



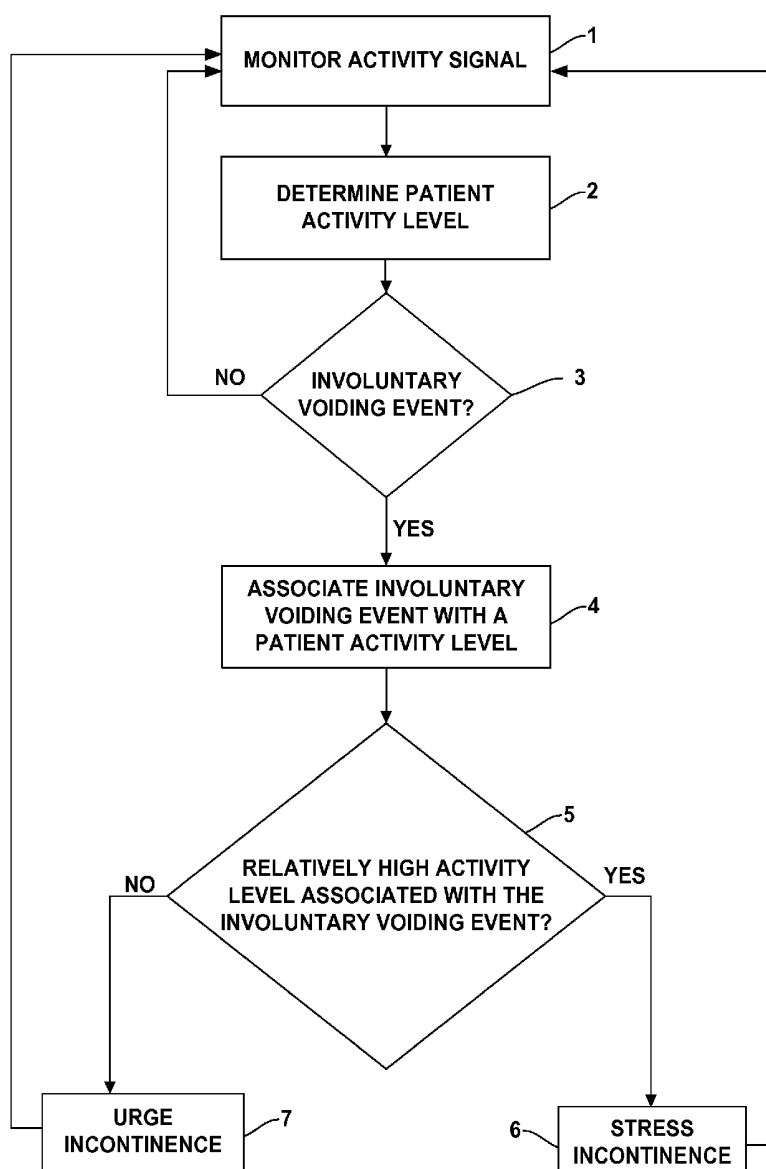
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(19) **United States**(12) **Patent Application Publication**
Gerber et al.(10) **Pub. No.: US 2008/0300470 A1**(43) **Pub. Date: Dec. 4, 2008**(54) **COLLECTING ACTIVITY DATA FOR
EVALUATION OF PATIENT INCONTINENCE****Publication Classification**(51) **Int. Cl.**
A61B 5/00 (2006.01)(52) **U.S. Cl.** **600/301**(57) **ABSTRACT**

Systems and methods for determining whether an involuntary voiding event was attributable to stress or urge incontinence include determining an activity level of a patient that coincides with the occurrence of the involuntary voiding event or the activity level within a certain time range of the involuntary voiding event. Patient activity data may be collected via a signal that varies as a function of patient activity. The signal may be generated with one or more sensors that detect motion, such as an accelerometer or a piezoelectric crystal, and/or one or more sensors that monitor a physiological parameter of the patient that varies as a function of patient activity, such as heart rate, respiratory rate, electrocardiogram morphology, respiration rate, respiratory volume, core temperature, muscular activity level or subcutaneous temperature of the patient.

(75) Inventors: **Martin T. Gerber**, Maple Grove,
MN (US); **John C. Rondoni**,
Plymouth, MN (US)

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

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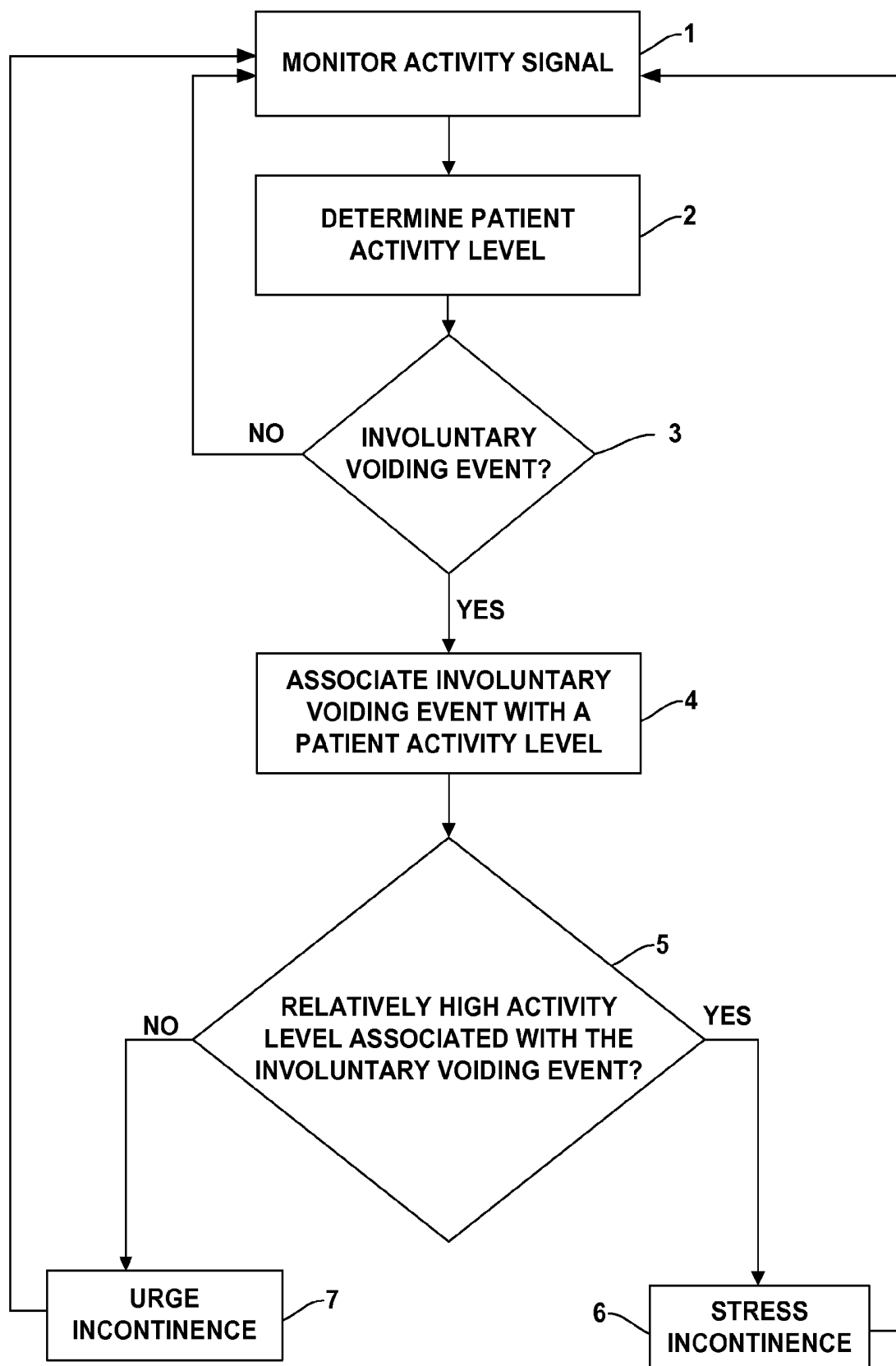


FIG. 1

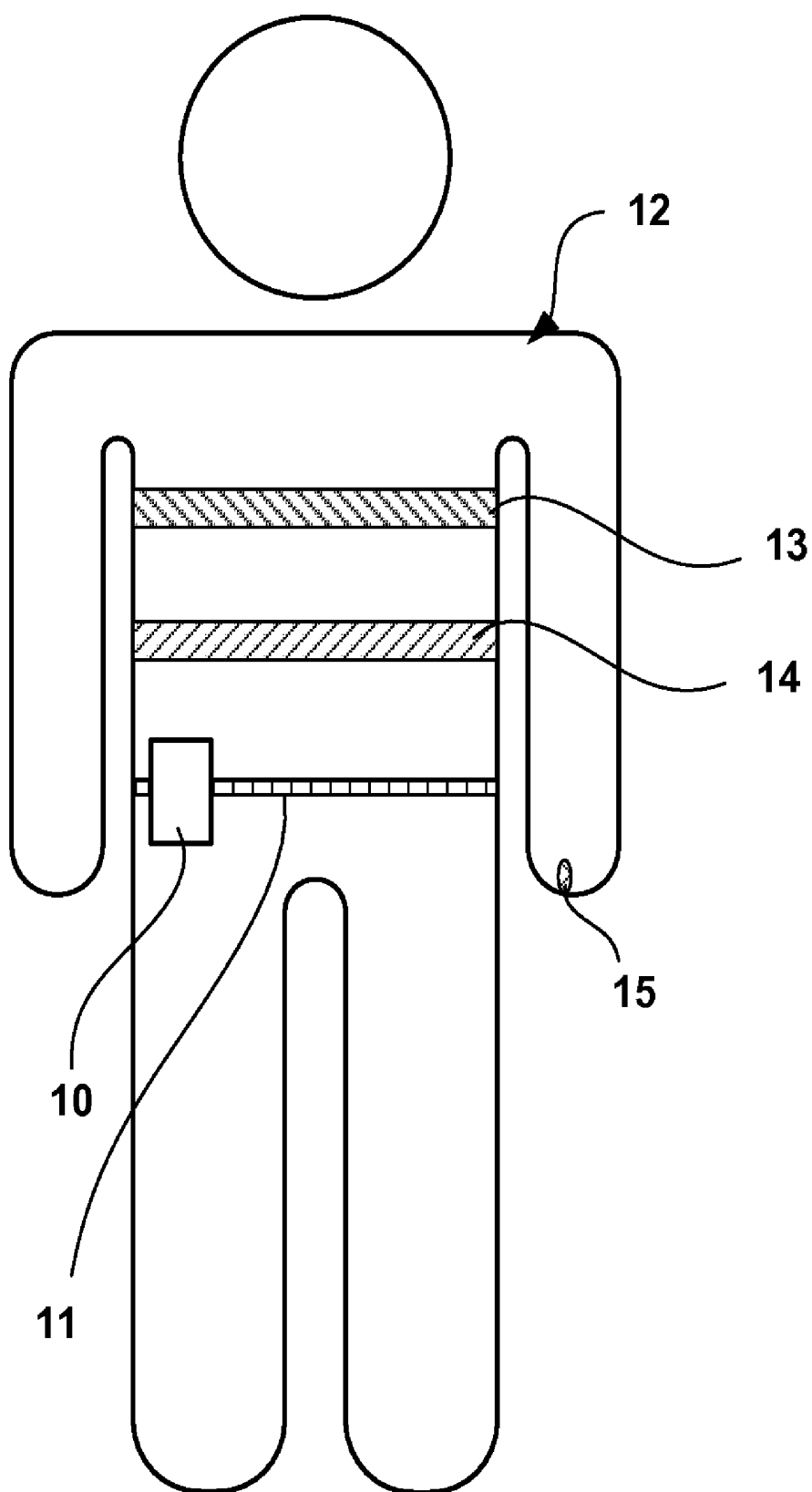
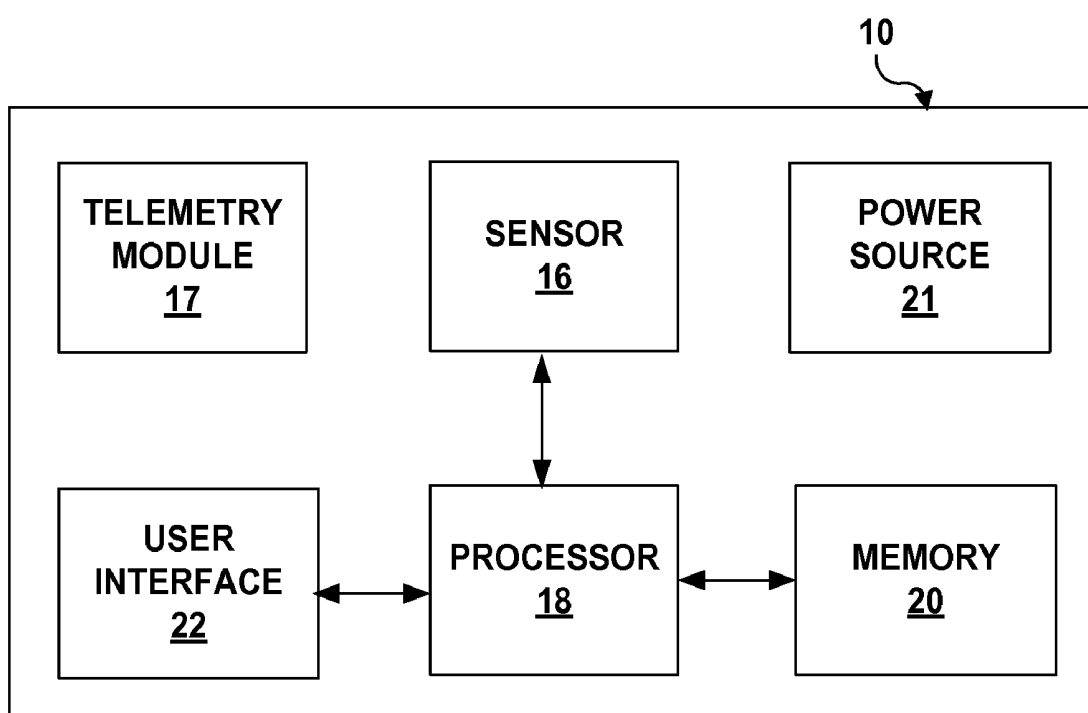


FIG. 2

**FIG. 3**

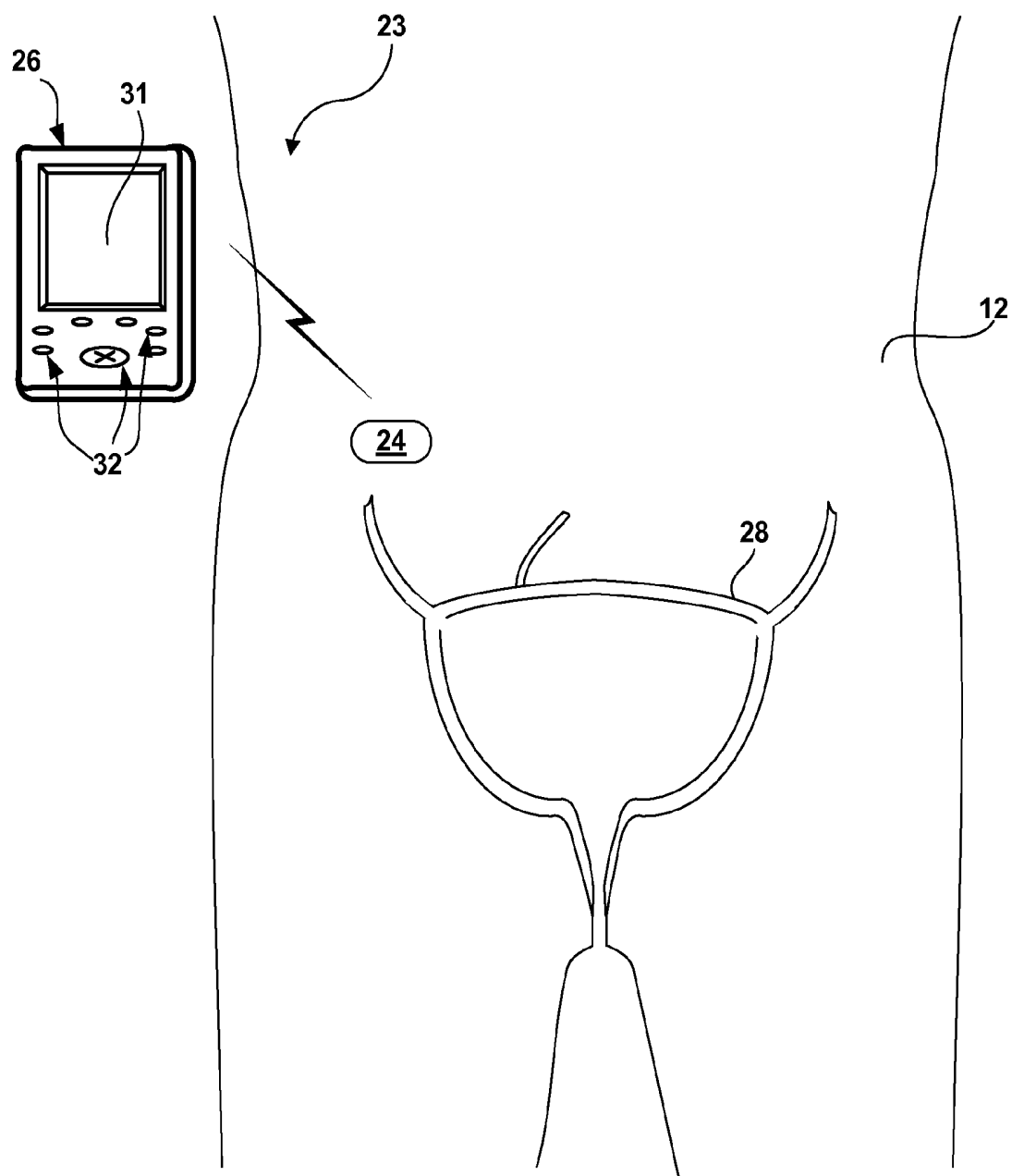
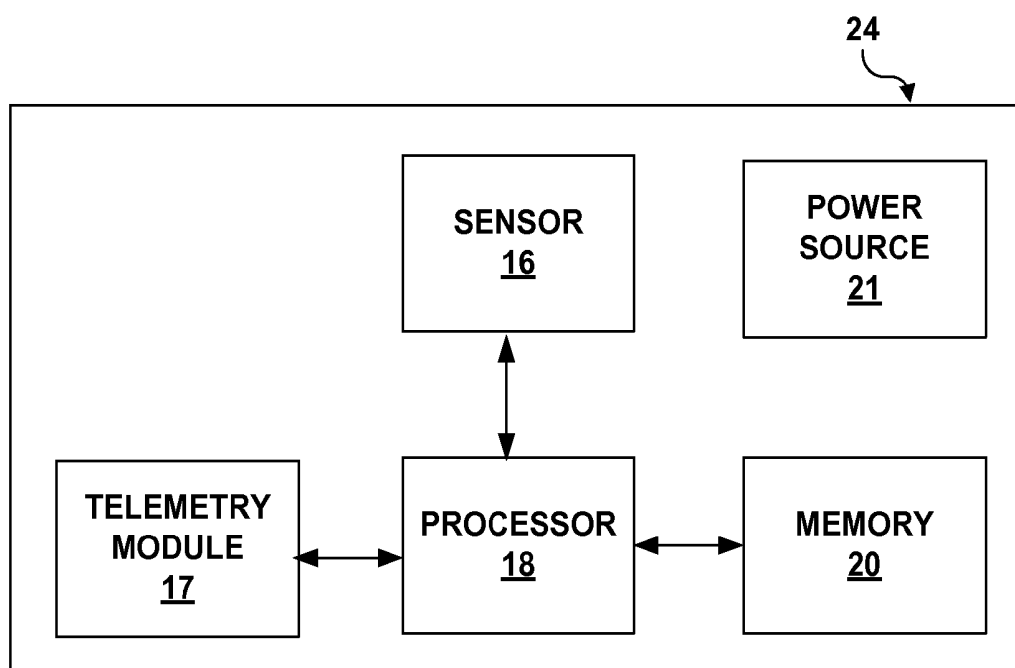
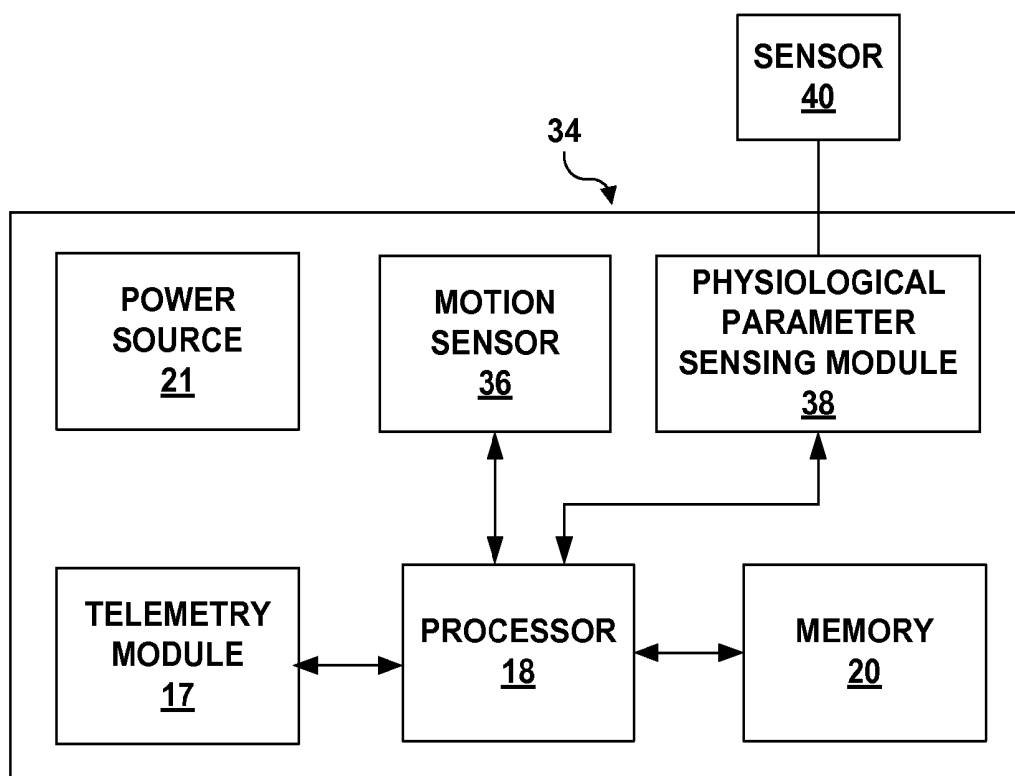


FIG. 4

**FIG. 5****FIG. 6**

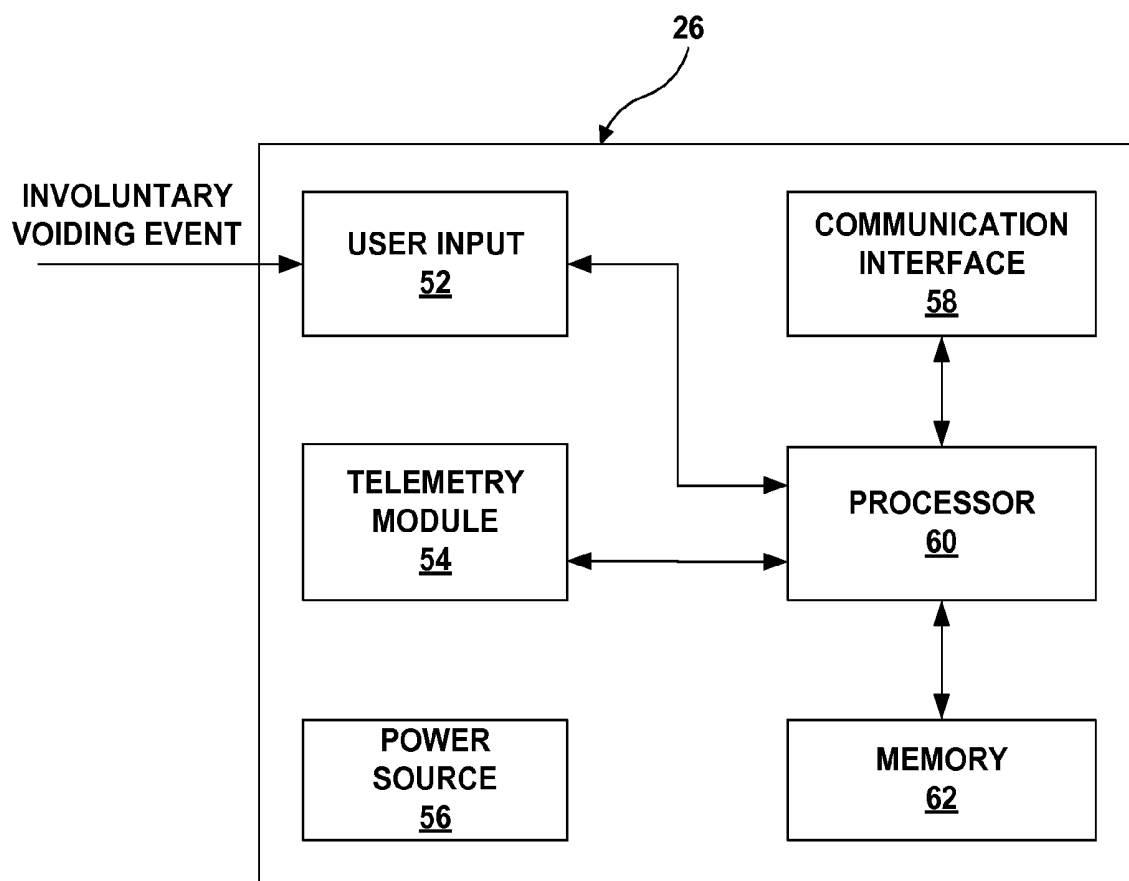


FIG. 7

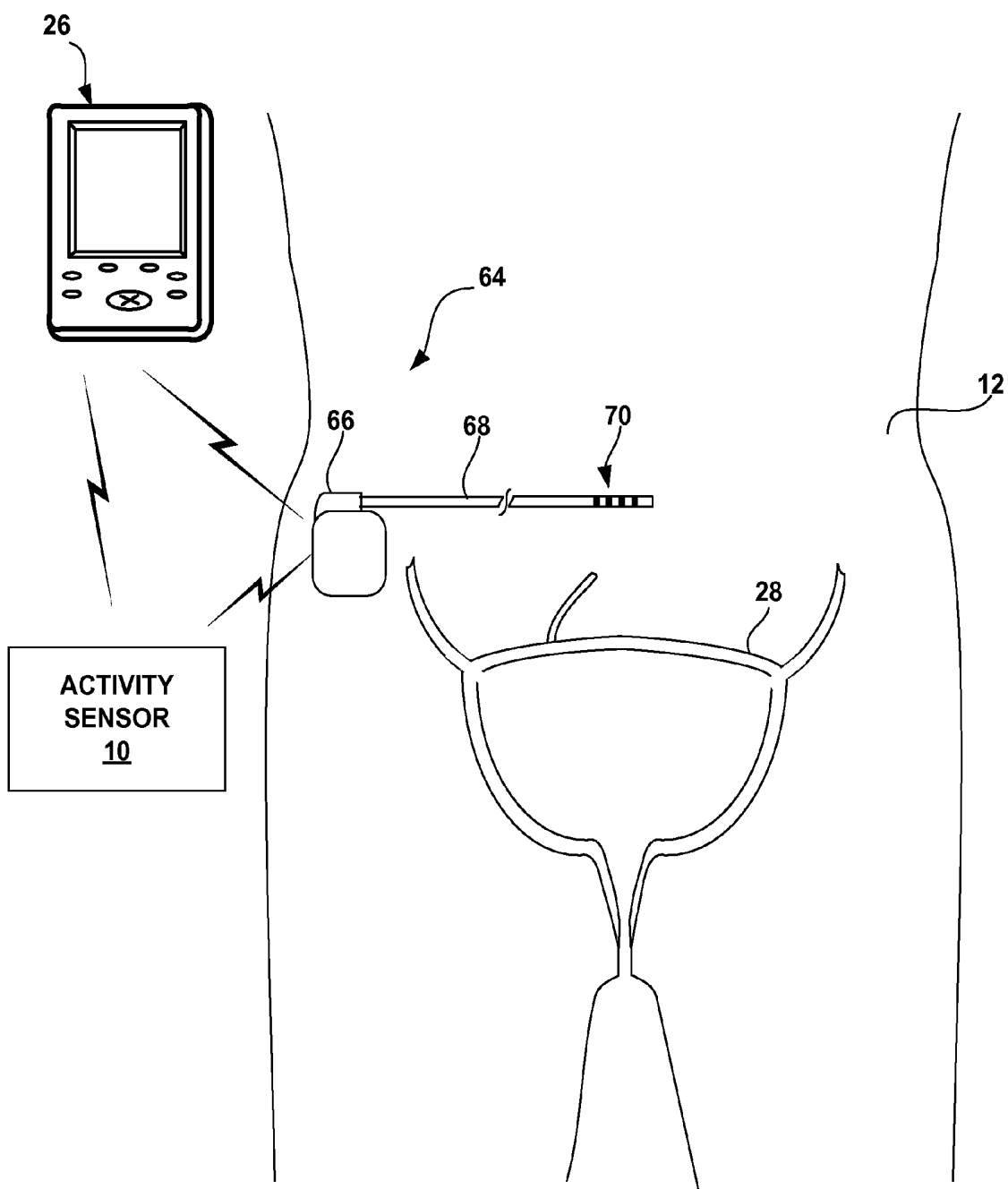


FIG. 8

COLLECTING ACTIVITY DATA FOR EVALUATION OF PATIENT INCONTINENCE

TECHNICAL FIELD

[0001] The invention relates to medical device systems, and more particularly, to medical device systems for evaluating patient incontinence.

BACKGROUND

[0002] Many people suffer from an inability to control urinary function, i.e., urinary incontinence. Different muscles, nerves, organs and conduits within the urinary tract cooperate to collect, store and release urine. A variety of disorders may compromise urinary tract performance and contribute to incontinence. Many of the disorders may be associated with aging, injury or illness. For example, aging can often result in weakened sphincter muscles, which cause incontinence, or weakened bladder muscles, which prevent complete emptying. Some patients also may suffer from nerve disorders that prevent proper triggering and operation of the bladder or sphincter muscles.

[0003] One common form of urinary incontinence, referred to as "stress incontinence," is attributable to a failure of muscles around the bladder neck and urethra to maintain closure of the urinary outlet. Patients with stress incontinence may experience minor leakage from physical activities that apply pressure to the bladder, such as coughing, sneezing, laughing, exercising or other movements that increase intraabdominal pressure. Another common form of urinary incontinence, referred to as "urge incontinence," (also called hyperactive or overactive bladder) involves the involuntary leakage of urine while suddenly feeling the need or urge to urinate. Urge incontinence may be attributable to abnormally heightened commands from the spinal cord to the bladder that produce unanticipated bladder contractions, or from damage to the nerves of the bladder, nervous system or the muscles. Patients with urge incontinence need to urinate frequently. When the bladder reaches capacity, the nerves appropriately signal the brain that the bladder is full, but the urge to void cannot be voluntarily suppressed.

[0004] Electrical stimulation of nerves in the pelvic floor may provide an effective therapy for a variety of disorders, including urinary incontinence. For example, an implantable electrical stimulator may deliver stimulation to treat urinary incontinence. The electrical stimulator may be a neurostimulator that delivers electrical stimulation to the sacral nerve to induce sphincter constriction and thereby close or maintain closure of the urethra at the bladder neck. In addition, electrical stimulation of the bladder wall may enhance pelvic floor muscle tone and assist fluid retention in the bladder or voiding fluid from the bladder. An appropriate course of electrical stimulation therapy may be aided by a sensor that monitors physiological conditions of the bladder. In some cases, an implantable stimulation device may deliver stimulation therapy based on the level or state of a sensed physiological condition.

SUMMARY

[0005] In general, the invention is directed toward systems and methods for determining whether an involuntary voiding event (i.e., involuntary leakage of urine) is attributable to stress or urge incontinence. In particular, the systems and methods include collecting patient activity data to determine

a patient activity level, and associating the involuntary voiding event with a patient activity level that coincides with the occurrence of the involuntary voiding event, or the patient activity level within a certain time range prior to the occurrence of the involuntary voiding event. "Patient activity data" refers generally to any information that is indicative of a patient activity level, such as, but not limited to, signals from an accelerometer, a piezoelectric crystal, mercury switch, a gyro or a physiological parameter sensor, or input from a patient or clinician. The associated patient activity level may be indicative of whether the patient was engaged in an activity that increases intraabdominal pressure at the time of the involuntary voiding event or within a certain range of time prior to the involuntary voiding event. The time range may be determined by the clinician.

[0006] A relatively high activity level associated with the involuntary voiding event may suggest that the involuntary voiding event was attributable to stress incontinence, rather than urge incontinence. Distinguishing between stress incontinence events and urge incontinence events may be useful for evaluating (e.g., diagnosing) a patient's condition to formulate a therapy program and/or to adjust therapy parameters, such as the parameters of electrical stimulation therapy or drug delivery therapy.

[0007] A device, such as a medical device, programming device or another computing device, may determine an activity level based on a signal generated by a sensor, where the signal varies as a function of patient activity. For example, a sensor that detects motion, such as an accelerometer or a piezoelectric crystal, may generate the signal. In addition or instead of the motion detecting sensor, the patient activity data may be collected via a sensor that generates a signal that indicates a physiological parameter that varies as a function of patient activity, such as heart rate, respiratory rate, electrocardiogram (ECG) morphology, respiration rate, respiratory volume, core temperature, a muscular activity level (e.g., by monitoring electromyographic activity) or subcutaneous temperature of the patient. In some embodiments, a single sensor is used to monitor the activity level of the patient. In other embodiments, multiple sensors are used, where the sensors may be positioned at the same or different locations on the patient. The sensors may be external or implanted.

[0008] In one embodiment, the invention is directed to a method comprising monitoring a signal that varies as a function of patient activity, receiving an indication of an occurrence of an involuntary voiding event, and determining whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based on the signal.

[0009] In another embodiment, the invention is directed to a system comprising an activity sensor that generates a signal that varies as a function of activity of a patient, and a processor. The processor receives the signal from the activity sensor, receives an indication of an occurrence of an involuntary voiding event, and determines whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based on the signal.

[0010] In another embodiment, the invention is directed to a medical system comprising means for generating a signal that varies as a function of patient activity, means for receiving the signal, means for receiving an indication of an occurrence of an involuntary voiding event, and means for determining whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based on the signal.

[0011] In another embodiment, the invention is directed to a computer-readable medium comprising instructions. The instructions cause a programmable processor to determine an activity level based on a signal received from a sensor, wherein the signal varies as a function of patient activity, determine whether an involuntary voiding event occurred, associate the involuntary voiding event with the activity level, and determine whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based the activity level associated with the involuntary voiding event.

[0012] The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF DRAWINGS

[0013] FIG. 1 is a flow diagram of an embodiment of a method of determining whether an involuntary voiding event was attributable to stress incontinence or urge incontinence.

[0014] FIG. 2 is a schematic block diagram of an external activity sensing device that may be used to determine a patient activity level.

[0015] FIG. 3 is a schematic block diagram of an activity sensing device, which includes a sensor, processor, memory, power source, and user interface.

[0016] FIG. 4 is a schematic diagram illustrating a medical system in which an activity sensing device is implanted near a bladder of a patient.

[0017] FIG. 5 is a schematic block diagram of implanted activity sensing device that includes a telemetry module.

[0018] FIG. 6 is a schematic block diagram of implantable activity sensing device, which is similar to the activity sensing device of FIG. 5, but includes a motion sensor and physiological parameter sensing module that is coupled to another sensor.

[0019] FIG. 7 is a schematic block diagram of external computing device, which includes a user input, telemetry module, power source, communication interface, processor, and memory.

[0020] FIG. 8 is a schematic diagram illustrating a medical system, which includes an external activity sensing device, external computing device, implantable electrical stimulator, lead coupled to the electrical stimulator, and electrodes disposed on the lead.

DETAILED DESCRIPTION

[0021] Urinary incontinence is a condition that affects the quality of life and health of many people. Two of the most common types of urinary incontinence are stress and urge incontinence. Distinguishing between stress and urge incontinence may be useful for formulating a diagnosis and treatment for a patient, and generally evaluating the patient's condition. Patients with stress incontinence may experience minor leakage from physical activities that apply pressure to the bladder, such as coughing, sneezing, laughing, exercising or other movements that increase intraabdominal pressure. Accordingly, a higher level of activity at the time of an involuntary voiding event (i.e., involuntary leakage of urine) or during a certain range of time prior to the involuntary voiding event may indicate that a particular patient is afflicted with stress incontinence, rather than urge incontinence. In some

cases, a patient may be afflicted with both stress and urge incontinence. In such cases, a higher level of activity may help distinguish between specific incidents of stress and urge incontinence or the relative number of stress incontinence events as compared to urge incontinence events.

[0022] Systems and methods described herein utilize an activity sensor to determine a patient activity level. An involuntary voiding activity may be associated with a patient activity level in order to determine whether the involuntary voiding event was attributable to stress or urge incontinence. That is, feedback from an activity sensor that senses a relative level of patient activity may aid in determining whether an involuntary voiding event was attributable to an increase in intraabdominal pressure due to a relatively high level of patient activity, and accordingly, was attributable to stress incontinence. The activity sensor may generate a signal that reflects relative patient motion by transforming mechanical, chemical or electrical conditions into electrical signals representative of an activity level of patient, such as accelerometer, piezoelectric crystal, mercury switch or a gyro. In addition or instead of generating a signal that reflects patient motion, the activity sensor may generate a signal indicative of one or more sensed physiological parameters that vary as a function of patient activity. The physiological parameters include, but are not limited to, heart rate, respiratory rate, electrocardiogram (ECG) morphology, respiration rate, respiratory volume, core temperature, a muscular activity level or subcutaneous temperature of the patient.

[0023] FIG. 1 is a flow diagram of an embodiment of a method of determining whether an involuntary voiding event was attributable to stress incontinence or urge incontinence. One or more activity signals are monitored by a medical device (1), which may be external or implanted within a patient. For example, the medical device may monitor a signal generated by a sensor that detects motion, such as an accelerometer or a piezoelectric crystal, and/or a sensor that monitors a physiological parameter that varies as a function of patient activity, such as heart rate, electrocardiogram (ECG) morphology, respiration rate, respiratory volume, core temperature, subcutaneous temperature or muscle activity.

[0024] The medical device may determine a patient activity level based on the activity signal (2). For example, the medical device, or a computing device that communicates with the medical device, may determine a number of activity counts based on the one or more sensor signals, as described in further detail below. Alternatively, the medical device may merely record the sensor signals for a later determination of a patient activity level by a clinician or another computing device. In some embodiments, the medical device continuously determines the patient activity level, while in other embodiments, the medical device only determines relevant activity levels, which are typically as the activity levels that coincide with an involuntary voiding event or the activity levels within a certain time range prior to the occurrence of the involuntary voiding event.

[0025] The medical device may determine whether involuntary voiding event occurred (3). In one embodiment, the patient indicates the occurrence of an involuntary voiding event by interacting with a user interface on the medical device upon the occurrence of the involuntary voiding event to indicate that the involuntary voiding event occurred. If the medical device is implanted, the patient may provide input by interacting with a programming device, which may then communicate the indication of the involuntary voiding event to the

implanted medical device via wireless telemetry. In another embodiment, the patient taps an implanted medical device to indicate that an involuntary voiding event occurred.

[0026] As described in commonly-assigned U.S. patent application Ser. No. _____ to Martin T. Gerber et al. (attorney docket number 1023-667US01/P29147.00) and filed on the same date as the present application, tapping an implanted medical device a certain amount of times or in a certain pattern may cause a processor within the implanted device to record the date and time of the tapping. The tapping feature provides a relatively easy way for a patient to log involuntary voiding events. In one embodiment, an involuntary voiding event may be detected via one or more sensors incorporated into an undergarment, as described in commonly-assigned U.S. patent application Ser. No. 11/414,504 to John C. Rondoni et al., entitled, "VOIDING DETECTION WITH LEARNING MODE" and filed on Apr. 28, 2006. The one or more sensors detect the presence of fluid which indicates that wetting, and most likely, an involuntary voiding event has occurred. In some cases, the sensor may be also capable of also detecting fluid pH or other characteristic of the fluid to identify that the fluid is urine. In some embodiments, a pocket that holds a sensor may also include absorption material that absorbs voided urine, such that the undergarment is similar to a diaper or protective garment. U.S. patent application Ser. No. _____ to Martin T. Gerber et al. (attorney docket number 1023-667US01/P29147.00) and U.S. patent application Ser. No. 11/414,504 to John C. Rondoni et al. are each incorporated herein by reference in their entireties.

[0027] If an involuntary voiding event did not occur, the medical device continues monitoring the activity signal (1). If the medical device determines that an involuntary voiding event occurred, the involuntary voiding event may be associated with a patient activity level (4). In one embodiment, the patient activity levels are stored in a memory of the medical device, and upon receiving an indication of an involuntary voiding event, the involuntary voiding event may be associated with one or more patient activity levels. For example, a patient activity level that coincides with the occurrence of the involuntary voiding event, i.e., the patient activity level at the time of the involuntary voiding event, may be associated with the voiding event. Additionally or alternatively, an activity level of the patient during a certain time range (e.g., less than one minute) prior to the occurrence of the involuntary voiding event may be associated with the voiding event. A relatively high patient activity level associated with the involuntary voiding event (5) suggests that the involuntary voiding event was attributable to stress incontinence (6). An associated activity level that was relatively low suggests that the involuntary voiding event was attributable to urge incontinence (7). After determining whether the involuntary voiding event was attributable to stress incontinence (6) or urge incontinence (7), the medical device may continue monitoring the activity signal (1), determining a patient activity level (2), and so forth. The process shown in FIG. 1 may continue indefinitely or for a specific period of time, which may be determined by the clinician or another user.

[0028] In order to determine whether the activity level is relatively "high" or "low," the activity level associated with the involuntary voiding event may be compared to a chart comprising one or more thresholds. For example, if the activity level crosses a certain threshold, it may indicate a relatively high activity state. Other techniques may be used to determine whether the activity level associated with the invol-

untary voiding event is relatively high or low. For example, a clinician may manually review the activity level and rely on his knowledge and experience to make the determination.

[0029] Activity levels that are considered high for one patient may not be considered high for another patient. Accordingly, the threshold(s) may be selected based on the patient's lifestyle, thereby "tuning" the thresholds to a particular patient. Active patients may share one set of thresholds, while sedentary patients may share another set of thresholds.

[0030] In some embodiments, as will be described in greater detail below, a medical device does not associate an involuntary voiding event with a patient activity level (4) or determine whether the associated activity level was relatively high (5), but instead provides the activity levels to a computing device, such as a clinician programmer or a patient programmer. In such embodiments, the computing device associates the patient activity levels with an involuntary voiding event and may determine whether the involuntary voiding event was attributable to stress or urge incontinence. Additionally, the medical device need not determine the activity levels, but may instead store samples of the signals generated by the activity sensor. In such embodiments, the computing device may determine both activity levels and associate the involuntary voiding event with an activity level. Furthermore, either the medical device or the computing device, or even another device in communication with the medical device or computing device, may receive the indication of the involuntary voiding event.

[0031] FIG. 2 is a schematic block diagram illustrating external activity sensing device 10 that may be used to determine an activity level of patient 12. As shown in FIG. 2, external activity sensing device 10 is an external device that may be attached to patient 12 via a belt 11. Alternatively, activity sensing device 10 may be attached to patient 12 by any other suitable technique, such as a clip that attaches to the patient's clothing, or activity sensing device 10 may be worn on a necklace that is worn around the patient's neck or a watch on the patient's wrist. Activity sensing device 10 may include a sensor that generates a signal indicative of patient motion, such as accelerometer or a piezoelectric crystal. If activity sensing device 10 includes a sensor that senses relative motion, such as an accelerometer, it may be desirable to attach sensing device 10 to a torso of patient 12 in order to gather the most relevant activity data. For example, if sensing device 10 is implanted within an arm or leg of patient 12, sensing device 10 may erroneously mistake regular motion (e.g., walking motion) for a high level of patient activity. However, in other embodiments sensing device 10 may be configured to determine the relative levels of patient activity, e.g., sensing device 10 may be calibrated to recognize a walking motion as a normal level of activity.

[0032] In addition to or instead of a motion sensor, sensing device 10 may include or be coupled to a sensor that generates a signal that indicates a physiological parameter that varies as a function of patient activity to determine an activity level of patient 12. The physiological parameter may be heart rate, respiratory rate, ECG morphology, respiration rate, respiratory volume, core temperature, a muscular activity level, subcutaneous temperature or electromyographic activity of patient 12. For example, in some embodiments, patient 12 may wear an ECG belt 13 that incorporates a plurality of electrodes for sensing the electrical activity of the heart of patient 12. The heart rate and, in some embodiments, ECG

morphology of patient 12 may monitored based on the signal provided by ECG belt 13. Examples of suitable ECG belts for sensing the heart rate of patient 12 are the “M” and “F” heart rate monitor models commercially available from Polar Electro. In some embodiments, instead of ECG belt 13, patient 12 may wear a plurality of ECG electrodes (not shown in FIG. 2) attached, e.g., via adhesive patches, at various locations on the chest of patient 12, as is known in the art. An ECG signal derived from the signals sensed by such an array of electrodes may enable both heart rate and ECG morphology monitoring, as is known in the art.

[0033] A respiration belt 14 that outputs a signal that varies as a function of respiration of the patient may also be worn by patient 12 to monitor activity. Respiration belt 14 may be a plethysmography belt, and the signal output by respiration belt 14 may vary as a function of the changes in the thoracic or abdominal circumference of patient 12 that accompany breathing by patient 12. An example of a suitable respiration belt is the TSD201 Respiratory Effort Transducer commercially available from Biopac Systems, Inc. Alternatively, respiration belt 14 may incorporate or be replaced by a plurality of electrodes that direct an electrical signal through the thorax of patient 12, and circuitry to sense the impedance of the thorax, which varies as a function of respiration of patient 12, based on the signal. In some embodiments, the ECG and respiration belts 13, 14 may be a common belt worn by patient 12.

[0034] Patient 12 may also wear transducer 15 that outputs a signal as a function of the oxygen saturation of the blood of patient 12. Transducer 15 may be an infrared transducer. Transducer 15 may be located on one of the fingers or earlobes of patient 12. Each of the types of sensors 13, 14, and 15 described above may be used alone or in combination with each other. As used below, reference to “activity sensing device 10” generally refers to all types of activity sensing devices that are configured to sense a relative level of patient activity, and is not limited to embodiments that include ECG belt 13, respiration belt 14, or transducer 15.

[0035] FIG. 3 is a schematic block diagram of activity sensing device 10, which includes sensor 16, telemetry module 17, processor 18, memory 20, power source 21, and user interface 22. Activity sensing device 10 is configured to generate a signal indicative of a relative level of patient activity. Sensor 16 may be any sensor such as an accelerometer, a bonded piezoelectric crystal, a mercury switch, or a gyro, or any other sensor that transforms mechanical, chemical or electrical conditions into electrical signals representative of an activity level of patient 12. The electrical signals may be amplified, filtered, and otherwise processed as appropriate by circuitry known in the art, which may be provided as part of sensor 16 or processor 18. In some embodiments, the signals may be converted to digital values and processed by processor 18 before being saved to memory 20 or uploaded to another device (e.g., a clinician computing device).

[0036] In some cases, sensor 16 may measure a physiological parameter of patient 12 that varies as a function of patient activity. However, because sensor 16 is worn externally to patient 12, some physiological parameter measurements may not be as accurate as when sensor 16 is implanted within patient 12. An embodiment in which a physiological parameter sensor is implanted within patient 12 is shown in FIG. 4 and described below.

[0037] Processor 18 may include a microprocessor, a controller, a DSP, an ASIC, an FPGA, discrete logic circuitry, or

the like. Processor 18 is electrically coupled to sensor 16 and receives a signal from sensor 16 in order to monitor the signal and determine a patient activity level based on a signal. In one embodiment, processor 18 determines a patient activity level by sampling the signal and determining a number of activity counts during the sample period. In one embodiment, processor 18 compares the signal generated by sensor 16 to one or more amplitude thresholds stored within memory 20. Processor 18 may identify each threshold crossing as an activity count. Where processor 18 compares the sample to multiple thresholds with varying amplitudes, processor 18 may identify crossing of higher amplitude thresholds as multiple activity counts. Using multiple thresholds to identify activity counts, processor 18 may be able to more accurately determine the extent of patient activity. In embodiments in which a sensor 16 takes the form of a mercury switch, processor 18 may identify the number of switch contacts indicated during the sample period as the number of activity counts. Processor 18 may then store the determined number of activity counts in memory 20 as an activity level in addition to or instead of storing the signals generated by sensor 16.

[0038] Alternatively, processor 18 does not determine an activity level, but merely stores the signals from sensor 16 in memory 20 for later retrieval and analysis by a clinician. The clinician may, for example, upload the data from memory 20 onto another computing device, which may then determine the activity levels based on the stored signals.

[0039] In embodiments in which sensor 16 generates a signal indicative of a physiological parameter of a patient, processor 18 may monitor a signal from sensor 16 and determine a physiological parameter measurement based on the signal. The physiological parameter measurement may be mean or median values of the physiological parameter over a certain period of time. Based on the physiological parameter values, processor 18 may determine an activity level by comparing the determined physiological parameter measurement to one or more thresholds stored within memory 20. A first threshold may indicate a first activity level, a second threshold may indicate a second activity level that is greater than the first activity level, and so forth for as many activity levels as desired. Processor 18 may compare the measured physiological parameter to the thresholds to determine the activity level corresponding to the measured physiological parameter. For example, if the measured parameter exceeds the second threshold, but not a third threshold, the measured parameter falls within the second activity level. As an example of how the thresholds may be used to determine an activity level, the third activity level may indicate an “active” state of the patient, and thus, a relatively high activity level that may indicate that an involuntary voiding event was attributable to stress incontinence.

[0040] If one or more physiological parameters are measured to determine a patient activity level, the activity levels that represent active and inactive states may differ between patients, depending on the type of physiological parameter that is measured to determine an activity level. For example, patients that are physically fit may have a different heart rate at an elevated activity state than patients that are not physically fit. Thus, between those two groups of patients, using the same heart rate threshold for both patients as an indicator of activity level may not be entirely accurate. Accordingly, it may be desirable to modify the thresholds to a particular patient.

[0041] As an alternative to using thresholds, the relative changes in a patient's activity level may be used to determine when the patient is in an elevated activity state that might result in an increase in intraabdominal pressure, and accordingly, may trigger stress incontinence events. For example, after associating the involuntary voiding event with a patient activity level, processor 18 may compare the associated activity level with prior activity levels to determine whether there was an increase in activity, and thus, whether the activity level associated with the involuntary voiding event is relatively high.

[0042] The activity levels may also be used to determine a severity of a patient's incontinence. For example, if the patient is afflicted with stress incontinence, the activity level associated with involuntary voiding events may be used determine at what activity level the stress incontinence becomes a problem. If the activity level is determined based on input from a multi-axis accelerometer or multiple single-axis accelerometers arranged along different axes, the accelerometer output may be used to differentiate between the activity level (e.g., the severity or type of activity) at the time of an involuntary voiding event. For example, the amplitude of the electrical signal generated by an accelerometer may be useful for differentiating between a low level of activity (e.g., walking) and a high level of activity (e.g., aerobic activity). A clinician may diagnose the severity of the patient's stress incontinence based on whether the patient experiences an involuntary voiding event during a high level of activity, e.g., an aerobic activity, a low level, e.g., relatively slow walking, or both (or other activity levels in between "high" and "low").

[0043] In another embodiment, regardless of whether sensor 16 monitors patient motion or one or more physiological parameters, processor 18 may compare the signal generated by sensor 16 to one or more amplitude thresholds stored within memory 20, where each threshold crossing counts as an activity count, and the total number of activity counts indicates the patient activity level.

[0044] The data from sensor 16 and/or patient activity levels determined by processor 18 may be stored in memory 20 of activity sensing device 10. The data from memory 20 may be uploaded to another device via telemetry module 17, which may be controlled by processor 18. Telemetry module 17 may communicate with another device using any of a variety of local wireless communication techniques, such as RF communication according to the 802.11 or Bluetooth specification sets, infrared communication, e.g., according to the IrDA standard, or other standard or proprietary telemetry protocols.

[0045] Memory 20 may include any volatile or non-volatile media, such as a RAM, ROM, NVRAM, EEPROM, flash memory, and the like. Memory 20 stores instructions for execution by processor 18 in addition to patient activity data. In one embodiment, memory 20 may implement loop recorder functionality in which processor 18 overwrites the oldest contents within memory 20 with new data as storage limits are met, thereby conserving data storage resources within sensing device 10. Because the capacity of memory 20 is limited, in order to record large amounts of data and/or record data over a relatively long period of time, it may be useful to record the patient activity data from sensor 16 with a loop recorder. However, overwriting of the patient activity data can be halted when processor 18 detects an involuntary

voiding event. Alternatively, processor 18 may record the relevant patient activity data in a segment of memory 20 that is not overwritten.

[0046] Sensor 16 and processor 18 may be coupled to power source 21. Power source 21 may take the form of a rechargeable or non-rechargeable battery. In the case of a rechargeable battery, power source 21 similarly may include an inductive power interface for transfer of recharge power.

[0047] Feedback from activity sensing device 10 may aid in determining whether an involuntary voiding event was stress or urge incontinence. In particular, an involuntary voiding event may be associated with a patient activity level that is determined based on signals from activity sensing device 10 in order to help distinguish between stress or urge incontinence events. The associated patient activity level may be an activity level that coincides with the occurrence of the involuntary voiding event or the activity level during a certain time range prior to the occurrence of the involuntary voiding event. In the latter situation, the mean or median patient activity for the range of time may be used as the relevant patient activity level. Distinguishing between stress and urge in patients may help a clinician formulate a therapy program for the patient.

[0048] Incontinence may be treated with electrical stimulation therapy that prevents urine from leaving the bladder when a patient does not wish to void urine. In combination with tracking voiding events, the electrical stimulation may be delivered to nerves, i.e. sacral or pudendal nerves, or directly to a urinary sphincter, where the stimulation causes the urinary sphincter to constrict and retain urine within the bladder. Electrical stimulation may also be directed to other muscles of the pelvic floor because some of these muscles play a role in controlling urinary voiding events.

[0049] An exemplary range of electrical stimulation pulse parameters likely to be effective in treating incontinence, e.g., when applied to the sacral or pudendal nerves, are as follows:

[0050] 1. Frequency: between approximately 0.5 Hertz (Hz) and approximately 500 Hz, such as between approximately 5 Hz and approximately 250 Hz or such as between approximately 10 Hz and approximately 50 Hz.

[0051] 2. Amplitude: between approximately 0.1 volts and approximately 50 volts, such as between approximately 0.5 volts and approximately 20 volts or between approximately 1 volt and approximately 10 volts. The amplitude may be representative of a biological load between 10 ohms and approximately 10,000 ohms.

[0052] 3. Pulse Width: between approximately 10 microseconds and approximately 5000 microseconds, such as between approximately 100 microseconds and approximately 1000 microseconds or between approximately 180 microseconds and 450 approximately microseconds.

[0053] Stress and urge incontinence may be treated by different therapy parameters and, in some cases, the therapy may be activated by different physiological conditions. For example, in patients with stress incontinence, electrical stimulation may be activated during relatively high levels of patient activity. A relatively high level of the patient activity may indicate that the patient is undergoing an activity that increases intraabdominal pressure, thereby increasing the risk of an involuntary voiding event. In patients with urge incontinence, the electrical stimulation may be delivered substantially continuously or upon the detection of, for example, an increase in bladder pressure that is not accompanied by increases in overall abdominal pressure.

[0054] Distinguishing between stress and urge incontinence may be useful as a diagnostic tool before any therapy program is provided on a chronic basis. Patient 12 may wear external activity sensing device 10 during a diagnostic period, which may be, for example, a few days to a few months. During the diagnostic period the clinician may gather information relating to the frequency of involuntary voiding events, the time of day the involuntary voiding events occurred, the activity levels coinciding with the involuntary voiding events, and so forth.

[0055] Distinguishing between stress and urge incontinence may also be useful for diagnosing an ongoing patient condition. For example, if patient 12 is initially diagnosed with urge continence and provided with a treatment tailored to treating urge incontinence, but continues to be afflicted by involuntary voiding events, a clinician may find it useful to determine whether patient 12 is also afflicted by stress incontinence in order to modify the electrical stimulation parameters to treat substantially all incidences of involuntary voiding events. By correlating the patient activity level with the involuntary voiding events may help the clinician determine whether patient 12 has "mixed incontinence," which is more than one type of incontinence, or whether patient 12 only has one type of incontinence, but the patient's therapy program needs to be modified.

[0056] Patient 12 may indicate an occurrence of an involuntary voiding event. For example, upon the occurrence of an involuntary voiding event, patient 12 may depress button, keypad, or otherwise provide feedback via user interface 22 of external activity sensing device 10, which may cause processor 18 to record the date and time of the involuntary voiding event in memory 20. One or more involuntary voiding events may be associated with an activity level of patient 12 by processor 18. Alternatively, the activity data and patient feedback regarding the occurrence of one or more involuntary voiding events may be retrieved by a clinician, who may then manually correlate a patient activity level with the involuntary voiding event or utilize another computing device to correlate the patient activity level with the involuntary voiding event. As yet another alternative, in embodiments in which memory 20 is a loop recorder, memory 20 may only store patient activity levels that occurred within a specific time range (e.g., less than one minute) prior to an involuntary voiding event, and record over the other patient activity data. In this way, relevant activity data is stored within memory 20 and easily identified by the clinician during an analysis stage.

[0057] FIG. 4 is a schematic diagram illustrating a medical system 23 in which activity sensing device 24 is implanted near bladder 28 of patient 12. Medical system 23 also includes external computing device 26. FIG. 5 is a schematic block diagram of implantable activity sensing device 24, which is substantially similar to external activity sensing device 10 of FIGS. 1 and 2, but is implantable within patient 12, and does not include user interface 22. Activity sensing device 24 may be enclosed in a biocompatible material, such as titanium or silicone.

[0058] External computing device 26 (FIG. 4) is a handheld device, such as a clinician programmer or a patient programmer, configured to communicate with implanted sensing device 24. Sensing device 24 and computing device 26 are configured for bidirectional communication. As described in further detail below, computing device 26 has a telemetry module configured to communicate via wireless telemetry with telemetry module 17 of activity sensing device 24. In

particular, external computing device 26 may interrogate sensing device 24 to retrieve patient activity data generated by sensor 16 and stored in memory 20. Wireless telemetry may be accomplished by radio frequency (RF) communication or proximal inductive interaction of sensing device with another device. Communicating via wireless telemetry enables a clinician to interact with activity sensing device 24 while activity sensing device 24 is implanted within patient 12. Processor 18 may also initiate communication with computing device 26 by controlling telemetry module 17.

[0059] External computing device 26 is not limited to handheld devices. In other embodiments, external computing device 26 may be any sort of computing device. For example, external computing device 26 may be a tablet-based computing device, a desktop computing device, or a workstation.

[0060] Just as with activity sensing device 10, activity sensing device 24 generates signals indicative of patient activity (i.e., patient activity data) and determine an activity level based on the signals. External computing device 26 or another computing device may then retrieve the patient activity data from memory 20. In another embodiment, activity sensing device 24 generates and stores the signals indicative of patient activity, and external computing device 26 or another computing device retrieves the stored signals and determines an activity level based on retrieved signals.

[0061] External computing device 26 has a user interface, which may include display 31 to present information to a user and input keys 32 or other media (e.g., buttons, a touch screen or a joy stick) to receive user input. Display 31 may be, for example, an LCD or LED display. A clinician, patient 12 or another user may interact with external computing device 26 via input keys 32, which may be alphanumeric keypad or a reduced set of keys associated with particular functions. For example, a clinician may initiate interrogation of sensing device 24 via input keys 32, and after downloading the patient activity data from memory 20, external computing device 26 may present the patient activity data on display 31. In some embodiments, display 31 may be a touch screen display, and the user may interact with computing device 26 via display 31.

[0062] In accordance with the present invention, patient 12 may indicate that an involuntary voiding event occurred via any one of the implanted activity sensing device 24 (e.g., via tapping the device), via external computing device 26, or another input mechanism. If external computing device 26 is a device carried by patient 12, patient 12 may provide an indication of an involuntary voiding event via input keys 32 or a touch screen display 31. For example, upon the occurrence of an involuntary voiding event, patient 12 may input an indication of the event by depressing one of input keys 32. The input may then cause a processor (shown in FIG. 7) within external computing device 26 to record the current date and time. In this way, a log of the involuntary voiding events may be created for later analysis by a clinician. In other embodiments, a smaller, more discreet input mechanism may be used to record the involuntary voiding event data. For example, a device that resembles a key fob for a keyless vehicle entry system that includes a small number (e.g., one) of buttons may be carried by patient 12 to record the date and time of an involuntary voiding event.

[0063] The clinician may correlate an activity level determined via data from implanted sensing device 24 with the involuntary voiding event by matching up the dates and times of the voiding event and the activity levels. Based on the

activity level correlated with the involuntary voiding event, the clinician may determine whether the voiding event was attributable to stress or urge incontinence.

[0064] Although activity sensing device 24 is shown to be implanted in the abdomen of patient 12 proximate to bladder 28 in FIG. 4, in other embodiments, activity sensing device 24 may be implanted in any suitable location within patient 12 that enables sensing device 24 to generate relevant patient activity data. For example, in another embodiment, sensing device 24 may be implanted within a chest cavity of patient 12. It may be desirable to implant sensing device 24 in the torso of patient 12 in order to gather activity data that is most relevant to activities that increase intraabdominal pressure, and accordingly, increase the chances of a stress incontinence event. For example, if sensing device 24 is implanted within an arm of patient 12, movement of the arm may not necessarily result in increase intraabdominal pressure, and activity sensed by sensing device 24 may erroneously sense a high level of activity.

[0065] In addition to or instead of utilizing activity an sensor that senses motion, such as an accelerometer, a bonded piezoelectric crystal, a mercury switch or a gyro, an implanted activity sensing device may include one or more physiological sensors, such as one or more sensing electrodes, for detecting physiological parameters of patient 12 that are indicative of a patient activity level. FIG. 6 is a schematic block diagram of implantable activity sensing device 34, which is similar to activity sensing device 24, but includes motion sensor 36 and physiological parameter sensing module 38 that is coupled to physiological sensor 40. Physiological sensor 40 may be coupled to sensing device 34 via a medical lead that electrically couples to physiological parameter sensing module 38 of sensing device 34. Alternatively, one or more sensors (e.g., one or more sensing electrodes) may be disposed on a housing of sensing device 34. In another embodiment, one or more physiological sensors may be coupled to sensing device 34 via wireless telemetry (supported by telemetry module 17).

[0066] Motion sensor 36 may be a sensor that generates a signal that varies with patient motion, such as an accelerometer, a bonded piezoelectric crystal, a mercury switch or a gyro. In some embodiments, implantable activity sensing device 34 does not include motion sensor 36.

[0067] Physiological parameter sensing module 38 includes the sensing circuitry, and may generate a signal indicative of a physiological parameter sensed by sensor 40 and transmit the signal to processor 18. Sensor 40 may include one or more electrodes located on one or more leads that are coupled to sensing device 34, or integrated as part of the housing of sensing device 34 that generates an electrogram signal as a function of electrical activity of the heart of patient 12, and processor 18 may periodically determine the heart rate of patient 12 based on the electrogram signal. In other embodiments, sensor 40 may include an acoustic sensor within sensing device 34, a pressure sensor within the bloodstream or cerebrospinal fluid of patient 12, or a temperature sensor located within tissue or the bloodstream of patient 12. The signals generated by such a sensor 40 may vary as a function of contraction of the heart of patient 12, and can be used by processor 18 to periodically determine the heart rate of patient 12, which may indicate an activity level of patient 12.

[0068] In some embodiments, sensor 40 may include an electrode pair, including one electrode integrated with the

housing of sensing device 34, which generates a signal as a function of the thoracic impedance of patient 12, which varies as a function of respiration by patient 12. In other embodiments, sensor 40 may include a strain gauge, bonded piezoelectric element, or pressure sensor within the blood or cerebrospinal fluid that generates a signal that varies based on patient respiration. Processor 18 may monitor the signals generated by such a sensor 40 to periodically determine a respiration rate and/or respiratory volume of patient 12. An electrogram generated by electrodes as discussed above may also be modulated by patient respiration, and processor 18 may use the electrogram as an indirect representation of respiration rate. Additionally, sensor 40 may include electrodes that generate an electromyogram (EMG) signal as a function of muscle electrical activity, or may include any of a variety of known temperature sensors to generate a signal as a function of a core temperature of patient 12. Such electrodes and temperature sensors may be incorporated within the housing of sensing device 34, or coupled to sensing device 34 via one or more leads.

[0069] Processor 18 may determine a patient activity level based on the measured physiological parameter values. As described above, two or more activity levels may be demarcated from a previous activity level by a threshold value for the physiological parameter. Hence, the measured physiological parameter values may be compared to threshold values in order to determine what patient activity level corresponds to the measured physiological parameter.

[0070] In some embodiments, processor 18 compares a determined value of a physiological parameter measurement to one or more thresholds or a look-up table stored in memory 20 to determine a number of activity counts, and stores the determined number of activity counts in memory 20 as a determined activity level. The use of activity counts may allow processor 18 to determine an activity level based on a plurality of signals generated by a plurality of sensors 36, 40. For example, processor 18 may determine a first number of activity counts based on a sample of an accelerometer signal from sensor 36 and a second number of activity counts based on a heart rate determined from an electrogram signal from sensor 40 at the time the accelerometer signal was sampled. Processor 18 may determine an activity level by calculating the sum or average, which may be a weighted sum or average, of first and second activity counts, and comparing the sum or average to the look-up table or thresholds stored in memory 20.

[0071] Processor 18 may determine and record activity levels continuously or periodically, e.g., one sample every minute or continuously for ten minutes each hour. In some embodiments, processor 18 limits recording of activity levels to relevant time periods, i.e., when patient 12 is awake or likely to be awake, and therefore likely to be active. For example, patient 12 may indicate via external computing device 26 when patient is going to sleep or awake. Processor 18 may receive these indications via a telemetry module 17 of sensing device 34, and may suspend or resume recording of activity levels based on the indications. In other embodiments, processor 18 may maintain a real-time clock, and may record activity levels based on the time of day indicated by the clock, e.g., processor 18 may limit activity level recording to daytime hours.

[0072] The patient activity levels, along with the parameter values or signals from the sensors, may be stored within memory 20 for later retrieval and analysis by a clinician.

Alternatively, processor 18 may store the signals from the sensors and/or actual physiological parameter values in memory 20, and a clinician may retrieve the signals and/or physiological parameter values from memory 20 via external computing device 26 and determine the patient activity levels from the retrieved signals. In some embodiments, processor 18 is also configured to receive an indication of an involuntary voiding event, associate the event with a patient activity level, and determine whether the event was attributable to stress or urge incontinence based on the associated activity level. Processor 18 may store the determination within memory 20, along with any other relevant data, such as the activity level associated with the involuntary voiding event.

[0073] FIG. 7 is a schematic block diagram of external computing device 26, which includes user input 52, telemetry module 54, power source 56, communication interface 58, processor 60, and memory 62. User input 52 may include display 31 and input keys 32, which are shown in FIG. 4. While activity sensing device 10 is referred to throughout the description of FIG. 7, either activity sensing devices 24 or 34 may be substituted for activity sensing device 10.

[0074] Memory 62 may include, for example, volatile or non-volatile media, such as a RAM, ROM, NVRAM, EEPROM or flash memory. Memory 62 stores instructions for execution by processor 60 in addition to data retrieved from activity sensing device 10, patient 12, and the clinician. Memory 62 may include separate memories for storage of instructions and information received from sensing device 10, patient 12, and the clinician.

[0075] Processor 60 controls telemetry module 54 to interrogate activity sensing device 10 and obtain activity data from memory 20 of activity sensing device 10, which may be, for example, the stored signals from sensor 16. Processor 60 may store the data within memory 62. Processor 60 may control telemetry module 54 to receive information from activity sensing device 10 on a substantially continuous basis, at periodic intervals, or only upon receipt of an activation command. Hence, external computing device 26 may obtain an ongoing indication of the physiological conditions sensed by activity sensing device 10, or receive periodic updates. For example, external computing device 26 may be configured to respond to a voiding event input entered by patient 12 via user input 52 to indicate the occurrence of an involuntary voiding event. In response to receiving the voiding event input, external computing device 26 generates an activation control signal and transmits the control signal to activity sensing device 10 via telemetry module 54 to retrieve patient activity data from activity sensing device 10.

[0076] Wireless telemetry may be accomplished by radio frequency (RF) communication or proximal inductive interaction of external computing device 26 with activity sensing device 10. In addition to an RF or inductive telemetry module 54, external computing device 26 may include a wired or wireless communication interface 58 for communication with other external devices, e.g., either directly or via a network. In some cases, external computing device 26 may also include a communication interface, such as another telemetry module or telemetry module 54, to communicate with an implanted medical device (e.g., an electrical stimulator) in order to initiate, stop or adjust electrical stimulation therapy to treat incontinence.

[0077] Upon receiving the stored signals from memory 20 of activity sensing device 24, 34, processor 60 may determine activity levels based on the stored signals, such as by com-

paring the amplitude of the signals to a threshold, as described above. Processor 60 may receive the indication of an involuntary voiding event from a patient via a touch screen display 31 or input keys 32, and associate the involuntary voiding event with a patient activity level. Based on the associated activity level, processor 60 may determine whether the involuntary voiding event was attributable to stress or urge incontinence. Processor 60 may store the determination within memory 62. In addition to or instead of storing the determination of whether the involuntary voiding event was attributable to stress or urge incontinence within memory 62, processor 60 may present an indication of the determination on display 31.

[0078] Processor 60 may be constructed in a variety of ways, as described above with respect to sensor processor 18 of FIG. 3, including as one or more microprocessors, an ASIC, an FPGA, or a combination thereof. It should also be understood that the functions of the processor 60 could be undertaken by processor 18 of activity sensing devices 10 or a processor of a therapy delivery device (e.g., an electrical stimulator or fluid delivery device) that provides stimulation to control the function of bladder 28. For example, in one embodiment, the raw data gathered by activity sensing device 10 could be translated to a patient activity level by processor 18 of activity sensing device 10 and then transmitted via wired or wireless telemetry to processor 60 in external computing device 26 to determine whether an involuntary voiding event was attributable to stress or urge incontinence. Similarly, the functions of processor 18 activity sensing devices 10 could also be undertaken by processor 60 of external computing device 26 or a processor of a therapy delivery device.

[0079] FIG. 8 is a schematic diagram illustrating medical system 64, which includes external activity sensing device 10, external computing device 26, implantable electrical stimulator 66, lead 68 coupled to electrical stimulator 66, and electrodes 70 disposed on lead 68. Electrical stimulator 66 and lead 68 are implanted within patient 12 to deliver electrical stimulation to bladder 28 to control the function of bladder 28. In particular, electrical stimulator 66 at least partially prevents unwanted urinary voiding events by stimulating a pelvic floor nerve, a pelvic floor muscle or the urinary sphincter. Electrical stimulator 66 includes a pulse generator that generates electrical pulses and delivers the electrical pulses to a target tissue, e.g., the urinary sphincter, via one or more electrodes 70 located at the distal end of lead 68.

[0080] After determining whether patient 12 is afflicted with stress incontinence, urge incontinence or both, a clinician may evaluate prospective therapy parameter sets and select parameter sets for use implanted electrical stimulator 66, or alternatively, adjust previously selected therapy parameters. During an initial electrical stimulator 66 set-up stage, a clinician may select one or more parameters (e.g., voltage or current amplitude, pulse width or pulse frequency of the stimulation) of electrical stimulation delivered by electrical stimulator 66 based on whether the patient is afflicted with stress or urge incontinence. As discussed above, a diagnosis of stress or urge incontinence may be made via one of activity sensing device 10 or another activity sensing device prior to implantation of electrical stimulator 66 within patient 12. In patients with stress incontinence, for example, the clinician may program electrical stimulator 66 to deliver stimulation or increase the duration or level of stimulation when increased patient activity levels are detected by activity sensor 10.

[0081] The clinician may also evaluate the efficacy of the therapy program during a follow-up clinic visit. If patient 12 is still experiencing involuntary voiding events, the clinician may utilize data from activity sensing device 10 and possibly external computing device 26, to determine the patient activity level that coincides with the involuntary voiding events, which may help the clinician determine whether the involuntary voiding events that are still occurring are attributable to stress or urge incontinence. Rather than relying on the patient's possibly incorrect account of the activity level at the time of the involuntary voiding event, the clinician may make determine the relevant activity level based on sensed activity signals. In addition, automatically monitoring patient activity eliminates any inconvenience to patient 12 that may result from asking the patient to monitor and record the level of activity (e.g., strenuous, moderate or resting) that coincided with any involuntary voiding events. However, in some embodiments, the patient 12 may provide such feedback to verify the monitored activity levels.

[0082] Determining whether the involuntary voiding events that are still occurring are attributable to stress or urge incontinence may help the clinician modify the stimulation parameters to better treat the incontinence. For example, if electrical stimulator 66 is configured to treat stress incontinence, but patient 12 continues to experience involuntary voiding events, the clinician may review the activity levels associated with the involuntary voiding events to determine whether the involuntary voiding events are stress or urge incontinence. If the clinician determines that the involuntary voiding events are attributable to urge incontinence, the clinician may modify the stimulation parameters to treat both stress and urge incontinence. On the other hand, if the clinician determines that the involuntary voiding events are attributable to stress incontinence, the clinician may modify the stimulation parameters to better treat the stress incontinence.

[0083] Stimulation parameter adaptation logic that may be implemented by electrical stimulator 66 or external computing device 26 is discussed in commonly-assigned U.S. patent application Ser. No. 11/117,058, entitled, "IMPLANTABLE MEDICAL DEVICE PROVIDING ADAPTIVE NEURO-STIMULATION THERAPY FOR INCONTINENCE," and filed on Apr. 28, 2005, which is incorporated herein by reference in its entirety.

[0084] Electrical stimulator 66 and activity sensing device 10 may be directly coupled by wired or wireless telemetry or may be coupled via external computing device 26. External computing device 26 may interrogate activity sensing device 10 and upon detecting a relatively high level of patient activity, external computing device 26, which is configured to communicate with electrical stimulator 66, may activate the delivery of electrical stimulation via electrical stimulator 66 or inputting adjustments to the stimulation parameters. Alternatively, activity sensing device 10 and electrical stimulator 66 may be integrated within the same housing and implanted together in patient 12.

[0085] Electrical stimulator 66 (or another implantable medical device) may receive an indication of an involuntary voiding event from computing device 26, activity sensing device 10, via patient input by tapping electrical stimulator 66, a sensor in an undergarment or otherwise. Upon receiving the indication of the involuntary voiding event, a processor within electrical stimulator 66 may associate the involuntary voiding event with a patient activity level in order to determine whether the involuntary voiding event was attributable

to stress incontinence or urge incontinence. Based on the determination of whether the involuntary voiding event was attributable to stress incontinence or urge incontinence, electrical stimulator may adjust the electrical stimulation therapy. In this way, feedback from activity sensing device 10 may be used in a closed loop system to adjust therapy parameters for chronic therapy delivery or during a trial period in which the therapy parameters are optimized. If activity sensing device 10 provides feedback for adjusting therapy parameters during a trial period, electrical stimulator 66 may be external.

[0086] Although activity sensing device 10 is shown in FIG. 7, on other embodiments, system 64 may include implanted activity sensing device 24 (FIG. 5) or activity sensing device 34 (FIG. 6).

[0087] In other embodiments, in addition to or instead of delivering electrical stimulation therapy via electrical stimulator 66, the therapy system may include a fluid delivery device, such as a fluid pump, to deliver a pharmaceutical agent to patient 12 to treat urinary incontinence. The fluid delivery device may also use feedback from an activity sensing device to adjust the therapy parameters, such as the size of a drug bolus or the frequency of delivery.

[0088] A clinician may also utilize an adjunct therapy in addition to or instead of electrical stimulation therapy to treat a patient's incontinence. An example of an adjunct therapy that is useful in female patients is a sling procedure. A sling is typically material formed in the shape of a narrow ribbon that is placed under the urethra through vaginal incision and small abdominal incisions. The sling may act as a "hammock" of support under the urethra or bladder neck and aid deficient pelvic floor muscles. The sling may be constructed of different materials, such as a synthetic mesh material, such as polypropylene, a biomaterial (e.g., bovine or porcine tissue) or a patient's tissue. Determining whether the involuntary voiding events that are still occurring are attributable to stress or urge incontinence may provide useful information the clinician may consider when selecting a therapy, such as a sling, electrical stimulation therapy, drug delivery therapy or otherwise, to better treat the patient's incontinence.

[0089] In accordance with some embodiments of the present invention, more than one activity sensors may be used to determine a patient activity level. The activity sensors may be worn externally and/or implanted within different regions of the body. For example, a motion detection sensor may be used in combination with an implanted sensor that detects a heart rate of the patient or another physiological parameter. Detecting more than one signal that indicates patient activity may help achieve a more accurate determination of patient activity level.

[0090] Various embodiments of the invention have been described. These and other embodiments are within the scope of the following claims.

1. A method comprising:

- monitoring a signal that varies as a function of patient activity;
- receiving an indication of an occurrence of an involuntary voiding event; and
- determining whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based the signal.

2. The method of claim 1, wherein the signal comprises a signal generated by at least one of an accelerometer, a bonded piezoelectric crystal, a mercury switch or a gyro.

3. The method of claim 1, wherein the signal is indicative of a physiological parameter measurement of the patient.

4. The method of claim 3, wherein the physiological parameter comprises at least one of a heart rate, respiratory rate, electrocardiogram morphology, respiration rate, respiratory volume, core temperature, muscular activity level or subcutaneous temperature of the patient.

5. The method of claim 3, further determining an activity level of the patient by comparing the physiological parameter measurement to at least one threshold.

6. The method of claim 1, further comprising determining an activity level of the patient based on the signal.

7. The method of claim 6, wherein determining whether the involuntary voiding event was stress incontinence or urge incontinence comprises associating the involuntary voiding event with at least one activity level.

8. The method of claim 7, wherein associating the involuntary voiding event with at least one activity level comprises determining the activity level that substantially coincides with the occurrence of the involuntary voiding event.

9. The method of claim 7, wherein associating the involuntary voiding event with at least one activity level comprises determining the activity level during a predetermined range of time prior to the occurrence of the involuntary voiding event.

10. The method of claim 7, wherein determining whether the involuntary voiding event was stress incontinence or urge incontinence further comprises comparing the at least one activity level associated with the involuntary voiding event to at least one threshold.

11. The method of claim 1, further comprising storing the signal in a memory of a device.

12. The method of claim 1, further comprising storing an indication of whether the involuntary voiding event was stress incontinence or urge incontinence in a memory of a device.

13. The method of claim 1, wherein receiving the indication of the involuntary voiding event comprises receiving user input indicating the occurrence of the involuntary voiding event.

14. The method of claim 13, wherein receiving user input indicating the occurrence of the involuntary voiding event comprises receiving user input via a therapy delivery device.

15. The method of claim 13, wherein receiving user input indicating the occurrence of the involuntary voiding event comprises receiving user input via a medical device programmer.

16. The method of claim 1, further comprising adjusting a stimulation parameter of electrical stimulation therapy for the patient based on the determination of whether the involuntary voiding event was stress incontinence or urge incontinence.

17. The method of claim 1, further comprising selecting a therapy program for the patient based on the determination of whether the involuntary voiding event was stress incontinence or urge incontinence.

18. The method of claim 1, further comprising presenting an indication of whether the involuntary voiding event was stress incontinence or urge incontinence on a display.

19. A system comprising:

an activity sensor that generates a signal that varies as a function of activity of a patient; and

a processor that receives the signal from the activity sensor, receives an indication of an occurrence of an involuntary voiding event, and determines whether the involuntary

voiding event was attributable to stress incontinence or urge incontinence based the signal.

20. The system of claim 19, further comprising a medical device that delivers at least one of electrical stimulation therapy or a drug therapy to the patient to treat incontinence.

21. The system of claim 20, wherein the processor further adjusts a therapy parameter of the electrical stimulation therapy or the drug therapy based on the determination of whether the involuntary voiding event was stress incontinence or urge incontinence.

22. The system of claim 20, wherein the medical device includes the processor.

23. The system of claim 20, wherein the activity sensor and medical device are disposed within the same housing.

24. The system of claim 19, further comprising a programming device that includes the processor.

25. The system of claim 19, further comprising an implantable medical device and an external computing device, wherein the processor comprises a first processor that receives the signal from the activity sensor and a second processor that receives the indication of the occurrence of the involuntary voiding event, wherein the first processor is disposed within the implantable medical device and the second processor is located within the external computing device.

26. The system of claim 19, further comprising an implantable medical device and an external computing device, wherein the processor comprises a first processor that receives the signal from the activity sensor and receives the indication of the occurrence of the involuntary voiding event and a second processor that determines whether the involuntary voiding event was stress incontinence or urge incontinence based the signal, wherein the first processor is disposed within the implantable medical device and the second processor is located within the external computing device.

27. The system of claim 19, wherein the activity sensor is implantable.

28. The system of claim 19, wherein the activity sensor is an external activity sensor.

29. The system of claim 19, wherein the activity sensor comprises of a physiological parameter sensor, an accelerometer, a bonded piezoelectric crystal, a mercury switch or a gyro.

30. The system of claim 19, wherein the processor further determines an activity level of the patient based on the signal.

31. The system of claim 30, wherein the processor determines an activity level of the patient based on the signal by comparing an amplitude of the signal to at least one threshold.

32. The system of claim 30, wherein the processor associates the involuntary voiding event with at least one activity level to determine whether the involuntary voiding event was attributable to stress incontinence or urge incontinence.

33. The system of claim 19, further comprising a memory, wherein the processor stores an indication of whether the involuntary voiding event was stress incontinence or urge incontinence in the memory.

34. The system of claim 19, further comprising a user interface, wherein the processor receives the indication of the involuntary voiding event via the user interface.

35. The system of claim 34, wherein the user interface comprise a display, and wherein after the processor determines whether the involuntary voiding event was stress incontinence or urge incontinence based the signal, the pro-

cessor presents an indication of whether the involuntary voiding event was stress incontinence or urge incontinence via the display.

36. The system of claim **19**, wherein the processor further selects a therapy program for the patient based on the determination of whether the involuntary voiding event was stress incontinence or urge incontinence.

37. A medical system comprising:

means for generating a signal that varies as a function of patient activity;

means for receiving an indication of an occurrence of an involuntary voiding event; and

means for determining whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based the signal.

38. The medical system of claim **37**, further comprising means for adjusting a therapy parameter based on the deter-

mination of whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based the signal.

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

determine an activity level based on a signal received from a sensor, wherein the signal varies as a function of patient activity;

determine whether an involuntary voiding event occurred; associate the involuntary voiding event with the activity level; and

determine whether the involuntary voiding event was attributable to stress incontinence or urge incontinence based the activity level associated with the involuntary voiding event.

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[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司, INC.		
当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	GERBER MARTIN T RONDONI JOHN C		
发明人	GERBER, MARTIN T. RONDONI, JOHN C.		
IPC分类号	A61B5/00		
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摘要(译)

用于确定非自愿排尿事件是否可归因于压力或急迫性尿失禁的系统和方法包括确定患者的活动水平, 该活动水平与非自主排尿事件的发生或非自愿排尿事件的特定时间范围内的活动水平一致。可以通过随患者活动而变化的信号收集患者活动数据。可以利用检测运动的一个或多个传感器(例如加速度计或压电晶体)和/或监测患者的生理参数的一个或多个传感器生成信号, 所述生理参数根据患者活动而变化, 例如心脏患者的心率, 呼吸频率, 心电图形态, 呼吸率, 呼吸量, 核心温度, 肌肉活动水平或皮下温度。

