitted to an EMG detector 9612 of the implanted device 9610 through leads or using a wireless communications link. The EMG detector 9612 receives signals from the EMG sensor or sensors 9620 and processes the signals for use by a diagnosis processor 9616 and/or a sleep detector 9614, for example.

A number of muscle-related disorders occur primarily while the patient is asleep. Information about the patient's sleep stage may be used to enhance sleep monitoring and/or diagnosis of a variety of disorders. In addition, it may be useful to provide a first therapy while the patient is awake and a second therapy while the patient is asleep. Detection of EMG signals may be used to diagnose disorders as well as trigger sleep-time therapy. Collected data may be stored, displayed, printed, or transmitted to a separate device.

By way of example, the sleep detector 9614 may use EMG information to determine various sleep stages, including REM sleep. In one implementation, one or more EMG sensors 9620 may be placed on the patient's face to facilitate the detection of REM sleep. For example, one or more surface EMG sensors 9620 may be placed on the patient's chin or jaw, e.g., on the mentalis muscle and/or submentalis muscle, to detect muscle atonia associated with rapid eye movement sleep.

In another implementation, one or more EMG sensors 9620 may be placed on the housing, header, or lead of an implanted device 9610 positioned in the pectoral region of the patient. In this configuration, the EMG sensors 9620 may be used to detect atonia of the pectoral muscles during REM sleep. A sleep detector 9614 may use information from the EMG detector 9612 to facilitate the detection of sleep onset and offset, and to determine the various stages of sleep. Detection of sleep stages may be used, for example, in patient monitoring, diagnosis and/or therapy for various disorders.

The diagnosis processor 9616 may use EMG-related information to diagnose a variety of diseases or disorders such as those listed above. Disease/disorder diagnosis may be facilitated using information acquired from the EMG detector 9612 associated with the patient's muscle activity, limb movements, and respiratory motions, for example. The diagnosis processor 9616 may also use information about the patient's sleep stages to aid in diagnosis.

In various embodiments, the diagnosis processor 9616 may use EMG information to diagnose muscle and/or nerve disorders, such as those caused by muscle inflammation and/or muscular dystrophy for example. The EMG information may be used to diagnose muscle weakness due to nerve disorders, including pinched nerves, peripheral nerve damage, amyotrophic lateral sclerosis (ALS), myasthenia gravis, and disc herniation, for example. The EMG information may be used to diagnose a variety of movement disorders, such as periodic limb movement disorders and/or restless legs syndrome.

In yet another embodiment, diagnosis of various movement disorders, such as PLMD, RLS, and bruxism (nighttime teeth grinding) may be facilitated using one or more

EMG sensors 9620 coupled to an implantable device 9610. Periodic limb movement disorder and restless leg syndrome are disorders that involve undesirable movements of the limbs as described in more detail below.

One or more EMG sensors 9620 may be placed in or on the muscles of the limbs or other muscles to detect limb movements. For example, EMG sensors 9620 placed on or in the anterior tibialis muscles may be used to identify leg movements associated with PLMD and/or RLS. EMG sensors 9620 placed on the jaw may be used to identify tempomanidibular disorders such as nighttime teeth grinding or other involuntary jaw movements.

EMG-related information may be trended, stored, displayed, or transmitted from the implantable device 9610 to another device. In one embodiment, information from the EMG detector 9612, the sleep detector 9614, and/or the diagnosis processor 9616 is downloaded to a remote device, such as a programmer 9660 or an advanced patient management (APM) device 9630 for further analysis by the APM device 9630, programmer 9660 and/or the patient's physician.

Information from the EMG detector, 9612 the sleep detector 9614, and/or the diagnosis processor 9616 may optionally be used to adjust therapy provided to a patient. Therapy provided by the implanted device 9610 may be adjusted by the patient's physician or by a remote device, such as the APM device130 or programmer 9660. In one example, the patient's physician may send a command through the programmer 9660 or APM device 9630 to a therapy control unit 9618 in the implanted device 9610 to initiate, terminate, or modify therapy.

In another example, the APM device 9630 and/or the programmer 9660 may automatically command the implanted device 9610 to adjust therapy based on analysis performed in the APM device 9630 and/or the programmer 9660. In another embodiment, the therapy control unit 9618 of the implanted device 9610 may use information from the EMG detector 9612, the sleep detector 9614, and/or the diagnosis processor 9616, to automatically adjust therapy provided to a patient.

The EMG-related information acquired by the implantable device 9610 may be transferred to other therapy devices (internal or external), such as drug delivery devices 9650 and/or nerve stimulation therapy devices 9655. For example, transcutaneous electric nerve stimulation may improve symptoms in some RLS sufferers who also have PLMD. Electrical stimulation may be applied to an area of the legs or feet, usually before bedtime,

for about 15 to 30 minutes. Transcutaneous electric nerve stimulation therapy has been found to be helpful in reducing nighttime leg jerking.

The transferred information may be used to adjust the therapy delivered by the drug therapy device 9650, nerve stimulation therapy device 9655, and/or other therapy device, or used in further diagnosis and/or monitoring functions, for example. Examples of drugs useful with the drug therapy device 9650 include dopamine agents (muscle relaxers), benzodiazepines (sedatives), anti-convulsants (to reduce muscle activity), and opioids (narcotics to reduce motor activity).

Although the sleep detector 9614, the diagnosis processor 9616, and the therapy control unit 9618 are illustrated internal to the implantable device 9610, it is contemplated that any or all of these components may be patient-external in alternate embodiments, and may be incorporated into other components such as the APM 9630, for example. Similarly, the drug delivery devices 9650 and/or nerve stimulation devices 9655, illustrated patient-external in Figure 96, may be included in the implantable device 9610 in alternate embodiments.

The following discussion, with reference to Figures 97A-97B, describes embodiments of the invention involving detection of movement disorders. The processes and systems exemplified by these embodiments may be implemented alone or in combination with one or more processes and systems exemplified by other embodiments described herein to provide a coordinated approach to patient monitoring, diagnosis, and/or therapy.

In accordance with embodiments of the invention, PLMD, RLS, and/or other movement disorders such as bruxism, for example, may be diagnosed using a system that is fully or partially implantable. Figure 97A illustrates an implantable medical device, e.g., a CRM that incorporates a movement detector 9712. One or more movement sensors 9720 are coupled to the movement detector 9712 within an implantable device 9710.

The movement sensors 9720 may include any sensor or any combination of sensors capable of detecting motion and/or muscle activity associated with motion. For example, the patient's movements may be detected using one or more accelerometers, one or more EMG sensors, and/or a combination of one or more accelerometers and one or more EMG sensors.

In one embodiment, one or more movement sensors (e.g., accelerometers and/or EMG sensors) are coupled to the patient at appropriate locations to detect movements of the extremities, e.g., limb movements, or other movements. Signals from the movement

sensors 9720 are received and processed by a movement detector 9712 in the implantable device 9710. The movement detector 9712 may cooperate with a memory in a monitoring unit 9714 to store information about the detected movements. Movement information may be stored, trended, displayed, and/or transmitted to a separate device, such as an APM system 9730 or a programmer 9740 for further operations.

In another embodiment, illustrated in Figure 97B, one or more movement sensors 9720 are coupled to a movement detector 9712 within the implantable device 9710, as previously discussed. The implantable device 9710 also includes a movement disorder diagnosis processor 9715 that receives movement information from the movement detector 9712. The movement disorder diagnosis processor 9715 evaluates the movement information to determine if the movements are consistent with various movement disorders such as RLS and/or PLMD.

In one example, the movement sensors 9720 may include one of more EMG sensors placed on or in the anterior tibialis. Typical EMG bursts due to PLMD movements may last between 0.5-5 seconds and may recur every 20-40 seconds, for example. The movement disorder diagnosis processor 9715 may make a diagnosis of PLMD if at least about 40 EMG bursts are detected within an 8-hour sleep period, for example.

Sleep disruption caused by the PLMD movements may be determined by any or a combination of the sleep detection techniques described herein, including, for example, brain wave (EEG) sensing and/or a combination of respiration (e.g., minute ventilation) and activity sensing, among others. Alternately or additionally, detection of sleep disruption, such as by using a minute ventilation sensor, may be used to confirm PLMD. Movement disorder diagnosis may be downloaded to a programmer 9740, an APM system 9730, or other therapeutic or diagnostic device.

In accordance with another embodiment of the invention, RLS diagnosis may involve patient input regarding their symptoms. For example, as illustrated in Figures 97A and 97B, a patient input device 9750 may be used to acquire information from the patient regarding the patient's perception of symptoms. The patient may be prompted to rate their symptoms on a scale of 0 to 4, or some other scale, for example with a lower number representing fewer RLS symptoms and higher number representing greater RLS symptoms, for example. The patient input may be acquired using the patient input device 9750 over a period of days, for example, about three days to about nine days to establish a diagnosis. Patient input through the patient input device 9750 may also be acquired after diagnosis and/or treatment, for example to assess status of the disorder or the efficacy of treatment.

For example, if the patient input is acquired over a period of six days, the maximum score is 24, i.e., a score of four for each or six days. In this scenario, a score greater than about 12 suggests a diagnosis of severe RLS. A score of about six to about twelve suggests a diagnosis of moderate RLS.

In the embodiment illustrated in Figure 97A, information about RLS symptoms may be acquired by the patient input device 9750 and transmitted to an APM device 9730, the programmer 9740, or other device for monitoring, display, storage, evaluation, and/or diagnosis. In the embodiment illustrated in Figure 97B, the information acquired by the patient input device 9750, along with the movement information, may be used by the movement disorder diagnosis processor 9715 in the implantable device 9710 to make a diagnosis of RLS .

Embodiments of the present invention are directed to methods and systems for diagnosis of movement disorders such as PLMD and RLS. RLS diagnosis may be complicated due to the symptom based nature of the RLS diagnosis. The use of patient input through a patient-input device provides a system for collection of symptom based information. Because PLMD and RLS are related disorders, the diagnosis of PLMD through movement detection techniques described herein may be used to enhance the RLS diagnosis.

Use of the methods and systems of the invention may reduce the need for in-clinic sleep studies typically used for movement disorder diagnosis. Further, daily measurements may be made over a number of days which is not practical for in-clinic studies. Earlier and more frequent diagnosis of movement disorders may be enabled using the systems and methods of the invention.

Figures 98A-98D illustrate various configurations of an EMG sensor mechanically coupled to an implanted medical device 9820, such as an implantable pacemaker or implantable cardioverter/defibrillator in accordance with embodiments of the invention, which may be useful for diagnosing diseases such as sleep-related muscle disorders. The implantable medical device 9820 may include a housing 9822 enclosing the medical device circuitry and a header 9824 for coupling a lead system 9840 to the circuitry of the medical device 9820.

A movement sensor may be implemented, for example, to include an EMG sensor that employs one or more EMG electrodes 9826 or a force responsive sensor 9830 positioned on the housing 9822 of the medical device 9820 as illustrated in Figures 98C and 98D, respectively. Figure 98C illustrates one or more EMG electrodes 9828 positioned

on the header 9824 of the medical device 9820. Alternatively, a movement sensor 9842 (e.g., one that includes one or more EMG electrodes or a strain gauge) may be positioned on the lead system 9840 or may be coupled to the housing 9822 through a catheter or lead system 9840, such as by using the header 9824, as illustrated in Figure 98D.

Figure 99 illustrates a method 9900 of implantably sensing and detecting movement used for diagnosis of sleep-related muscle disorders. A muscle activity signal is sensed at a block 9902. Muscle activity may be sensed, for example, using EMG sensors, accelerometers, or other sensors suitable for determining patient movement. A determination block 9904 is used to decide if the patient is sleeping. If determination 9904 decides the patient is not sleeping, the method 9900 loops back to the beginning.

If the patient is determined to be sleeping at block 9904, the muscle activity sensed at block 9902 provides information recorded at block 9906. For example, date, time, sensor data, sense signal amplitudes or other information may be useful for updating, developing, and/or determining an muscle disorder index, a diagnosis, a sleep-related muscle activity history, and other parameters useful for patient diagnosis and treatment. The information recorded at block 9906 may be useful, for example, to predict, verify, classify, and/or determine the existence of a sleep-related muscle disorder.

If intervention and/or treatment is desired at determination block 9908, the intervention and/or treatment may be performed at block 9910 before re-starting the method 9900. For example, the intervention at block 9910 may be the automatic activation of a medical process, modification of a patient's CRM stimulation, modification of a therapy, notification to a patient-external device and/or a physician, or other desirable action.

It will, of course, be understood that various modifications and additions can be made to the preferred embodiments discussed hereinabove without departing from the scope of the present invention. Accordingly, the scope of the present invention should not be limited by the particular embodiments described above, but should be defined only by the claims set forth below and equivalents thereof.

# CLAIMS

What is claimed is:

1. A system, comprising:

an implantable device configured to perform at least one cardiac-related function;

a patient-external respiratory therapy device; and

a communication channel configured to facilitate communication between the implantable device and the respiratory therapy device, the implantable and respiratory therapy devices configured to operate cooperatively via the communication channel to provide one or more of patient monitoring, diagnosis, and therapy.

2. The system of claim 1, wherein the implantable and respiratory therapy devices are configured to operate cooperatively to detect disordered breathing.

3. The system of claim 1, further comprising a disordered breathing discrimination system, comprising:

a disordered breathing detector configured to detect a disordered breathing event;

a motion sensor configured to sense motion associated with respiratory effort of a patient during the disordered breathing event; and

a disordered breathing classification processor coupled to the motion sensor and the disordered breathing detector, the disordered breathing classification processor configured to classify the disordered breathing event based on the respiratory effort motion, wherein at least one of the disordered breathing detector, the motion sensor, and the disordered breathing classification processor comprises an implantable component and the implantable and respiratory therapy devices are configured to operate cooperatively based on the classification of the disordered breathing event.

4. The system of claim 1, further comprising a disordered breathing prediction system, comprising:

a detector system configured to detect conditions associated with disordered breathing; and

a prediction engine coupled to the detector system and configured to compare the detected conditions to one or more sets of prediction criteria and predict the disordered breathing based on the comparison, wherein the prediction engine includes an implantable component, and wherein the implantable and respiratory therapy devices are configured to operate cooperatively to make or use the prediction of the disordered breathing.

5. The system of claim 1, wherein the implantable device and the patient-external respiratory therapy device are configured to operate cooperatively to adapt a therapy for disordered breathing.

6. The system of claim 1, wherein the implantable device further comprises:

a circuit configured to detect cardiac beats and obtain cardiac intervals between cardiac beats;

a controller coupled to the circuit and configured to determine a first indicated pacing interval based at least on a cardiac interval duration and a previous value of the first indicated pacing interval; and

a cardiac pacing circuit coupled to the controller and configured to provide cardiac pacing to mitigate disordered breathing based on the first indicated pacing interval.

7. The system of claim 1, further comprising a sleep detector coupled to at least one of the implantable and respiratory therapy devices.

8. The system of claim 7, wherein the sleep detector comprises:

a first sensor configured to sense a first sleep-related signal;

a second sensor configured to sense a second sleep-related signal; and

a sleep detector coupled to the first and the second sensors and configured to adjust a sleep threshold associated with the first sleep-related signal using the second sleep-related signal, and to detect a sleep condition by comparing the first sleep-related signal with the adjusted threshold, wherein one of the first sensor, second sensor and sleep detector comprises an implantable component, and wherein the implantable device and the patient-external respiratory device are configured to operate cooperatively to detect sleep or to use information related to sleep detection.

9. The system of claim 1, further comprising a sleep stage detection apparatus coupled to one or both of the implantable device and the patient external respiratory therapy device, the sleep stage detection apparatus comprising:

a detector system, the detector system comprising a sensor configured to detect a condition associated with REM sleep; and

a classification system coupled to the detector system and configured to classify one or more sleep stages based on the one or more sleep-related conditions, wherein the implantable device and the patient external respiratory therapy device are configured to operate cooperatively to classify the one or more sleep stages or use the information related to the classification of sleep stages.

10. The system of claim 1, further comprising an autonomic arousal detector coupled to at least one of the implantable device and the patient external respiratory therapy device, the autonomic arousal detector configured to detect autonomic arousal events of the patient.

11. The system of claim 10, wherein the autonomic arousal detector comprises:

one or more sensors configured to sense one or more physiological conditions associated with a patient's autonomic arousal response; and

an implantable arousal detector coupled to the one or more sensors, the arousal detector configured to detect autonomic arousal events based on the one or more physiological conditions, wherein the implantable device and the patient external respiratory therapy device are configured to operate cooperatively based on the detection of the autonomic arousal events.

12. The system of claim 1, further comprising a sleep quality monitor coupled to at least one of the implantable device and the patient external respiratory therapy device, the sleep quality monitor configured to collect sleep quality data.

13. The system of claim 12, wherein the sleep quality monitor comprises:

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

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

patient external respiratory therapy device are configured to operate cooperatively to collect or use the sleep quality data.

14. The system of claim 1, further comprising a system for characterizing respiration, the respiration characterization system coupled to at least one of the implantable device and the patient external respiratory device, the respiration characterization system comprising:

a respiration waveform sensor configured to acquire a respiration waveform;

a respiration processor configured to determine one or more characteristics associated with the respiration; and

a waveform generator coupled to the respiration waveform sensor and the respiration processor, the waveform generator configured to generate a marked respiration waveform comprising the respiration waveform and symbols indicating the one or more characteristics associated with the respiration, wherein the implantable device and the patient external respiratory device are configured to work cooperatively to generate or use the marked respiration waveform.

15. The system of claim 1, further comprising a respiratory event logbook coupled to at least one of the implantable device and the patient external respiratory device, the respiratory event logbook comprising:

an event detector configured to detect or predict a respiratory event affecting the patient;

a data acquisition unit coupled to the event detector and configured to collect medical information associated with the respiratory event responsive to the detection or prediction of the respiratory event; and

a processor coupled to the data acquisition unit, the processor configured to organize the collected medical information associated with the respiratory event as a respiratory event log entry of the respiratory event logbook, wherein the implantable device and the patient external respiratory device are configured to operate cooperatively to generate the respiratory event logbook or use respiratory event logbook information.

16. The system of claim 1, further comprising a medical event logbook coupled to at least one of the implantable device and the patient external respiratory device, the medical event logbook comprising:

an event detector configured to detect or predict a medical event affecting the patient;

a data acquisition unit, coupled to the event detector, and configured to collect respiratory information associated with the medical event responsive to the detection or prediction of the medical event; and

a processor, coupled to the data acquisition unit, and configured to organize the collected respiratory information associated with the medical event as a medical event log entry, wherein the implantable device and the patient external respiratory device are configured to operate cooperatively to generate the medical event logbook or use medical event logbook information.

17. The system of claim 1, further comprising a sleep logbook system coupled to at least one of the implantable device and the patient external respiratory therapy device, the sleep logbook system comprising:

a sleep detector configured to detect sleep;

a data acquisition unit configured to acquire information related to sleep; and

a processor, coupled to the sleep detector and the data acquisition unit, the processor configured to organize the acquired sleep information as a sleep logbook entry of the sleep logbook, wherein the implantable device and the patient external respiratory therapy device are configured to operate cooperatively to generate the sleep logbook or use sleep logbook information.

18. The system of claim 1, further comprising a system for detecting snoring disposed in or on the implantable device, the system for detecting snoring, comprising:

a sensor configured to generate a signal modulated by snoring; and

a processor configured to detect snoring using the snoring signal, wherein the implantable device and the patient external respiratory device are configured to operate cooperatively to use snoring information to provide one or more of patient monitoring, diagnosis, and therapy.

19. The system of claim 1, wherein at least one of the implantable device and the patient-external respiratory therapy device comprises one or more components of a posture detector, and the communications channel is configured to transfer at least posture

information between the implantable device and the patient-external respiratory therapy device.

20. The system of claim 1, further comprising a cardiac electrical activity detection system, comprising:

one or more sensors coupled to the external respiratory therapy device, the one or more sensors configured to sense electrical activity of a heart and to generate a cardiac electrical signal based on the sensed electrical activity; and

a cardiac event detector coupled to the one or more sensors and configured to detect one or more cardiac events based on the sensed electrical activity, wherein the implantable and respiratory therapy devices are configured to operate cooperatively based on the sensed cardiac electrical activity.

21. The system of claim 1, further comprising a sensing system configured to sense conditions associated with therapy delivered by the patient-external respiratory therapy device, wherein the implantable device comprises a monitoring device coupled to the sensing system, the monitoring device configured to monitor the patient-external breathing therapy based on the one or more sensed conditions.

22. The system of claim 1, wherein:

the implantable device comprises a monitoring unit configured to monitor one or more patient conditions; and

the patient external respiratory therapy device is configured to provide disordered breathing therapy, and further comprising a processor coupled to the monitoring unit and configured to provide feedback information to the patient-external respiratory therapy device, the feedback information related to the disordered breathing therapy and based on the one or more monitored conditions.

23. The system of claim 1, further comprising:

a detector system configured to detect one or more parameters influenced by disordered breathing, the one or more parameters comprising at least one of a blood chemistry parameter and an expired respiratory gas parameter;

a therapy delivery system, comprising:

the respiratory therapy delivery device configured to deliver a respiratory therapy to a patient; and

the implantable device configured to deliver a cardiac therapy to the patient; and

a therapy controller coupled to the therapy delivery system and the detector system, the therapy controller configured to adjust the respiratory and cardiac therapies based on the detected one or more detected parameters.

24. The system of claim 1, wherein the patient external respiratory therapy device comprises a sensor system configured to sense one or more conditions associated with a pulmonary disease other than a breathing rhythm disorder, and further comprising a diagnosis unit coupled to the sensor system and configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions, wherein the implantable device and the patient external respiratory therapy device operate cooperatively perform one or more functions using the assessment of the non-rhythm pulmonary disease.

25. The system of claim 1, wherein the patient external respiratory therapy device comprises a sensor system configured to sense one or more conditions associated with a non-rhythm pulmonary disease, and further comprising:

a diagnosis unit coupled to the sensor system and configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions; and

a drug therapy control system to treat a non-rhythm pulmonary disease.

26. The system of claim 1, wherein the patient-external respiratory therapy device comprises a sensor system configured to sense one or more physiological conditions, and further comprising a therapy control system, comprising:

a cardiopulmonary status processor coupled to the sensor system and configured to determine a cardiopulmonary status of a patient based on the sensed physiological conditions; and

a therapy controller coupled to the cardiopulmonary status processor and configured to control a therapy delivered to the patient based on the patient's cardiopulmonary status, the implantable and respiratory therapy device configured to operate cooperatively to perform one or more functions associated with cardiopulmonary status.

27. The system of claim 1, further comprising a gas therapy system, comprising:

a sensor configured to sense concentration of a blood gas; and

a therapy controller coupled to the sensor and configured to adapt a gas therapy, wherein the patient external respiratory therapy device is coupled to the therapy controller and is configured to delivery the gas therapy to a patient and wherein the implantable device comprises at least one of the sensor and the controller.

28. The system of claim 1, wherein the implantable device and the patient external respiratory therapy device each comprise a sensing system configured to sense one or more physiological conditions, and further comprising:

a selection processor coupled to the implantable device and the patient external respiratory therapy device, the selection processor configured to select one or more of the devices to sense one or more physiological conditions; and

a diagnosis processor coupled to the sensing systems of the implantable device and the patient external respiratory therapy device and configured to assess a presence of a medical disorder based on the one or more physiological conditions.

29. The system of claim 1, wherein:

the implantable device comprises a pulse generator configured to deliver cardiac pacing pulses to a patient's heart; and

the respiratory therapy device is configured to deliver an airway pressure to the patient, and further comprising a control unit coupled to the pulse generator, the control unit configured to control the airway pressure delivered to the patient based on the delivery of the cardiac pacing pulses.

30. The system of claim 1, further comprising:

a data acquisition unit configured to acquire data associated with a patient while the patient is awake; and

a therapy controller configured to adjust a therapy delivered to the patient during patient sleep using the acquired data, the therapy comprising one or both of a respiratory therapy and a therapy to treat a sleep-related disorder, wherein the implantable device and the patient external respiratory device are configured to operate cooperatively implement one or both of the data acquisition unit and the therapy controller.

31. The system of claim 1, further comprising:

a sensor system having one or more sensors configured to sense brain activity;

a brain activity detector coupled to the sensor system and configured to determine a brain state based on signals received from the sensor system; and

a controller coupled to the brain activity detector, the controller configured to activate, de-activate or adjust the at least one cardiac function performed by the implantable device or a respiratory function performed by the patient external respiratory therapy device based on the brain state.

32. The system of claim 1, further comprising:

one or more movement sensors configured for sensing movement of skeletal musculature;

a sleep-disordered breathing (SDB) sensor configured to sense a parameter associated with sleep-disordered breathing; and

a processor communicatively coupled to the one or more movement sensors and the SDB sensor, the processor detecting sleep-disordered breathing based on the sensed parameter and detecting an involuntary muscle movement disorder using signals produced by the one or more movement sensors.

33. The system of claim 1, further comprising:

a sensor configured to sense movement of skeletal musculature;

a detector coupled to the sensor; and

an implantable processor coupled to the detector, the processor configured to determine presence of an involuntary muscle movement disorder.

34. A system for classifying disordered breathing, comprising:

a disordered breathing detector configured to detect a disordered breathing event;

a motion sensor configured to sense motion associated with respiratory effort of a patient during the disordered breathing event; and

a disordered breathing classification processor coupled to the motion sensor and the disordered breathing detector, the disordered breathing classification processor configured to classify the disordered breathing event based on the respiratory effort motion, wherein at

least one of the disordered breathing detector, the motion sensor, and the disordered breathing classification processor is at least in part implantable.

35. A system for providing disordered breathing therapy to a patient, comprising:

a circuit configured to detect cardiac beats and obtain cardiac intervals between cardiac beats;

a controller coupled to the circuit and configured to determine a first indicated pacing interval based at least on a cardiac interval duration and a previous value of the first indicated pacing interval; and

a cardiac pacing circuit coupled to the controller and configured to provide cardiac pacing to mitigate disordered breathing based on the first indicated pacing interval.

36. A medical system for detecting autonomic arousal events occurring during sleep, comprising:

one or more sensors configured to sense one or more physiological conditions associated with a patient's autonomic arousal response; and

an implantable arousal detector coupled to the one or more sensors, the arousal detector configured to detect autonomic arousal events based on the one or more physiological conditions.

37. A system for characterizing respiration of a patient, comprising:

a respiration waveform sensor configured to acquire a respiration waveform;

a respiration processor configured to determine one or more characteristics associated with the respiration; and

a waveform generator coupled to the respiration waveform sensor and the respiration processor, the waveform generator configured to generate a marked respiration waveform comprising the respiration waveform and symbols indicating the one or more characteristics associated with the respiration, wherein at least one of the respiration waveform sensor, the respiration processor, and the waveform generator comprises an implantable component.

38. A medical event logbook system, comprising:

an event detector configured to detect or predict a medical event;

a data acquisition unit, coupled to the event detector, and configured to collect, responsive to the detection or prediction of the medical event, respiratory information associated with the medical event; and

a processor, coupled to the data acquisition unit, and configured to organize the acquired respiratory information as a medical event log entry, wherein at least one of the event detector, the data acquisition unit, and the processor includes an implantable component.

39. A respiratory event logbook system, comprising:

an event detector configured to detect or predict a respiratory event affecting the patient;

a data acquisition unit, coupled to the event detector, and configured to collect medical information associated with the respiratory event responsive to the detection or prediction of the respiratory event; and

a processor, coupled to the data acquisition unit, and configured to organize the collected medical information associated with the respiratory event as a respiratory event log entry, wherein at least one of the event detector, the data acquisition unit, and the processor includes an implantable component.

40. A sleep logbook system, comprising:

a sleep detector configured to detect sleep;

a data acquisition unit configured to acquire information related to sleep; and

a processor, coupled to the sleep detector and the data acquisition unit, the processor configured to organize the acquired sleep information as a sleep logbook entry, wherein at least one of the sleep detector, the data acquisition unit, and the processor comprises an implantable component.

41. A system for detecting snoring in a patient, comprising:

a sensor configured to generate a signal modulated by snoring; and

a processor configured to detect snoring using the snoring signal, wherein at least one of the sensor and the processor comprises a component disposed in or on a cardiac rhythm management device.

42. A posture detection system, comprising:

an implantable cardiac device;

a patient-external respiratory therapy device; and

a communications channel between the implantable cardiac device and the a patient-external respiratory therapy device, the communications channel configured to transfer information between the implantable cardiac device and the patient-external therapy respiratory device, wherein at least one of the implantable cardiac device and the patient-external respiratory therapy device comprises one or more components of a posture detector, and the communications channel is configured to transfer at least posture information between the implantable cardiac device and the patient-external respiratory therapy device.

43. A medical system, comprising:

one or more sensors coupled to an external respiratory therapy device, the one or more sensors configured to sense electrical activity of a heart and to generate a cardiac electrical signal based on the sensed electrical activity; and

a cardiac event detector coupled to the one or more sensors and configured to detect one or more cardiac events based on the sensed electrical activity.

44. A medical system, comprising:

a sensing system configured to sense conditions associated with a patient-external breathing therapy; and

an implantable monitoring device, coupled to the sensing system, the implantable monitoring device configured to monitor the patient-external breathing therapy based on the one or more sensed conditions.

45. A medical system, comprising:

a monitoring unit having components disposed within an implantable housing, the monitoring unit configured to monitor one or more patient conditions;

a processor coupled to the monitoring unit and configured to provide feedback information related to sleep disordered breathing therapy delivered to a patient based on the one or more monitored conditions, wherein components of a therapy device delivering the

disordered breathing therapy are disposed within a therapy device housing and the therapy device housing is separate from the implantable housing of the monitoring device.

46. A medical system, comprising:

a detector system configured to detect one or more parameters influenced by disordered breathing, the one or more parameters comprising at least one of a blood chemistry parameter and an expired respiratory gas parameter;

a therapy delivery system, comprising:

a respiratory therapy delivery device configured to deliver a respiratory therapy to a patient; and

an implantable cardiac therapy delivery device configured to deliver a cardiac therapy to the patient; and

a therapy controller coupled to the therapy delivery system and the detector system, the therapy controller configured to adjust the respiratory and cardiac therapies based on the detected one or more detected parameters.

47. A medical system, comprising:

a respiratory therapy device, the respiratory therapy device comprising:

a therapy unit configured to deliver respiration therapy to a patient;

a sensor system configured to sense one or more conditions associated with a pulmonary disease other than a breathing rhythm disorder; and

a diagnosis unit coupled to the sensor system and configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions.

48. A medical system for controlling therapy for a non-breathing rhythm related pulmonary disease, comprising:

an external respiratory therapy device, the external respiratory therapy device comprising:

a therapy unit configured to deliver respiration therapy to a patient;

a sensor system configured to sense one or more conditions associated with a non-rhythm pulmonary disease;

a diagnosis unit coupled to the sensor system and configured to assess a presence of the non-rhythm pulmonary disease based on the one or more sensed conditions; and

a drug therapy controller coupled to the diagnosis unit and configured to control a drug therapy delivered to the patient to treat the non-rhythm pulmonary disease.

49. A medical therapy control system, comprising:

an external respiratory device comprising a sensor system configured to sense one or more physiological conditions;

a cardiopulmonary status processor coupled to the sensor system and configured to determine a cardiopulmonary status of a patient based on the sensed physiological conditions; and

a therapy controller coupled to the cardiopulmonary status processor and configured to control a therapy delivered to the patient based on the patient's cardiopulmonary status, wherein at least one of the cardiopulmonary status processor and the therapy controller are at least in part implantable.

50. A gas therapy system, comprising:

a sensor configured to sense concentration of a blood gas;

a therapy controller coupled to the sensor and configured to adapt a gas therapy; and

a gas therapy delivery unit coupled to the therapy controller and configured to deliver the adapted gas therapy to a patient;

wherein at least one of the sensor and the controller comprises an implantable component.

51. A system for assessing a disease presence, comprising:

a plurality of medical devices, each medical device comprising a sensing system configured to sense one or more physiological conditions;

a selection processor coupled to the plurality of medical devices, the selection processor configured to select one or more medical devices to sense one or more physiological conditions; and

a diagnosis processor coupled to the sensing systems of the plurality of medical devices and configured to assess a presence of a medical disorder based on the one or more physiological conditions.

52. A medical system, comprising:

a pulse generator configured to deliver cardiac pacing pulses to a patient's heart; and

a control unit coupled to the pulse generator, the control unit configured to control airway pressure delivered to the patient based on the delivery of the cardiac pacing pulses.

53. A system, comprising:

a data acquisition unit configured to acquire data associated with a patient while the patient is awake; and

a therapy delivery system configured to adjust a therapy delivered to the patient during patient sleep using the acquired data, the therapy comprising one or both of a respiratory therapy and a therapy to treat a sleep-related disorder.

54. A system, comprising:

a sensor system having one or more sensors configured to sense brain activity;

a brain activity detector coupled to the sensor system and configured to determine a brain state based on signals received from the sensor system;

a medical system configured to perform at least one respiratory or cardiac process; and

a controller coupled to the brain activity detector and the medical system, the controller configured to activate, de-activate or adjust the at least one cardiac or respiratory process based on the brain state.

55. A system for detecting sleep-related disorders, comprising:

one or more movement sensors configured for sensing movement of skeletal musculature;

a sleep-disordered breathing (SDB) sensor configured to sense a parameter associated with sleep-disordered breathing; and

a processor communicatively coupled to the one or more movement sensors and the SDB sensor, the processor detecting sleep-disordered breathing based on the sensed parameter and detecting an involuntary muscle movement disorder using signals produced by the one or more movement sensors.

56. A system for evaluating a pathological condition, comprising:

a sensor configured to sense movement of skeletal musculature;

a detector coupled to the sensor; and

an implantable processor coupled to the detector, the processor configured to determine presence of an involuntary muscle movement disorder.