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(54) **CHANGE IN PHYSIOLOGICAL PARAMETER IN RESPONSE TO EXERTION EVENT**

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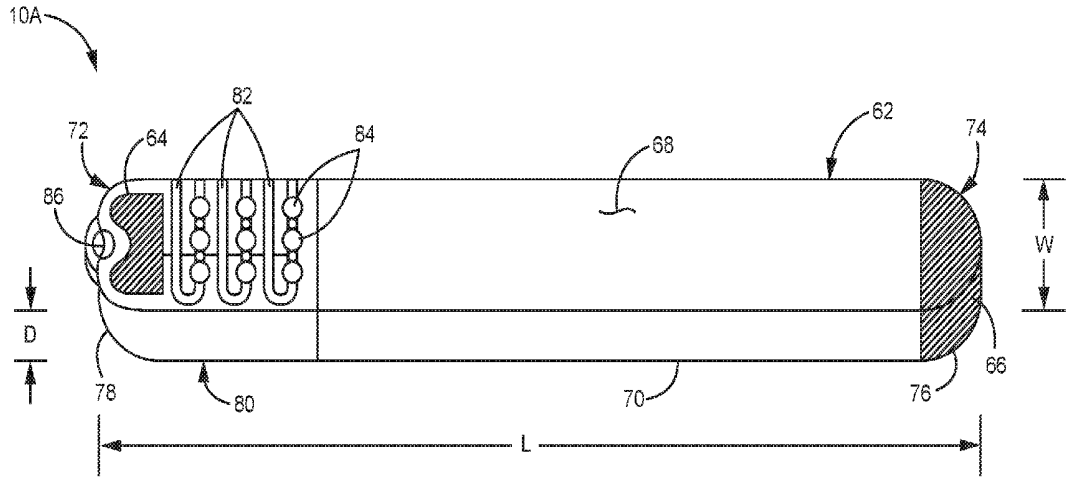
(57) **ABSTRACT**

A method for monitoring health of a subject based on a physiological response to physical exertion, by processing circuitry of a medical device system, is described that includes detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject. The method further includes determining a response of a physiological parameter of the subject to the exertion event for each of the detected exertion events based on second sensed signal that varies as a function of the physiological parameter. The method further includes determining that a change in the responses over time crosses threshold and generating an alert to a user based on the determination that the change crosses the threshold.



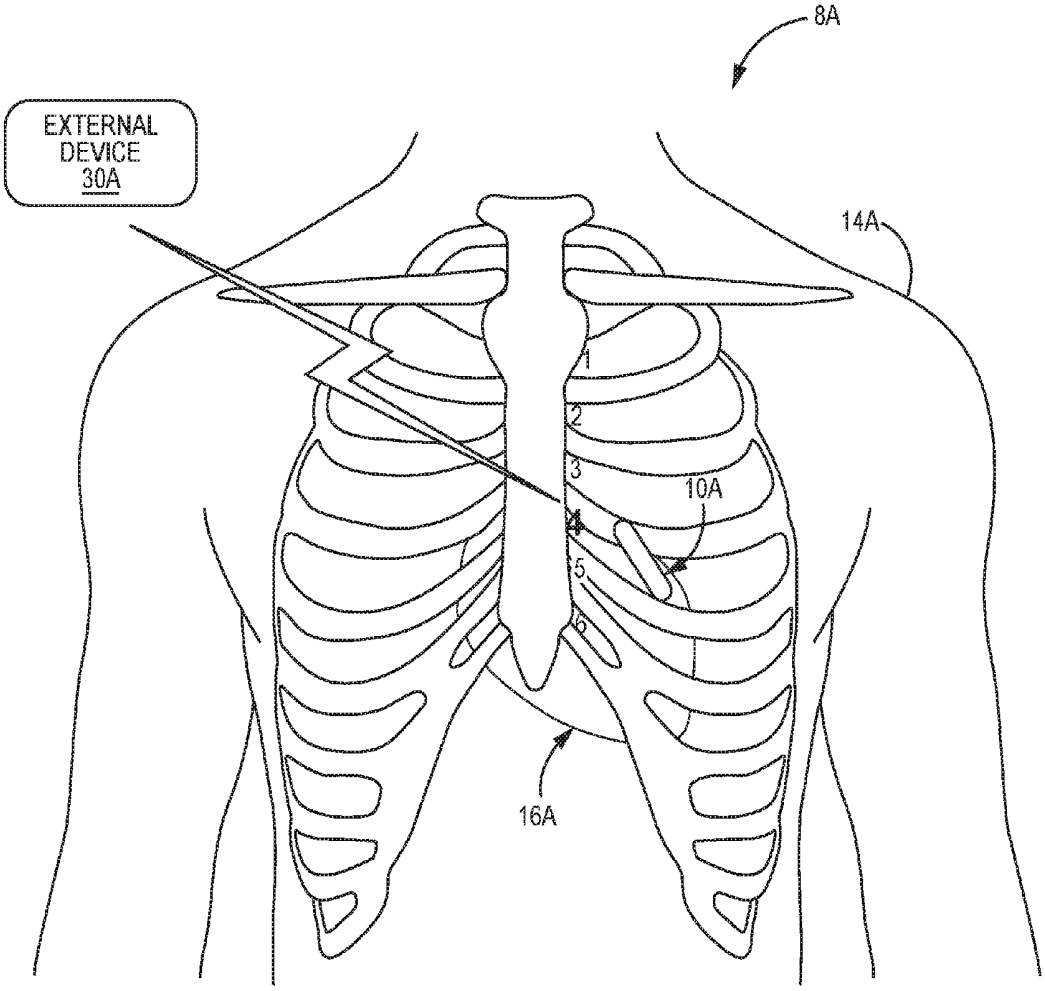



FIG. 1

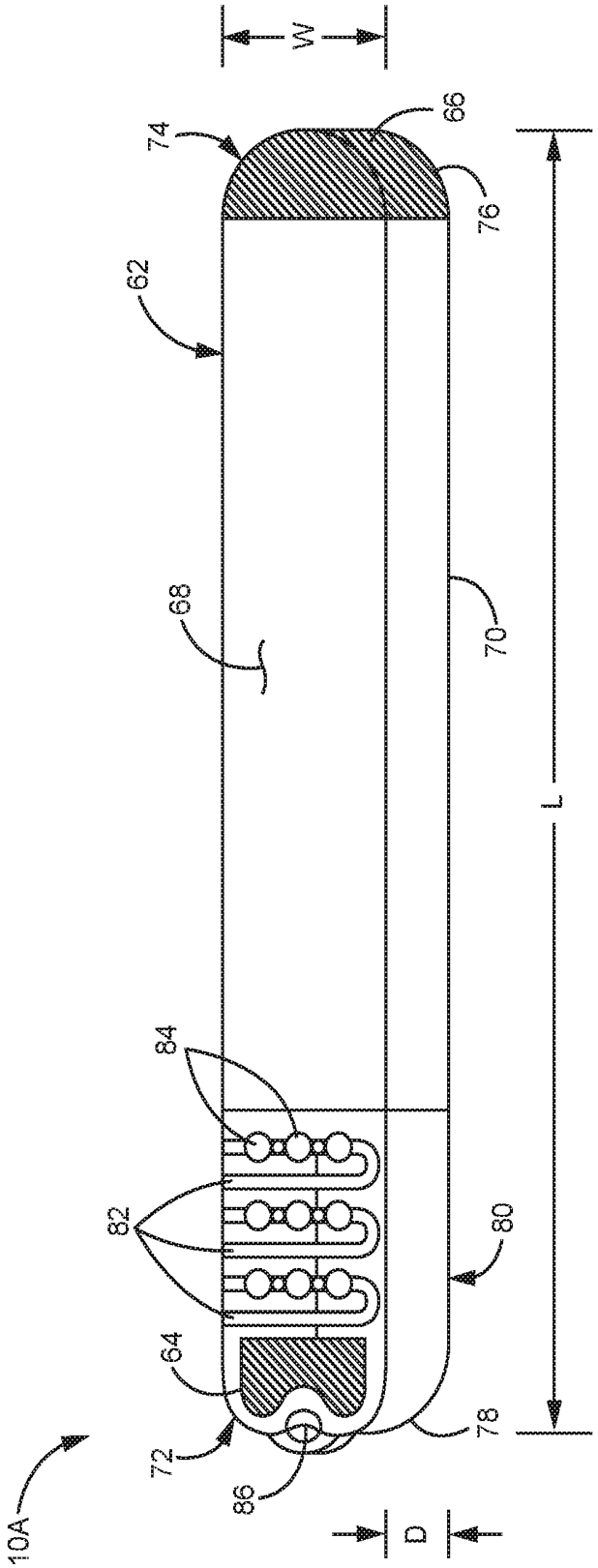



FIG. 2

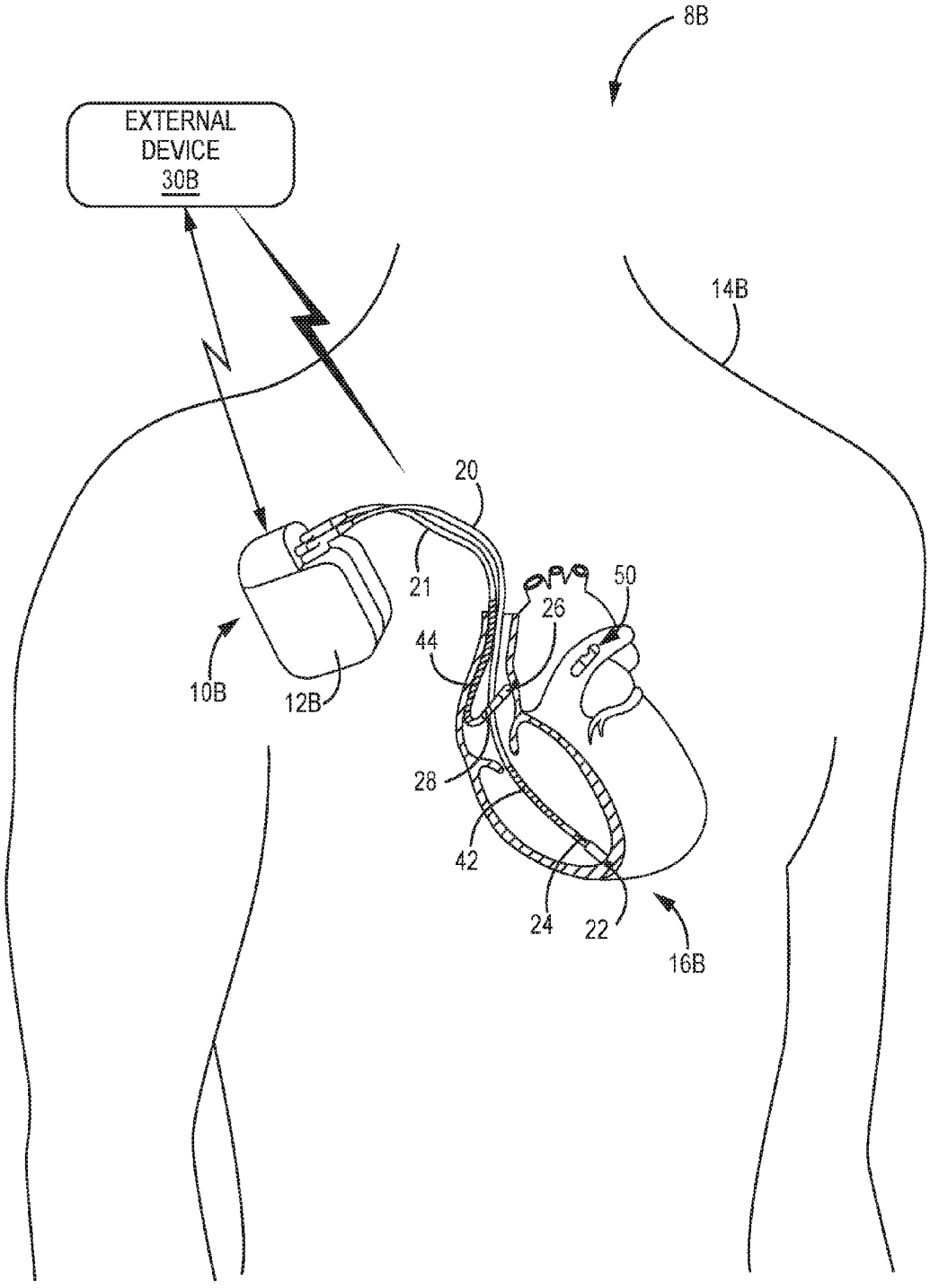



FIG. 3

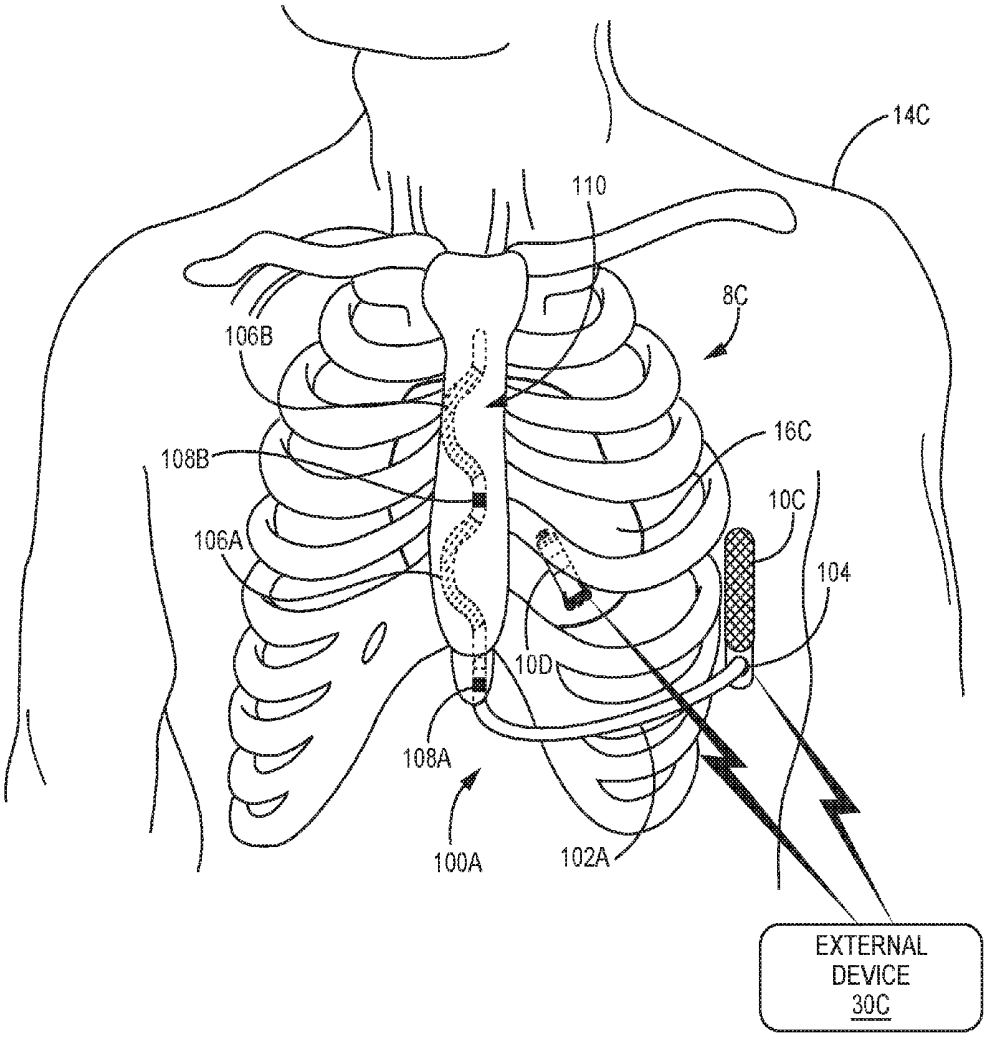

14C
110
8C
106B
16C
108B
10C
106A
104
10D
108A
100A
102A
EXTERNAL
DEVICE
30C

FIG. 4A

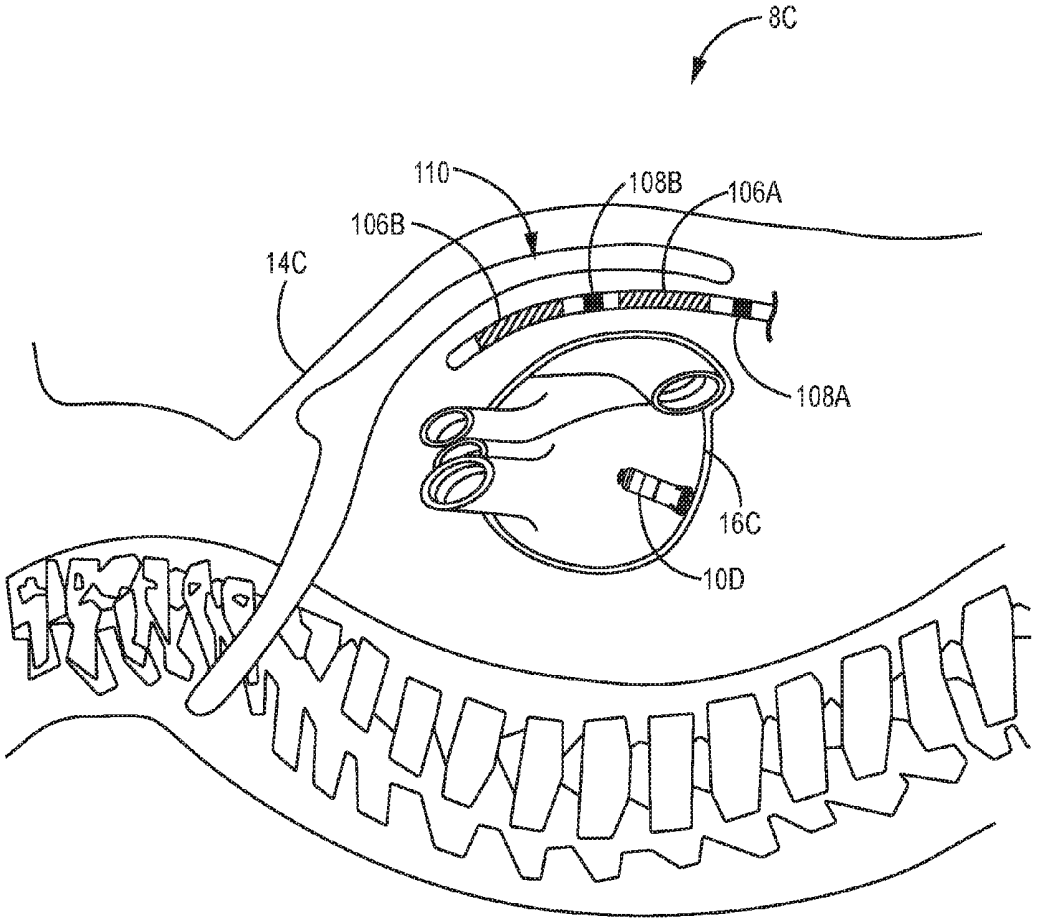



FIG. 4B

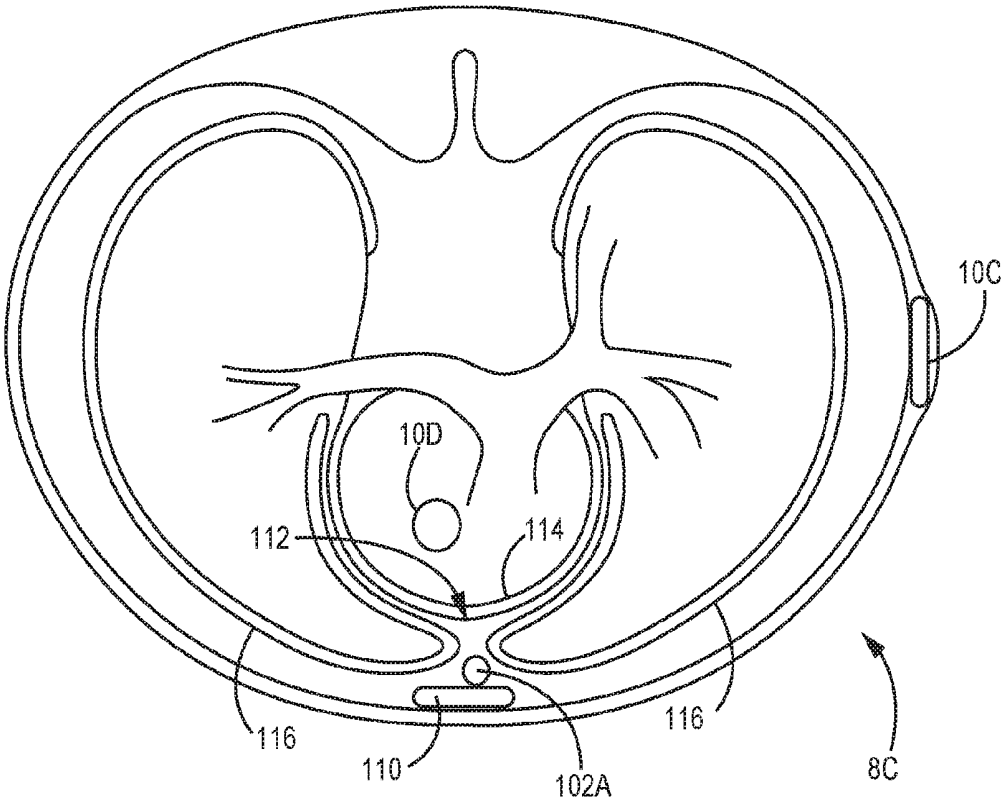



FIG. 4C

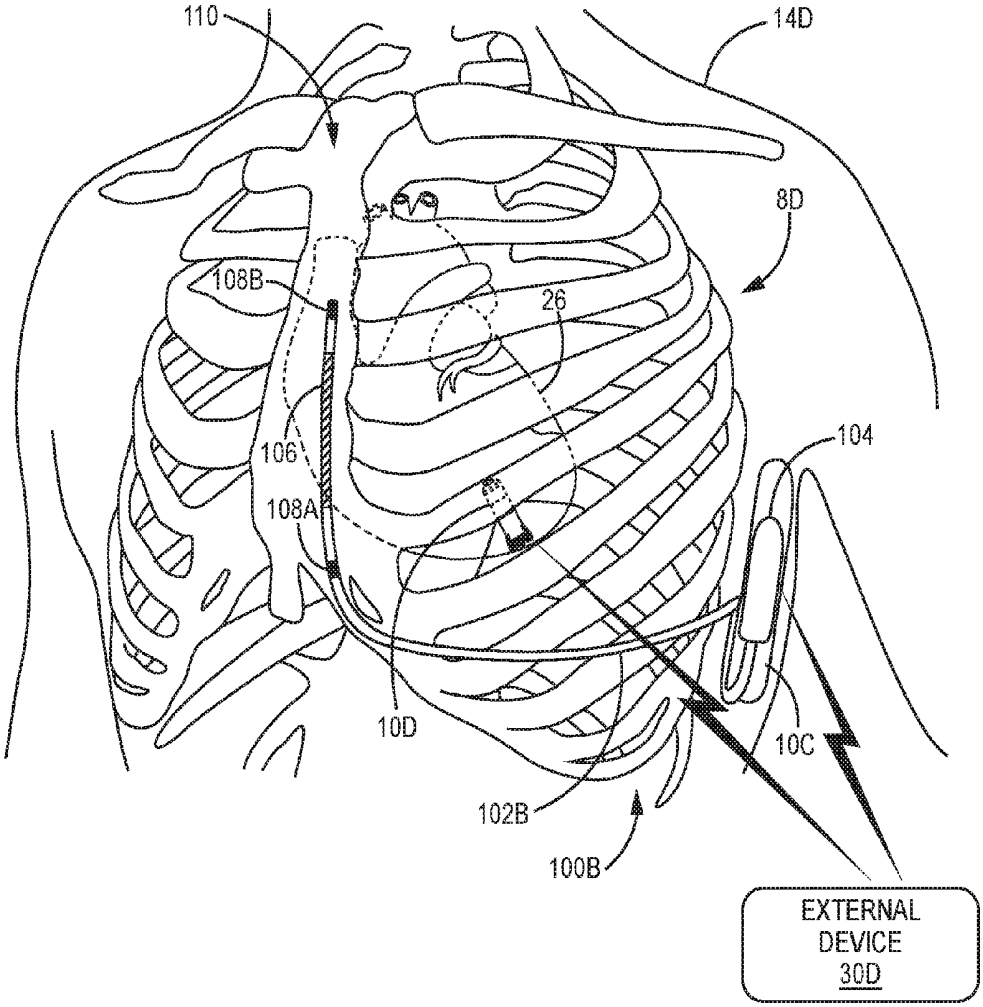

110
14D
8D
108B
26
106
104
108A
10D
10C
102B
100B
EXTERNAL
DEVICE
30D

FIG. 5

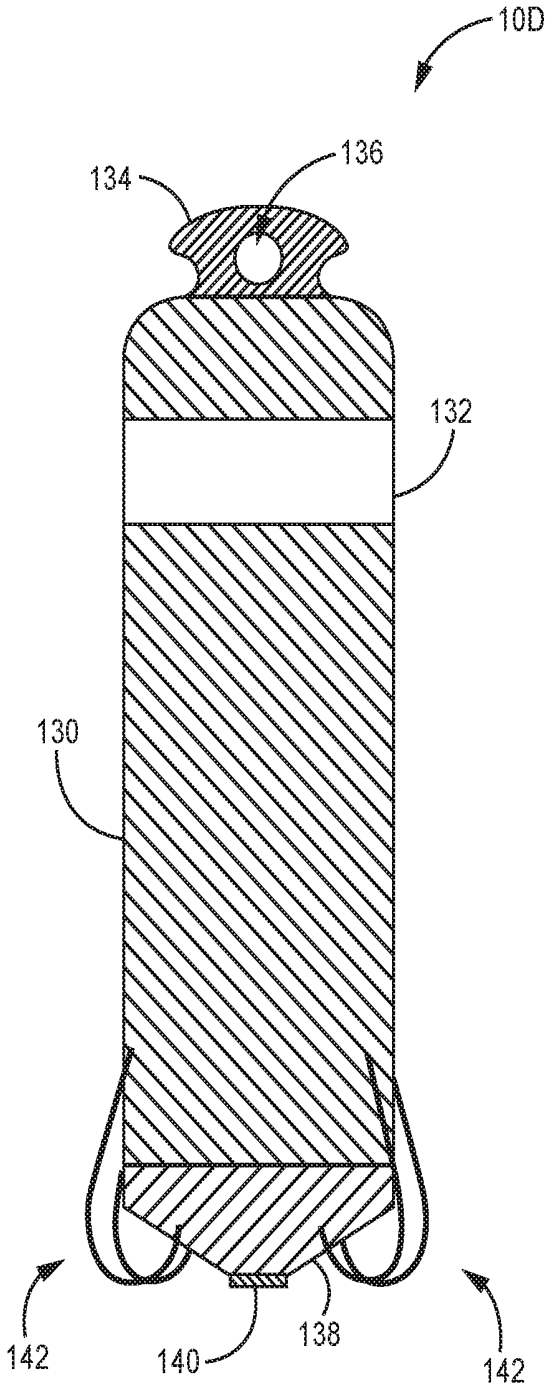



FIG. 6

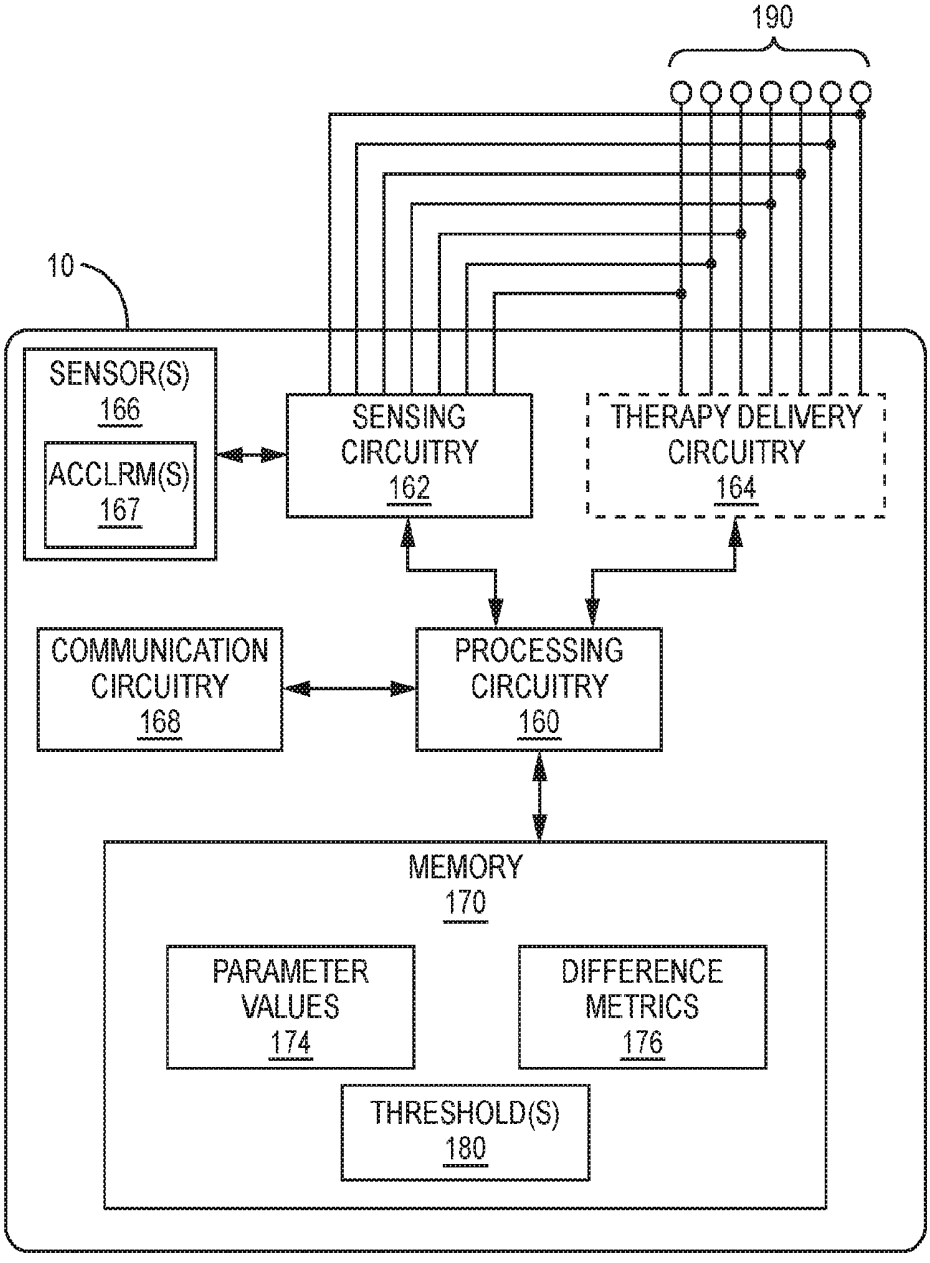

190
10
SENSOR(S)
166
ACCLRM(S)
167
SENSING
CIRCUITRY
162
THERAPY DELIVERY
CIRCUITRY
164
COMMUNICATION
CIRCUITRY
168
PROCESSING
CIRCUITRY
160
MEMORY
170
PARAMETER
VALUES
174
DIFFERENCE
METRICS
176
THRESHOLD(S)
180

FIG. 7

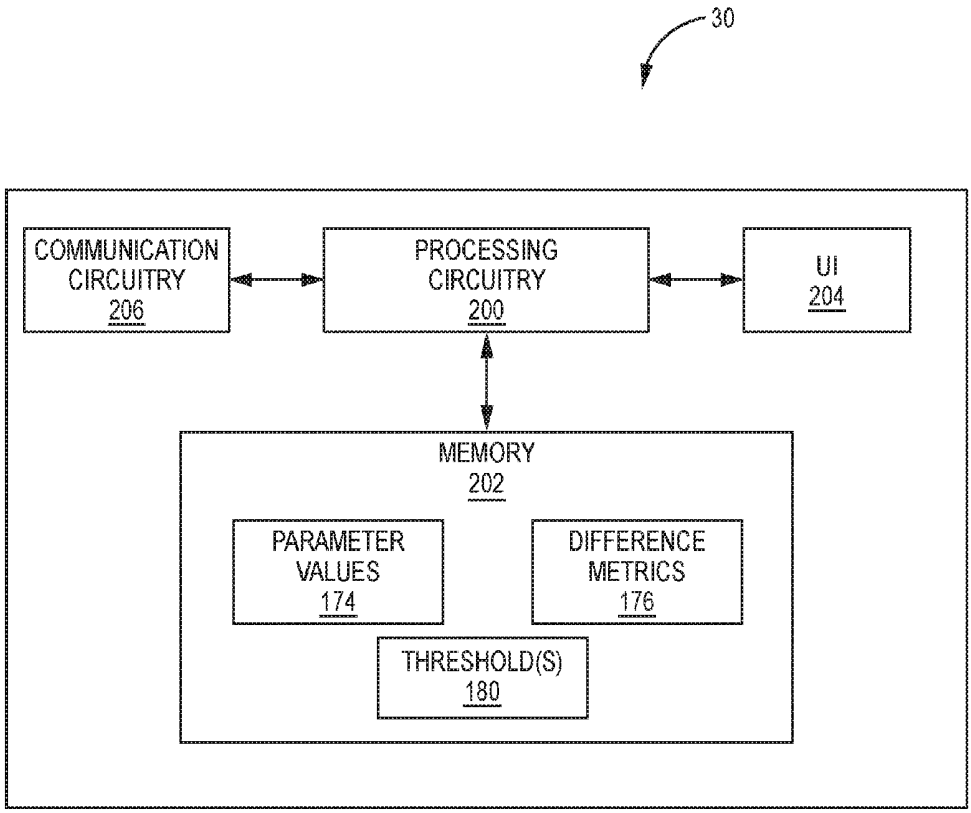

30
COMMUNICATION CIRCUITRY 206
PROCESSING CIRCUITRY 200
UI 204
MEMORY 202
PARAMETER VALUES 174
DIFFERENCE METRICS 176
THRESHOLD(S) 180

FIG. 8

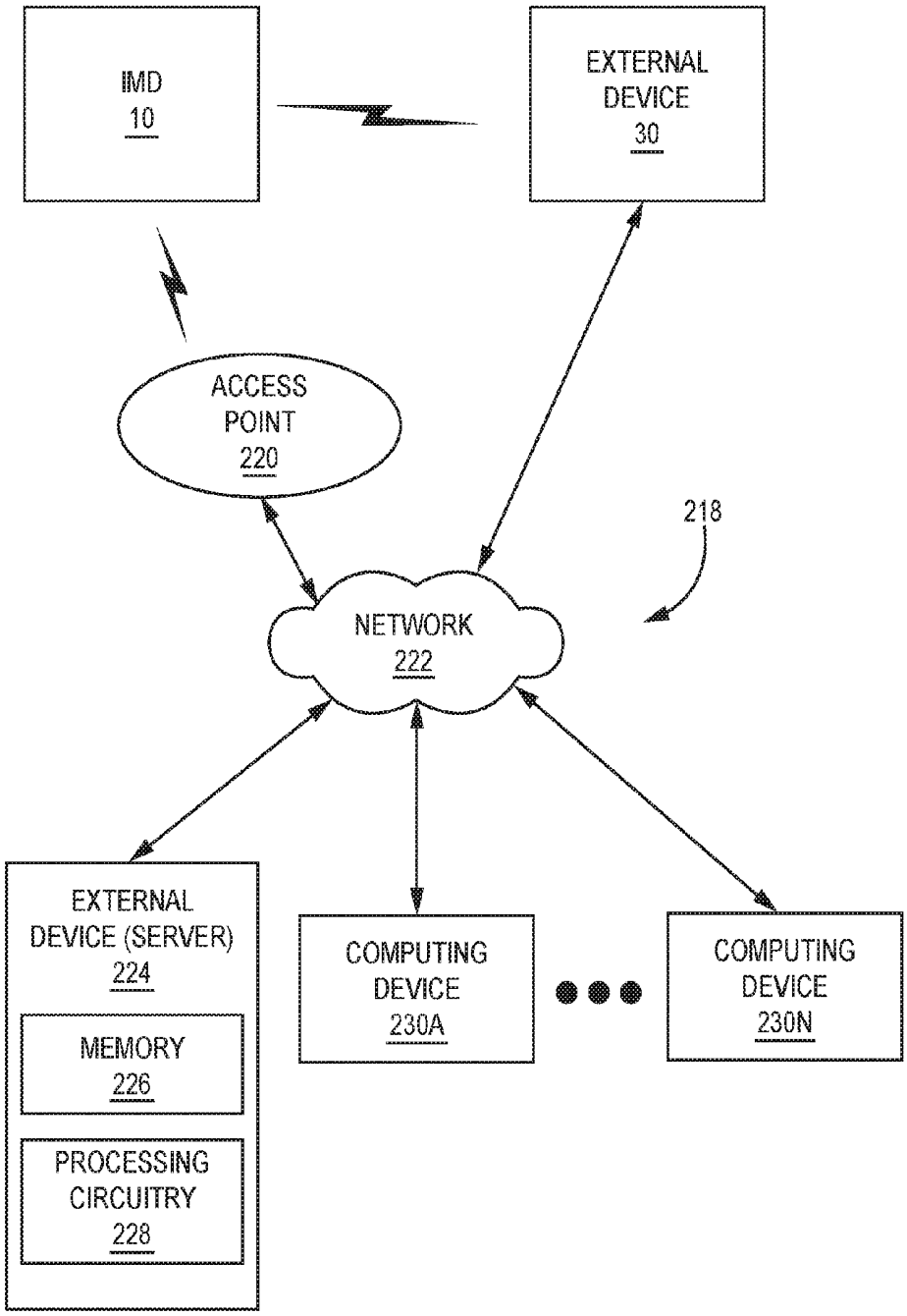

IMD
10
EXTERNAL
DEVICE
30
ACCESS
POINT
220
218
NETWORK
222
EXTERNAL
DEVICE (SERVER)
224
MEMORY
226
PROCESSING
CIRCUITRY
228
COMPUTING
DEVICE
230A
COMPUTING
DEVICE
230N

FIG. 9

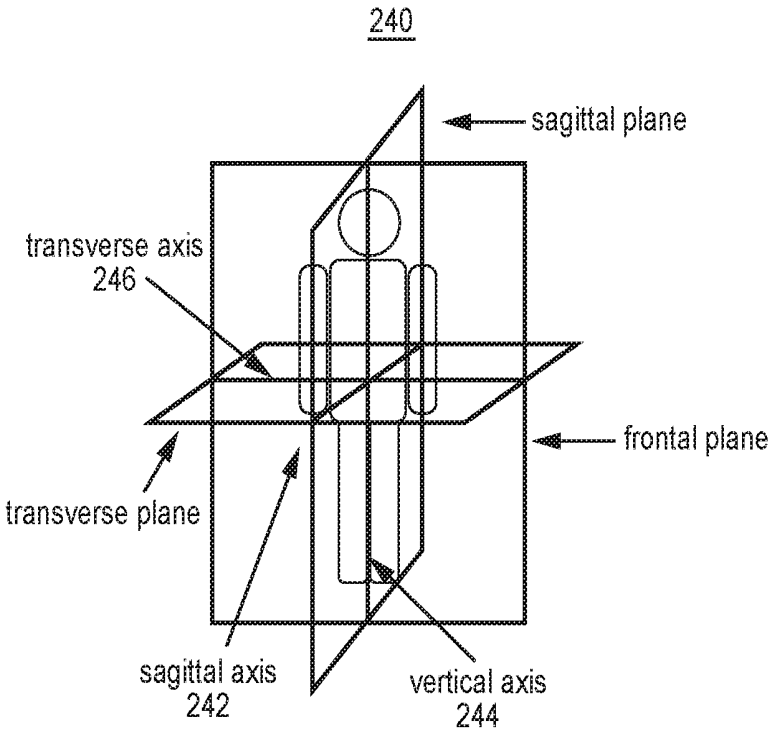

240
sagittal plane
transverse axis
246
frontal plane
transverse plane
sagittal axis
242
vertical axis
244

FIG. 10

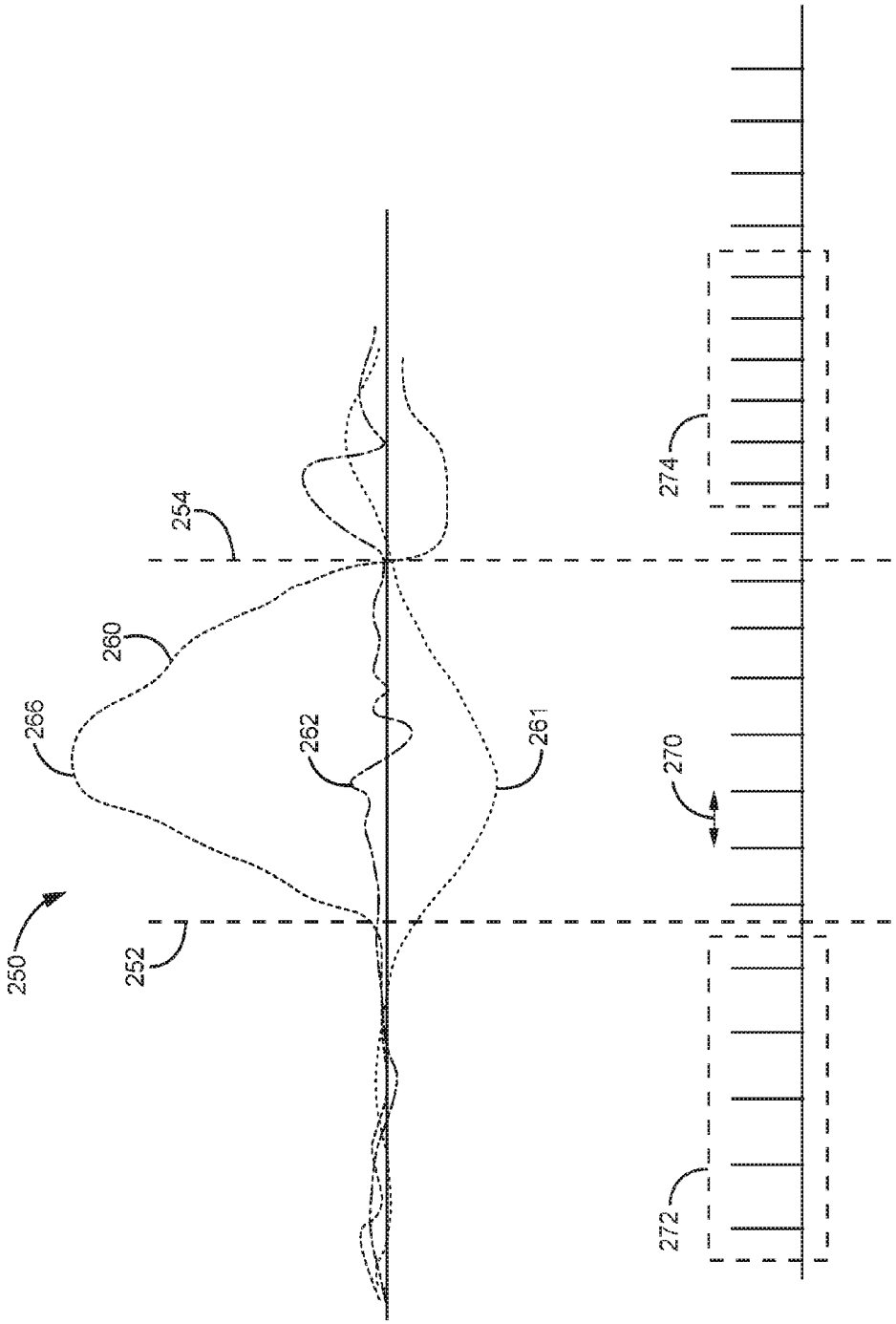



FIG. 11

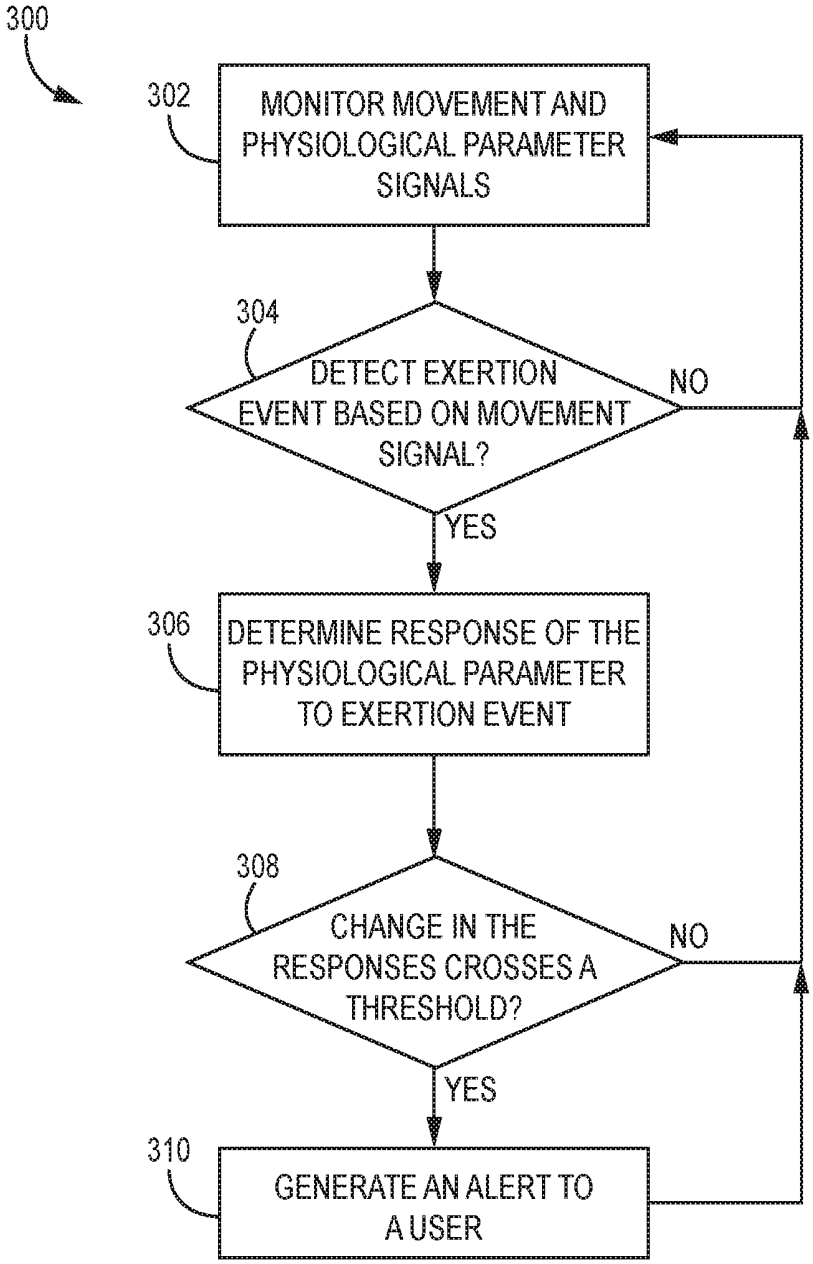

300
302
MONITOR MOVEMENT AND PHYSIOLOGICAL PARAMETER SIGNALS
304
DETECT EXERTION EVENT BASED ON MOVEMENT SIGNAL?
NO
YES
306
DETERMINE RESPONSE OF THE PHYSIOLOGICAL PARAMETER TO EXERTION EVENT
308
CHANGE IN THE RESPONSES CROSSES A THRESHOLD?
NO
YES
310
GENERATE AN ALERT TO A USER

FIG. 12

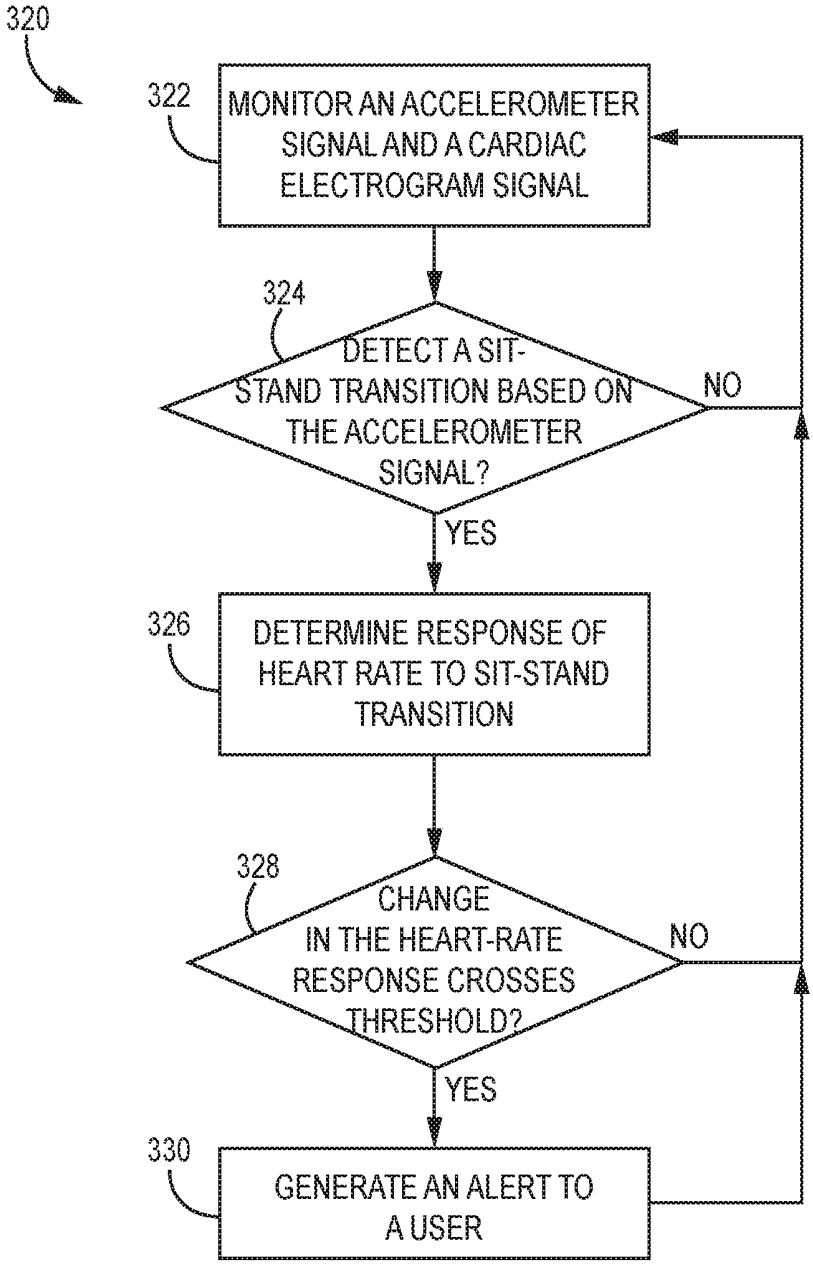

320
322
MONITOR AN ACCELEROMETER SIGNAL AND A CARDIAC ELECTROGRAM SIGNAL
324
DETECT A SIT-STAND TRANSITION BASED ON THE ACCELEROMETER SIGNAL?
NO
YES
326
DETERMINE RESPONSE OF HEART RATE TO SIT-STAND TRANSITION
328
CHANGE IN THE HEART-RATE RESPONSE CROSSES THRESHOLD?
NO
YES
330
GENERATE AN ALERT TO A USER

FIG. 13

# CHANGE IN PHYSIOLOGICAL PARAMETER IN RESPONSE TO EXERTION EVENT

## RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Application No. 62/370,113, filed Aug. 2, 2016 and is incorporated by reference herein.

## FIELD

**[0002]** The disclosure relates to methods and systems for measuring physiological parameters, such as heart rate.

## BACKGROUND

**[0003]** Implantable medical devices (IMDs) and external, e.g., wearable, medical devices, including implantable pacemakers and implantable cardioverter-defibrillators (ICDs), record cardiac electrogram (EGM) signals for sensing cardiac events, e.g., P-waves and R-waves. IMDs detect episodes of bradycardia, tachycardia and/or fibrillation from the sensed cardiac events, and respond to the episodes as needed with pacing therapy or high-voltage anti-tachyarrhythmia shocks, e.g., cardioversion or defibrillation shocks. Some IMDs include, or are or part of a system that includes, sensors that generate other physiological signals, such as signals that vary based on patient movement or activity, cardiovascular pressure, blood oxygen saturation, edema, or thoracic impedance.

## SUMMARY

**[0004]** In general, this disclosure is directed to techniques for monitoring physiological responses to physical exertion. The example techniques include monitoring first sensed signals that vary as a function of movement of the subject and second sensed signals that vary as a function of a physiological parameter. The example techniques include detecting exertion events based on the first sensed signals and determining a response of the physiological parameter to each exertion event based on the second sensed signals. The example techniques include determining that a change in the responses over time crosses, e.g., exceeds and/or falls below, a threshold or threshold range, and generating an alert to a user.

**[0005]** As one example, the disclosure is directed to a method for monitoring health of a subject based on a physiological response to physical exertion, by processing circuitry of a medical device system, that includes detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject. The method further includes determining a response of a physiological parameter of the subject to the exertion event for each of the detected exertion events based on second sensed signal that varies as a function of the physiological parameter. The method further includes determining that a change in the responses over time crosses a threshold and generating an alert to a user based on the determination that the change crosses the threshold.

**[0006]** A medical device system configured to monitor health of a subject based on a physiological response to physical exertion comprising sensing circuitry configured to generate a first sensed signal that varies as a function of movement of the subject. The sensing circuitry is further configured to generate a second sensed signal that varies as a function of a physiological parameter of the subject. The medical device system further comprises processing circuitry configured to detect a plurality of exertion events of the subject based on the first sensed signal. The processing circuitry is further configured to, for each of the detected exertion events, determine a response of the physiological parameter of the subject to the exertion event based on the second sensed signal. The processing circuitry is further configured to determine that a change in the responses over time crosses a threshold. The processing circuitry is further configured to generate an alert to a user in response to the determination that the change crosses the threshold.

**[0007]** As another example, the disclosure is directed to a method for monitoring health of a subject based on a physiological response to physical exertion comprising, by processing circuitry of a medical device system, detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject. The method further comprises, for each of the detected exertion events, determining a response of a physiological parameter of the subject to the exertion event based on second sensed signal that varies as a function of the physiological parameter. The method further comprises determining a trend in the responses over time crosses a threshold. The method further comprises generating an alert to a user based on the determination that the trend crosses the threshold.

**[0008]** In an additional example, the disclosure is directed to a non-transitory computer-readable storage medium comprising instructions, that when executed by processing circuitry of a medical device system, causes the medical device system to detect a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject. The instructions further cause the medical device system to determine a response of a physiological parameter of the subject to the exertion event for each of the detected exertion events based on second sensed signal that varies as a function of the physiological parameter. The instructions further cause the medical device system to determine that a change in the responses over time crosses a threshold and generate an alert to a user based on the determination that the change crosses the threshold.

**[0009]** In an additional example, the disclosure is directed to a medical device system comprising means for monitoring health of a subject based on a physiological response to physical exertion, by processing circuitry of a medical device system, that includes detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject. The medical device system further comprises means for determining a response of a physiological parameter of the subject to the exertion event for each of the detected exertion events based on second sensed signal that varies as a function of the physiological parameter. The medical device system further comprises means for determining that a change in the responses over time crosses a threshold and means for generating an alert to a user based on the determination that the change crosses the threshold.

**[0010]** This summary is intended to provide an overview of the subject matter described in this disclosure. It is not intended to provide an exclusive or exhaustive explanation of the apparatus and methods described in detail within the accompanying drawings and description below. The details

of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below.

## BRIEF DESCRIPTION OF DRAWINGS

**[0011]** The details of one or more examples of this disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of this disclosure will be apparent from the description and drawings, and from the claims.

**[0012]** FIG. **1** is a conceptual drawing illustrating an example medical device system in conjunction with a patient.

**[0013]** FIG. **2** is a perspective drawing illustrating an example configuration of the implantable cardiac monitor of FIG. **1**.

**[0014]** FIG. **3** is a conceptual drawing illustrating another example medical device system in conjunction with a patient.

**[0015]** FIGS. **4**A-**4**C are front-view, side-view, and top-view conceptual drawings, respectively, illustrating another example medical device system in conjunction with a patient.

**[0016]** FIG. **5** is a conceptual drawing illustrating another example medical device system in conjunction with a patient.

**[0017]** FIG. **6** is a conceptual diagram illustrating an example configuration of the intracardiac pacing device of FIGS. **4**A-**5**.

**[0018]** FIG. **7** is a functional block diagram illustrating an example configuration of an implantable medical device.

**[0019]** FIG. **8** is a functional block diagram illustrating an example configuration of an external device configured to communicate with one or more implantable medical devices.

**[0020]** FIG. **9** is a functional block diagram illustrating an example system that includes remote computing devices, such as a server and one or more other computing devices, that are connected to an implantable medical device and/or external device via a network.

**[0021]** FIG. **10** is a conceptual diagram illustrating sagittal, vertical and transverse axes in a three-dimensional coordinate system.

**[0022]** FIG. **11** is a timing diagram illustrating a chart of three accelerometer signals, where the three signals represent vertical acceleration, transverse acceleration, and sagittal acceleration, and a marker channel chart showing heart beats before, during, and after an exertion event.

**[0023]** FIG. **12** is a flowchart illustrating an example technique for determining whether a change in responses of a physiological parameter to an exertion event crosses a threshold, in accordance with this disclosure.

**[0024]** FIG. **13** is a flowchart illustrating an example technique for determining whether a change in heart-beat responses to a sit-stand transition crosses a specific threshold, in accordance with this disclosure.

**[0025]** The drawings and the description provided herein illustrate and describe various examples of the inventive methods, devices, and systems of the present disclosure. However, the methods, devices, and systems of the present disclosure are not limited to the specific examples as illustrated and described herein, and other examples and variations of the methods, devices, and systems of the present disclosure, as would be understood by one of ordinary skill in the art, are contemplated as being within the scope of the present application.

## DETAILED DESCRIPTION

**[0026]** In general, this disclosure describes example techniques related to monitoring the health of a subject based on physiological responses to physical exertion. To carry out the example techniques, a system may determine a response of a physiological parameter to exertion events, where the response may be an increase in heart rate, blood pressure, or respiration. The system may also determine that a change in the responses over time crosses a threshold. The change in the responses may indicate an abnormal or unhealthy condition in the subject. The system may generate an alert to inform a user of the possible abnormal or unhealthy condition, where the user may be the subject, a caretaker, a medical professional, an external device, or any other user. In the following description, references are made to illustrative examples. It is understood that other examples may be utilized without departing from the scope of the disclosure.

**[0027]** FIG. **1** is a conceptual drawing illustrating an example medical device system **8**A in conjunction with a patient **14**A. Medical device system **8**A is an example of a medical device system configured to implement the techniques described herein for monitoring health of patient **14**A based on the physiological response, such as heart rate, blood pressure, or respiration, to physical exertion, and responsively generating an alert in response to determining that a change in the physiological response over time crosses, e.g., exceeds and/or falls below, a threshold, e.g., threshold range. In the illustrated example, medical device system **8**A includes an implantable medical device (IMD) **10**A in communication with external device **30**A.

**[0028]** In the illustrated example, IMD **10**A is an insertable cardiac monitor (ICM) capable of sensing and recording cardiac EGM signals from a position outside of heart **16**A, and will be referred to as ICM **10**A hereafter. In some examples, ICM **10**A includes or is coupled to one or more additional sensors that generate one or more physiological signals, such as signals that vary based on patient motion and/or posture, blood flow, or respiration. ICM **10**A may monitor a physiological parameter such as heart rate, and ICM **10**A may measure a change in the physiological parameter in response to an exertion event, such as a sit-stand transition detected based on a signal that varies as a function of patient motion or movement. ICM **10**A may be implanted outside of the thorax of patient **14**B, e.g., subcutaneously or submuscularly, such as the pectoral location illustrated in FIG. **1**. In some examples, ICM **10**B may take the form of a Reveal LINQ™ ICM, available from Medtronic plc, of Dublin, Ireland.

**[0029]** ICM **10**A may transmit EGM signal data, cardiac rhythm episode data, and other physiological parameter data acquired by ICM **10**A, to an external device **30**A. For examples, ICM **10**A may transmit any data described herein related to detection of exertion events, responses of one or more physiological parameters to the exertion events, changes in such responses over time, or alerts based on such changes to external device **30**A. External device **30**A may be a computing device, e.g., used in a home, ambulatory, clinic, or hospital setting, to communicate with ICD **10**A via wireless telemetry. External device **30**A may be coupled to

a remote patient monitoring system, such as Carelink®, available from Medtronic plc, of Dublin, Ireland. External device **30**A may be, as examples, a programmer, external monitor, or consumer device, e.g., smart phone.

**[0030]** External device **30**A may be used to program commands or operating parameters into ICM **10**A for controlling its functioning, e.g., when configured as a programmer for ICM **10**A. External device **30**A may be used to interrogate ICM **10**A to retrieve data, including device operational data as well as physiological data accumulated in IMD memory. The interrogation may be automatic, e.g., according to a schedule, or in response to a remote or local user command. Programmers, external monitors, and consumer devices are examples of external devices **30**A that may be used to interrogate ICM **10**A. Examples of communication techniques used by ICM **10**A and external device **30**A include radiofrequency (RF) telemetry, which may be an RF link established via Bluetooth, WiFi, or medical implant communication service (MICS).

**[0031]** Medical device system **8**A is an example of a medical device system configured to monitor the physiological response of patient **14**A to physical exertion. The techniques described herein may be performed by processing circuitry of medical device system **8**A, such as processing circuitry of one or both of ICM **10**A and external device **30**A, individually, or collectively. The techniques include detecting a plurality of exertion events of patient **14**A based on a first sensed signal that varies as a function of movement of the patient **14**A. The movements may include common posture transitions such as sit-stand transitions, lay-sit transitions, and walking/running events. The processing circuitry may determine a response of a physiological parameter of patient **14**A to the exertion event based on second sensed signal that varies as a function of the physiological parameter. The processing circuitry may also determine that a change in the responses over time crosses a threshold, such as a number of hearts beat per minute. In some examples, ICM **10**A may include or be coupled to one or more other sensors that generate one or more physiological signals, such as signals that vary based on patient motion and/or posture, blood flow, respiration, or edema.

**[0032]** Medical device system **8**A is one example of a medical device system that may be configured to implement the techniques described herein for monitoring physiological responses to exertion events. Other example medical device systems that may be configured to implement the techniques are described with respect to FIGS. **2-6**. Although described herein primarily in the context of implantable medical devices monitoring signals indicating physiological parameters, a medical device system that implements the techniques described in this disclosure may additionally or alternatively include an external medical device, e.g., external cardiac monitor, and/or external pacemaker, cardioverter and/or defibrillator, configured to determine that a change in the responses to exertion events crosses a threshold and generate an alert.

**[0033]** Although not illustrated in the example of FIG. **1**, a medical device system configured to implement the techniques of this disclosure may include one or more implanted or external medical devices in addition to or instead of ICM **10**A. For example, a medical device system may include a pressure sensing IMD, vascular ICD (e.g., ICD **10**B of FIG. **3**), extravascular ICD, or cardiac pacemaker (e.g., IPD **10**D of FIGS. **4A-6** or a cardiac pacemaker implanted outside the heart but coupled to intracardiac or epicardial leads). One or more such devices may generate physiological signals, and include processing circuitry configured to perform, in whole or in part, the techniques described herein for monitoring physiological responses to exertion events. The implanted devices may communicate with each other and/or an external device **30**, and one of the implanted or external devices may ultimately determine whether the physiological responses to exertion events crosses a threshold.

**[0034]** FIG. **2** is a conceptual drawing illustrating an example configuration of ICM **10**A. In the example shown in FIG. **2**, ICM **10**A may be embodied as a monitoring device having housing **62**, proximal electrode **64** and distal electrode **66**. Housing **62** may further comprise first major surface **68**, second major surface **70**, proximal end **72**, and distal end **74**. Housing **62** encloses electronic circuitry located inside the ICM **10**A and protects the circuitry contained therein from body fluids. Electrical feedthroughs provide electrical connection of electrodes **64** and **66**.

**[0035]** In the example shown in FIG. **2**, ICM **10**A is defined by a length L, a width W and thickness or depth D and is in the form of an elongated rectangular prism wherein the length L is much larger than the width W, which in turn is larger than the depth D. In one example, the geometry of the ICM **10**A—in particular a width W greater than the depth D—is selected to allow ICM **10**A to be inserted under the skin of the patient using a minimally invasive procedure and to remain in the desired orientation during insertion. For example, the device shown in FIG. **2** includes radial asymmetries (notably, the rectangular shape) along the longitudinal axis that maintains the device in the proper orientation following insertion. For example, in one example the spacing between proximal electrode **64** and distal electrode **66** may range from 30 millimeters (mm) to 55 mm, 35 mm to 55 mm, and from 40 mm to 55 mm and may be any range or individual spacing from 25 mm to 60 mm. In addition, ICM **10**A may have a length L that ranges from 30 mm to about 70 mm. In other examples, the length L may range from 40 mm to 60 mm, 45 mm to 60 mm and may be any length or range of lengths between about 30 mm and about 70 mm. In addition, the width W of major surface **68** may range from 3 mm to 10 mm and may be any single or range of widths between 3 mm and 10 mm. The thickness of depth D of ICM **10**A may range from 2 mm to 9 mm. In other examples, the depth D of ICM **10**A may range from 2 mm to 5 mm and may be any single or range of depths from 2 mm to 9 mm. In addition, ICM **10**A according to an example of the present disclosure is has a geometry and size designed for ease of implant and patient comfort. Examples of ICM **10**A described in this disclosure may have a volume of three cubic centimeters (cm) or less, 1.5 cubic cm or less or any volume between three and **1.5** cubic centimeters. In addition, in the example shown in FIG. **2**, proximal end **72** and distal end **74** are rounded to reduce discomfort and irritation to surrounding tissue once inserted under the skin of the patient. ICM **10**A, including instrument and method for inserting ICM **10**A is described, for example, in U.S. Patent Publication No. 2014/0276928, incorporated herein by reference in its entirety.

**[0036]** In the example shown in FIG. **2**, once inserted within the patient, the first major surface **68** faces outward, toward the skin of the patient while the second major surface **70** is located opposite the first major surface **68**. Consequently, the first and second major surfaces may face in

directions along a sagittal axis of patient **14**A (FIG. **1**), and this orientation may be consistently achieved upon implantation due to the dimensions of ICM **10**A. Additionally, an accelerometer, or axis of an accelerometer, may be oriented along the sagittal axis.

**[0037]** Proximal electrode **64** and distal electrode **66** are used to sense cardiac signals, e.g. ECG signals, intrathoracically or extra-thoracically, which may be sub-muscularly or subcutaneously. ECG signals may be stored in a memory of the ICM **10**A, and ECG data may be transmitted via integrated antenna **82** to another medical device, which may be another implantable device or an external device, such as external device **30**A. In some example, electrodes **64** and **66** may additionally or alternatively be used for sensing any bio-potential signal of interest, which may be, for example, an EGM, EEG, EMG, or a nerve signal, from any implanted location.

**[0038]** In the example shown in FIG. **2**, proximal electrode **64** is in close proximity to the proximal end **72** and distal electrode **66** is in close proximity to distal end **74**. In this example, distal electrode **66** is not limited to a flattened, outward facing surface, but may extend from first major surface **68** around rounded edges **76** and/or end surface **78** and onto the second major surface **70** so that the electrode **66** has a three-dimensional curved configuration. In the example shown in FIG. **2**, proximal electrode **64** is located on first major surface **68** and is substantially flat, outward facing. However, in other examples proximal electrode **64** may utilize the three dimensional curved configuration of distal electrode **66**, providing a three dimensional proximal electrode (not shown in this example). Similarly, in other examples distal electrode **66** may utilize a substantially flat, outward facing electrode located on first major surface **68** similar to that shown with respect to proximal electrode **64**. The various electrode configurations allow for configurations in which proximal electrode **64** and distal electrode **66** are located on both first major surface **68** and second major surface **70**. In other configurations, such as that shown in FIG. **2**, only one of proximal electrode **64** and distal electrode **66** is located on both major surfaces **68** and **70**, and in still other configurations both proximal electrode **64** and distal electrode **66** are located on one of the first major surface **68** or the second major surface **70** (i.e., proximal electrode **64** located on first major surface **68** while distal electrode **66** is located on second major surface **70**). In another example, ICM **10**A may include electrodes on both major surface **68** and **70** at or near the proximal and distal ends of the device, such that a total of four electrodes are included on ICM **10**A. Electrodes **64** and **66** may be formed of a plurality of different types of biocompatible conductive material, e.g. stainless steel, titanium, platinum, iridium, or alloys thereof, and may utilize one or more coatings such as titanium nitride or fractal titanium nitride.

**[0039]** In the example shown in FIG. **2**, proximal end **72** includes a header assembly **80** that includes one or more of proximal electrode **64**, integrated antenna **82**, anti-migration projections **84**, and/or suture hole **86**. Integrated antenna **82** is located on the same major surface (i.e., first major surface **68**) as proximal electrode **64** and is also included as part of header assembly **80**. Integrated antenna **82** allows ICM **10**A to transmit and/or receive data. In other examples, integrated antenna **82** may be formed on the opposite major surface as proximal electrode **64**, or may be incorporated within the housing **62** of ICM **10**A. In the example shown in FIG. **2**, anti-migration projections **84** are located adjacent to integrated antenna **82** and protrude away from first major surface **68** to prevent longitudinal movement of the device. In the example shown in FIG. **2**, anti-migration projections **84** includes a plurality (e.g., nine) small bumps or protrusions extending away from first major surface **68**. As discussed above, in other examples anti-migration projections **84** may be located on the opposite major surface as proximal electrode **64** and/or integrated antenna **82**. In addition, in the example shown in FIG. **2** header assembly **80** includes suture hole **86**, which provides another means of securing ICM **10**A to the patient to prevent movement following insert. In the example shown, suture hole **86** is located adjacent to proximal electrode **64**. In one example, header assembly **80** is a molded header assembly made from a polymeric or plastic material, which may be integrated or separable from the main portion of ICM **10**A.

**[0040]** FIG. **3** is a conceptual drawing illustrating another example medical device system **8**B in conjunction with a patient **14**B. Medical device system **8**B is another example of a medical device system configured to implement the techniques described herein for monitoring the health of a patient by measuring physiological responses to exertion events. In the illustrated example, medical device system **8**B includes an IMD **10**B and an external device **30**B. IMD **10**B may be an implantable cardioverter-defibrillator (ICD) capable of delivering pacing, cardioversion and defibrillation therapy to the heart **16**B of a patient **14**B, and will be referred to as ICD **10**B hereafter. ICD **10**B may monitor a physiological parameter such as heart rate, and ICD **10**B may measure a change in the physiological parameter in response to an exertion event, such as a sit-stand transition.

**[0041]** ICD **10**B may acquire cardiac electrogram (EGM) signals from patient **14**B and to deliver therapy in response to the acquired data. Medical device system **8**B may employ a dual chamber ICD configuration or may include one or more additional leads, such as a coronary sinus lead extending into the right atrium, through the coronary sinus and into a cardiac vein to position electrodes along the left ventricle (LV) for sensing LV EGM signals and delivering pacing pulses to the LV. In other examples, a medical device system may be a single chamber system.

**[0042]** ICD **10**B may be coupled to a ventricular lead **20** and an atrial lead **21**. Ventricular lead **20** and atrial lead **21** are electrically coupled to ICD **10**B and extend into the patient's heart **16**B. Ventricular lead **20** includes electrodes **22** and **24** shown positioned on the lead in the patient's right ventricle (RV) for sensing ventricular EGM signals and pacing in the RV. Atrial lead **21** includes electrodes **26** and **28** positioned on the lead in the patient's right atrium (RA) for sensing atrial EGM signals and pacing in the RA.

**[0043]** Ventricular lead **20** additionally carries a high voltage coil electrode **42**, and atrial lead **21** carries a high voltage coil electrode **44**, used to deliver cardioversion and defibrillation shocks. The term "anti-tachyarrhythmia shock" may be used herein to refer to both cardioversion shocks and defibrillation shocks. In other examples, ventricular lead **20** may carry both of high voltage coil electrodes **42** and **44**, or may carry a high voltage coil electrode in addition to those illustrated in the example of FIG. **3**.

**[0044]** ICD **10**B may use both ventricular lead **20** and atrial lead **21** to acquire cardiac electrogram (EGM) signals from patient **14**B and to deliver therapy in response to the acquired data. Medical device system **8**B is shown as having

a dual chamber ICD configuration, but other examples may include one or more additional leads, such as a coronary sinus lead extending into the right atrium, through the coronary sinus and into a cardiac vein to position electrodes along the left ventricle (LV) for sensing LV EGM signals and delivering pacing pulses to the LV. In other examples, a medical device system may be a single chamber system, or otherwise not include atrial lead **21**.

**[0045]** Processing circuitry, sensing circuitry, and other circuitry configured for performing the techniques described herein are housed within a sealed housing **12**B. Housing **12**B (or a portion thereof) may be conductive so as to serve as an electrode for pacing or sensing or as an active electrode during defibrillation. As such, housing **12**B is also referred to herein as "housing electrode" **12**B.

**[0046]** ICD **10**B may transmit EGM signal data and cardiac rhythm episode data acquired by ICD **10**B, as well as data regarding delivery of therapy by ICD **10**B, to an external device **30**B. External device **30**B may be a computing device, e.g., used in a home, ambulatory, clinic, or hospital setting, to communicate with ICD **10**B via wireless telemetry. External device **30**B may be coupled to a remote patient monitoring system, such as Carelink®, available from Medtronic plc, of Dublin, Ireland. External device **30**B may be, as examples, a programmer, external monitor, or consumer device, e.g., smart phone.

**[0047]** External device **30**B may be used to program commands or operating parameters into ICD **10**B for controlling its functioning, e.g., when configured as a programmer for ICD **10**B. External device **30**B may be used to interrogate ICD **10**B to retrieve data, including device operational data as well as physiological data accumulated in IMD memory. The interrogation may be automatic, e.g., according to a schedule, or in response to a remote or local user command. Programmers, external monitors, and consumer devices are examples of external devices **30**B that may be used to interrogate ICD **10**B. Examples of communication techniques used by ICD **10**B and external device **30**B include radiofrequency (RF) telemetry, which may be an RF link established via Bluetooth, WiFi, or medical implant communication service (MICS).

**[0048]** In some examples, as illustrated in FIG. **3**, medical device system **8**B may also include a pressure-sensing IMD **50**. In the illustrated example, pressure-sensing IMD **50** is implanted in the pulmonary artery of patient **14**B. In some examples, one or more pressure-sensing IMDs **50** may additionally or alternatively be implanted within a chamber of heart **16**B, or generally at other locations in the circulatory system.

**[0049]** In one example, pressure-sensing IMD **50** is configured to sense blood pressure of patient **14**B. For example, pressure-sensing IMD **50** may be arranged in the pulmonary artery and be configured to sense the pressure of blood flowing from the right ventricle outflow tract (RVOT) from the right ventricle through the pulmonary valve to the pulmonary artery. Pressure-sensing IMD **50** may therefore directly measure the pulmonary artery diastolic pressure (PAD) of patient **14**B. The PAD value is a pressure value that can be employed in patient monitoring. For example, PAD may be used as a basis for evaluating congestive heart failure in a patient.

**[0050]** In other examples, however, pressure-sensing IMD **50** may be employed to measure blood pressure values other than PAD. For example, pressure-sensing IMD **50** may be arranged in right ventricle **28** of heart **16**B to sense RV systolic or diastolic pressure, or may sense systolic or diastolic pressures at other locations of the cardiovascular system, such as within the pulmonary artery. As shown in FIG. **1**, pressure-sensing IMD **50** is positioned in the main trunk of pulmonary artery **39**. In other examples, a sensor, such as pressure-sensing IMD **50** may be either positioned in the right or left pulmonary artery beyond the bifurcation of the pulmonary artery.

**[0051]** Moreover, the placement of pressure-sensing IMD **50** is not restricted necessarily to the pulmonary side of the circulation. Pressure-sensing IMD **50** could potentially be placed in the systemic side of the circulation. For example, under certain conditions and with appropriate safety measures, pressure-sensing IMD **50** could even be placed in the left atrium, left ventricle, or aorta. Additionally, pressure-sensing IMD **50** is not restricted to placement within the cardiovascular system. For example, the pressure-sensing IMD **50** might be placed in the renal circulation. Placement of pressure-sensing IMD **50** in the renal circulation may be beneficial, for example, to monitor the degree of renal insufficiency in the patient based on the monitoring of pressure or some other indication of renal circulation by pressure-sensing IMD **50**.

**[0052]** In some examples, pressure-sensing IMD **50** includes a pressure sensor configured to respond to the absolute pressure inside the pulmonary artery of patient **14**B. Pressure-sensing IMD **50** may be, in such examples, any of a number of different types of pressure sensors. One form of pressure sensor that may be useful for measuring blood pressure is a capacitive pressure sensor. Another example pressure sensor is an inductive sensor. In some examples, pressure-sensing IMD **50** may also comprise a piezoelectric or piezoresistive pressure transducer. In some examples, pressure-sensing IMD **50** may comprise a flow sensor.

**[0053]** In one example, pressure-sensing IMD **50** comprises a leadless pressure sensor including capacitive pressure sensing elements configured to measure blood pressure within the pulmonary artery. Pressure-sensing IMD **50** may be in wireless communication with ICD **10**B and/or external device **30**B, e.g., in order to transmit blood pressure measurements to one or both of the devices. Pressure-sensing IMD **50** may employ, e.g., radio frequency (RF) or other telemetry techniques for communicating with ICD **10**B and other devices, including, e.g., external device **30**B. In another example, pressure-sensing IMD **50** may include a tissue conductance communication (TCC) system by which the device employs tissue of patient **14**B as an electrical communication medium over which to send and receive information to and from ICD **10**B and/or external device **30**B.

**[0054]** External device **30**B may be configured in a manner substantially similar to that described above with respect to external device **30**A and FIG. **1**. External device **30**B may wirelessly communicate with ICD **10**B, e.g., to program the functionality of the ICD, and to retrieve recorded physiological signals and/or patient parameter values or other data derived from such signals from the ICD. Both ICD **10**B and external device **30**B include processing circuitry, and the processing circuitry of either or both device may perform the techniques described herein, such as detecting a plurality of exertion events of patient **14**B based a first sensed signal that varies as a function of movement of the patient **14**B,

determining a response of a physiological parameter of patient **14**B to the exertion event based on second sensed signal that varies as a function of the physiological parameter, and determining whether a change in the responses over time crosses a threshold.

**[0055]** Medical device system **8**B is an example of a medical device system configured to monitor the physiological response to exertion events. The techniques may be performed by processing circuitry of medical device system **8**B, such as processing circuitry of one or both of ICD **10**B and external device **30**B, individually, or collectively.

**[0056]** The techniques include determining a respective value for each of a plurality of parameters of a patient, e.g., physiological and/or pathophysiological, during each of a plurality of periods, which may be at least one hour, such as between approximately one day and approximately three days, e.g., in one example, approximately one day. The processing circuitry may determine the values of at least some the patient parameters based on physiological signals generated by sensing circuitry of one or both of ICD **10**B and pressure-sensing IMD **50**, such as a cardiac EGM signal generated by sensing circuitry of ICD **10**B, or a pulmonary artery or other cardiovascular pressure signal generated by pressure-sensing IMD **50**. In some examples, one or both of ICD **10**B and pressure-sensing IMD **50** may include or be coupled to one or more other sensors that generate one or more physiological signals, such as signals that vary based on patient motion and/or posture, blood flow, respiration, or edema. The processing circuitry may determine other patient parameters based on therapy delivered by ICD **10**B, such as patient parameters indicating the extent to which patient **14**B is dependent on pacing, e.g., a percentage of time or other characterization of amount of pacing delivered to the patient.

**[0057]** In some examples, the processing circuitry of medical device system **8**B detects a plurality of exertion events for patient **14**B based on a first sensed signal, such as one or more accelerometer signals. The exertion events may comprise common posture transitions such as sit-stand transitions, lay-sit transitions, stand-walk transitions, walking events, or any physical exertion event that may have an effect on a physiological parameter. The exertion events may also comprise periods of activity that exceed a threshold duration, such as walking for more than twenty seconds or more than twenty steps. The processing circuitry may determine the response of a physiological parameter based on a second sensed signal. The physiological parameter may comprise heart rate, blood pressure, respiration, or any other measurable physiological parameter. The processing circuitry may determine that a change in the responses over time crosses a threshold. For example, the processing circuitry may determine that, in response to a sit-stand transition, the heart rate of patient **14**B increased by a number or percentage of beats per minute. The processing circuitry may determine that this response crosses, e.g., exceeds and/or falls below, a threshold or threshold range for responses, which may be determined based on one or more prior responses, e.g., a median and baseline variability of prior responses. Based on determining that the change crosses the threshold, the processing circuitry may generate an alert to a user through a communication module or a user interface.

**[0058]** Medical device system **8**B is one example of a medical device system that may be configured to implement the techniques described herein for monitoring the physiological response to exertion events. Other example medical device systems that may be configured to implement the techniques are described with respect to FIGS. **4**A-**6**. Although described herein primarily in the context of implantable medical devices generating physiological signals and, in some examples, delivering therapy, a medical device system that implements the techniques described in this disclosure may additionally or alternatively include an external medical device, e.g., external cardiac monitor, and/or external pacemaker, cardioverter and/or defibrillator, configured to generate one or more of the physiological signals described herein, monitor physiological responses and/or generate an alert.

**[0059]** FIGS. **4**A-**4**C are front-view, side-view, and top-view conceptual drawings, respectively, illustrating another example medical device system **8**C in conjunction with a patient **14**C. Medical device system **8**C is another example of a medical device system configured to implement the techniques described herein for monitoring physiological responses to exertion events, and responsively generating an alert indicating that a physiological response crosses a threshold.

**[0060]** In the illustrated example, medical device system **8**C includes an extracardiovascular ICD system **100**A implanted within a patient **14**C. ICD system **100**A includes an IMD **10**C, which is an ICD and is referred to hereafter as ICD **10**C, connected to at least one implantable cardiac defibrillation lead **102**A. ICD **10**C may be configured to deliver high-energy cardioversion or defibrillation pulses to a patient's heart **16**C when atrial or ventricular fibrillation is detected. Cardioversion shocks are typically delivered in synchrony with a detected R-wave when fibrillation detection criteria are met. Defibrillation shocks are typically delivered when fibrillation criteria are met, and the R-wave cannot be discerned from signals sensed by ICD **10**C.

**[0061]** ICD **10**C is implanted subcutaneously or submuscularly on the left side of patient **14**C above the ribcage. Defibrillation lead **102**A may be implanted at least partially in a substernal location, e.g., between the ribcage and/or sternum **110** and heart **16**C. In one such configuration, a proximal portion of lead **102**A extends subcutaneously from ICD **10**C toward sternum **110** and a distal portion of lead **102**A extends superior under or below the sternum **110** in the anterior mediastinum **112** (FIG. **4**C). The anterior mediastinum **112** is bounded laterally by the pleurae **116**, posteriorly by the pericardium **114** (FIG. **4**C), and anteriorly by the sternum **110**. In some instances, the anterior wall of the anterior mediastinum may also be formed by the transversus thoracis and one or more costal cartilages. The anterior mediastinum includes a quantity of loose connective tissue (such as areolar tissue), some lymph vessels, lymph glands, substernal musculature (e.g., transverse thoracic muscle), branches of the internal thoracic artery, and the internal thoracic vein. In one example, the distal portion of lead **102**A extends along the posterior side of the sternum **110** substantially within the loose connective tissue and/or substernal musculature of the anterior mediastinum. Lead **102**A may be at least partially implanted in other intrathoracic locations, e.g., other non-vascular, extra-pericardial locations, including the gap, tissue, or other anatomical features around the perimeter of and adjacent to, but not attached to, the pericardium or other portion of the heart and not above the sternum **110** or ribcage.

**[0062]** In other examples, lead **102**A may be implanted at other extracardiovascular locations. For example, defibrillation lead **102**A may extend subcutaneously above the ribcage from ICD **10**C toward a center of the torso of patient **14**C, bend or turn near the center of the torso, and extend subcutaneously superior above the ribcage and/or sternum **110**. Defibrillation lead **102**A may be offset laterally to the left or the right of the sternum **110** or located over the sternum **110**. Defibrillation lead **102**A may extend substantially parallel to the sternum **110** or be angled lateral from the sternum **110** at either the proximal or distal end.

**[0063]** Defibrillation lead **102**A includes an insulative lead body having a proximal end that includes a connector **104** configured to be connected to ICD **10**C and a distal portion that includes one or more electrodes. Defibrillation lead **102**A also includes one or more conductors that form an electrically conductive path within the lead body and interconnect the electrical connector and respective ones of the electrodes.

**[0064]** Defibrillation lead **102**A includes a defibrillation electrode that includes two sections or segments **106**A and **106**B, collectively (or alternatively) defibrillation electrode **106**. The defibrillation electrode **106** is toward the distal portion of defibrillation lead **102**A, e.g., toward the portion of defibrillation lead **102**A extending along the sternum **110**. Defibrillation lead **102**A is placed below and/or along sternum **110** such that a therapy vector between defibrillation electrodes **106**A or **106**B and a housing electrode formed by or on ICD **10**C (or other second electrode of the therapy vector) is substantially across a ventricle of heart **16**C. The therapy vector may, in one example, be viewed as a line that extends from a point on defibrillation electrode **106** (e.g., a center of one of the defibrillation electrode sections **106**A or **106**B) to a point on the housing electrode of ICD **10**C. Defibrillation electrode **106** may, in one example, be an elongated coil electrode.

**[0065]** Defibrillation lead **102**A may also include one or more sensing electrodes, such as sensing electrodes **108**A and **108**B (individually or collectively, "sensing electrode(s) **108**"), located along the distal portion of defibrillation lead **102**A. In the example illustrated in FIG. **4**A and FIG. **4**B, sensing electrodes **108**A and **108**B are separated from one another by defibrillation electrode **106**A. In other examples, however, sensing electrodes **108**A and **108**B may be both distal of defibrillation electrode **106** or both proximal of defibrillation electrode **106**. In other examples, lead **102**A may include more or fewer electrodes at various locations proximal and/or distal to defibrillation electrode **106**. In the same or different examples, ICD **10**C may include one or more electrodes on another lead (not shown).

**[0066]** ICD system **100**A may sense electrical signals via one or more sensing vectors that include combinations of electrodes **108**A and **108**B and the housing electrode of ICD **10**C. In some instances, ICD **10**C may sense cardiac electrical signals using a sensing vector that includes one of the defibrillation electrode sections **106**A and **106**B and one of sensing electrodes **108**A and **108**B or the housing electrode of ICD **9**. The sensed electrical intrinsic signals may include electrical signals generated by cardiac muscle and indicative of depolarizations and repolarizations of heart **16**C at various times during the cardiac cycle. ICD **10**C analyzes the electrical signals sensed by the one or more sensing vectors to detect a physiological parameter, such as heart rate, blood pressure, respiration, and the like. ICD **10**C, e.g., using one or more accelerometers within ICD **10**C, may detect a plurality of exertion events based on first sensed signals from the accelerometers. The first sensed signals may vary as a function of the movement of patient **14**C. The processing circuitry within ICD **10**C may determine a physiological response to each exertion event and determine whether a change in the responses over time crosses a threshold. The change over time may be a trend in the measurements or a single measurement that crosses a threshold, which may be determined based on past measurements of the physiological response. For example, the heart-rate responses to sit-stand transitions may increase gradually over time for patient **14**C. If the trend in heart-rate responses, such as a trend in the mean or median heart-rate response to a sit-stand transition, exceeds and/or falls below a threshold or threshold range, which may be determined based on baseline or other past responses, ICD **10**C may generate an alert.

**[0067]** Medical device system **8**C also includes an IMD **10**D, which is implanted within heart **16**C and configured to deliver cardiac pacing to the heart, e.g., is an intracardiac pacing device (IPD). IMD **10**D is referred to as IPD **10**D hereafter. In the illustrated example, IPD **10**D is implanted within the right ventricle of heart **16**C. However, in other examples, system **8**C may additionally or alternatively include one or more IPDs **10**D within other chambers of heart **16**C, or similarly configured pacing devices attached to an external surface of heart **16**C (e.g., in contact with the epicardium) such that the pacing device is disposed outside of heart **16**C.

**[0068]** IPD **10**D may be configured to sense electrical activity of heart **16**C and deliver pacing therapy, e.g., bradycardia pacing therapy, cardiac resynchronization therapy (CRT), anti-tachycardia pacing (ATP) therapy, and/or post-shock pacing, to heart **16**C. IPD **10**D may be attached to an interior wall of heart **16**C via one or more fixation elements that penetrate the tissue. These fixation elements may secure IPD **10**D to the cardiac tissue and retain an electrode (e.g., a cathode or an anode) in contact with the cardiac tissue.

**[0069]** IPD **10**D may be capable sensing electrical signals using the electrodes carried on the housing of IPD **10**D. These electrical signals may be electrical signals generated by cardiac muscle and indicative of depolarizations and repolarizations of heart **16**C at various times during the cardiac cycle. IPD **10**D may analyze the sensed electrical signals to detect bradycardia and tachyarrhythmias, such as ventricular tachycardia or ventricular fibrillation. In response to detecting bradycardia, IPD **10**D may deliver bradycardia pacing via the electrodes of IPD **10**D. In response to detecting tachyarrhythmia, IPD **10**D may, e.g., depending on the type of tachyarrhythmia, deliver ATP therapy via the electrodes of IPD **10**D. In some examples, IPD **10**D may deliver post-shock pacing in response to determining that another medical device, e.g., ICD **10**C, delivered an anti-tachyarrhythmia shock.

**[0070]** IPD **10**D and ICD **10**C may be configured to coordinate their arrhythmia detection and treatment activities. In some examples IPD **10**D and ICD **10**C may be configured to operate completely independently of one another. In such a case, IPD **10**D and ICD **10**C are not capable of establishing telemetry communication sessions with one another to exchange information about sensing and/or therapy using one-way or two-way communication. Instead, each of IPD **10**D and ICD **10**C analyze the data

sensed via their respective electrodes to make tachyarrhythmia detection and/or therapy decisions. As such, each device does not know if the other will detect the tachyarrhythmia, if or when it will provide therapy, and the like. In some examples, IPD **10**D may be configured to detect anti-tachyarrhythmia shocks delivered by ICD system **100**A, which may improve the coordination of therapy between subcutaneous ICD **10**C and IPD **10**D without requiring device-to-device communication. In this manner, IPD **10**D may coordinate the delivery of cardiac stimulation therapy, including the termination of ATP and the initiation of the delivery of post-shock pacing, with the application of an anti-tachyarrhythmia shock merely through the detection of defibrillation pulses and without the need to communicate with the defibrillation device applying the anti-tachyarrhythmia shock.

**[0071]** In other examples, IPD **10**D and ICD **10**C may engage in communication to facilitate the appropriate detection of arrhythmias and/or delivery of therapy. The communication may include one-way communication in which one device is configured to transmit communication messages and the other device is configured to receive those messages. The communication may instead include two-way communication in which each device is configured to transmit and receive communication messages. Two-way communication and coordination of the delivery of patient therapies between IPD **10**D and ICD **10**C is described in commonly-assigned U.S. patent application Ser. No. 13/756,085, titled, "SYSTEMS AND METHODS FOR LEADLESS PACING AND SHOCK THERAPY," filed Jan. 31, 2013, the entire content of which is incorporated by reference herein.

**[0072]** External device **30**C may be configured substantially similarly to external device **30**A described above with respect to FIG. **1**. External device **30**C may be configured to communicate with one or both of ICD **10**C and IPD **10**D. In examples where external device **30**C only communicates with one of ICD **10**C and IPD **10**D, the non-communicative device may receive instructions from or transmit data to the device in communication with external device **30**C. In some examples, a user may interact with device **30**C remotely via a networked computing device. The user may interact with external device **30**C to communicate with IPD **10**D and/or ICD **10**C.

**[0073]** For example, the user may interact with external device **30**C to send an interrogation request and retrieve sensed physiological data or therapy delivery data stored by one or both of ICD **10**C and IPD **10**D, and program or update therapy parameters that define therapy, or perform any other activities with respect to ICD **10**C and IPD **10**D. Although the user is a physician, technician, surgeon, electrophysiologist, or other healthcare professional, the user may be patient **14**C in some examples. For example, external device **21** may allow a user to program any coefficients, weighting factors, or techniques for determining difference metrics, scores, and/or thresholds, or other data described herein as being used by a medical device system to determine whether a physiological response crosses a threshold.

**[0074]** Although FIGS. **4**A-**4**C are shown or described in the context of IPD **10**D and extracardiovascular ICD system **100**A that includes lead **102**A with a substernally placed distal portion, techniques in accordance with one or more aspects of the present disclosure may be applicable to other coexistent systems. For example, an extracardiovascular ICD system may include a lead having a distal portion that is implanted subcutaneously above the sternum (or other location) instead of being implanted substernally. As another example, instead of an IPD, a pacing system may be implanted having a pacemaker and one or more leads connected to and extending from the pacemaker into one or more chambers of the heart or attached to the outside of the heart to provide pacing therapy to the one or more chambers. As such, the example of FIGS. **4**A-**4**C is illustrated for example purposes only and should not be considered limiting of the techniques described herein.

**[0075]** FIG. **5** is a conceptual drawing illustrating another example medical device system **8**D that includes an extracardiovascular ICD system **100**B and IPD **10**D implanted within a patient. Medical device system **8**B may be configured to perform any of the techniques described herein with respect to medical device system **8**C of FIGS. **4**A-**4**C. Components with like numbers in FIGS. **4**A-**4**C and FIG. **5** may be similarly configured and provide similar functionality.

**[0076]** In the example of FIG. **5**, extracardiovascular ICD system **100**B includes ICD **10**C coupled to a defibrillation lead **102**B. Unlike defibrillation lead **102**A of FIGS. **4**A-**4**C, defibrillation lead **102**B extends subcutaneously above the ribcage from ICD **10**C. In the illustrated example, defibrillation lead **102**B extends toward a center of the torso of patient **14**D, bends or turns near the center of the torso, and extends subcutaneously superior above the ribcage and/or sternum **110**. Defibrillation lead **102**B may be offset laterally to the left or the right of sternum **110** or located over sternum **110**. Defibrillation lead **102**B may extend substantially parallel to sternum **102** or be angled lateral from the sternum at either the proximal or distal end.

**[0077]** Defibrillation lead **102**B includes an insulative lead body having a proximal end that includes a connector **104** configured to be connected to ICD **10**C and a distal portion that includes one or more electrodes. Defibrillation lead **102**B also includes one or more conductors that form an electrically conductive path within the lead body and interconnect the electrical connector and respective ones of the electrodes. In the illustrated example, defibrillation lead **102**B includes a single defibrillation electrode **106** toward the distal portion of defibrillation lead **102**B, e.g., toward the portion of defibrillation lead **102**B extending along sternum **110**. Defibrillation lead **102**B is placed along sternum **110** such that a therapy vector between defibrillation electrode **106** and a housing electrode formed by or on ICD **10**C (or other second electrode of the therapy vector) is substantially across a ventricle of heart **16**D.

**[0078]** Defibrillation lead **102**B may also include one or more sensing electrodes, such as sensing electrodes **108**A and **108**B, located along the distal portion of defibrillation lead **102**B. In the example illustrated in FIG. **5**, sensing electrodes **108**A and **108**B are separated from one another by defibrillation electrode **106**. In other examples, however, sensing electrodes **108**A and **108**B may be both distal of defibrillation electrode **106** or both proximal of defibrillation electrode **106**. In other examples, lead **102**B may include more or fewer electrodes at various locations proximal and/or distal to defibrillation electrode **106**, and lead **102**B may include multiple defibrillation electrodes, e.g., defibrillation electrodes **106**A and **106**B as illustrated in the example of FIGS. **4**A-**4**C.

**[0079]** FIG. **6** is a conceptual drawing illustrating an example configuration of IPD **10**D. As shown in FIG. **6**, IPD

10D includes case 130, cap 138, electrode 140, electrode 132, fixation mechanisms 142, flange 134, and opening 136. Together, case 130 and cap 138 may be considered the housing of IPD 10D. In this manner, case 130 and cap 138 may enclose and protect the various electrical components, e.g., circuitry, within IPD 10D. Case 130 may enclose substantially all of the electrical components, and cap 138 may seal case 130 and create the hermetically sealed housing of IPD 10D. Although IPD 10D is generally described as including one or more electrodes, IPD 10D may typically include at least two electrodes (e.g., electrodes 132 and 140) to deliver an electrical signal (e.g., therapy such as cardiac pacing) and/or provide at least one sensing vector.

[0080] Electrodes 132 and 140 are carried on the housing created by case 130 and cap 138. In this manner, electrodes 132 and 140 may be considered leadless electrodes. In the example of FIG. 6, electrode 140 is disposed on the exterior surface of cap 138. Electrode 140 may be a circular electrode positioned to contact cardiac tissue upon implantation. Electrode 132 may be a ring or cylindrical electrode disposed on the exterior surface of case 130. Both case 130 and cap 138 may be electrically insulating.

[0081] Electrode 140 may be used as a cathode and electrode 132 may be used as an anode, or vice versa, for delivering cardiac pacing such as bradycardia pacing, CRT, ATP, or post-shock pacing. However, electrodes 132 and 140 may be used in any stimulation configuration. In addition, electrodes 132 and 140 may be used to detect intrinsic electrical signals from cardiac muscle.

[0082] Fixation mechanisms 142 may attach IPD 10D to cardiac tissue. Fixation mechanisms 142 may be active fixation tines, screws, clamps, adhesive members, or any other mechanisms for attaching a device to tissue. As shown in the example of FIG. 6, fixation mechanisms 142 may be constructed of a memory material, such as a shape memory alloy (e.g., nickel titanium), that retains a preformed shape. During implantation, fixation mechanisms 142 may be flexed forward to pierce tissue and allowed to flex back towards case 130. In this manner, fixation mechanisms 142 may be embedded within the target tissue.

[0083] Flange 144 may be provided on one end of case 130 to enable tethering or extraction of IPD 10D. For example, a suture or other device may be inserted around flange 144 and/or through opening 146 and attached to tissue. In this manner, flange 144 may provide a secondary attachment structure to tether or retain IPD 10D within heart 16C (or 16D) if fixation mechanisms 142 fail. Flange 144 and/or opening 146 may also be used to extract IPD 10D once the IPD needs to be explanted (or removed) from patient 14D if such action is deemed necessary.

[0084] IPD 10D is one example of a pacing device configured to implement the techniques of this disclosure. However, other implantable medical devices may be used to perform the same or similar functions as IPD 10D. For example, an IPD may include a small housing that carries an electrode, similar to IPD 10D, and be configured to be implanted within a chamber of a heart 16. The IPD may also include one or more relatively short leads configured to place one or more respective additional electrodes at another location within the same chamber of the heart or a different chamber of the heart. In this manner, the housing of the IPD may not carry all of the electrodes used to perform functions described herein with respect to IPD 10D. In other examples, each electrode of the IPD may be carried by one or more leads (e.g., the housing of the IPD may not carry any of the electrodes). In some examples, an IPD or other pacing device may include or be coupled to three or more electrodes, where each electrode may deliver therapy and/or detect intrinsic signals.

[0085] In another example, a pacing device may be configured to be implanted external to the heart, e.g., near or attached to the epicardium of the heart. An electrode carried by the housing of the pacing may be placed in contact with the epicardium and/or one or more electrodes of leads coupled to the pacing may be placed in contact with the epicardium at locations sufficient to provide cardiac pacing. In still other examples, a pacing device configured to perform the techniques described herein may be implanted subcutaneously or submuscularly, and connected to one or more intracardiac leads carrying one or more electrodes.

[0086] Referring back to FIGS. 4A-5, medical device systems 8C and 8D are examples of medical device systems configured to determine whether a physiological response crosses a threshold. The techniques may be performed by processing circuitry of medical device system 8C or 8D, such as processing circuitry of one or more of ICD 10C, IPD 10D, and external device 30C or 30D, individually, or collectively. Although the example medical devices systems 8C and 8D of FIGS. 4A-5 are illustrated as including both ICD 10C and IPD 10D, other examples may include only one of ICD 10C or IPD 10D, alone, or in combination with other implanted or external devices.

[0087] The techniques include determining a respective value for each of a plurality of patient parameters of a patent during each of a plurality of periods, which may be at least one hour, such as approximately one day. The processing circuitry may determine the values of at least some the patient parameters based on physiological signals generated by sensing circuitry of one or both of ICD 10C and IPD 10D, such as cardiac EGM signals generated by sensing circuitry of the IMDs. In some examples, one or both of ICD 10C and IPD 10D may include or be coupled to one or more other sensors that generate one or more physiological signals, such as signals that vary based on patient motion and/or posture, blood flow, blood pressure (e.g., systems 8C and 8D may include pressure sensing IMD 50, described above with respect to FIG. 1), respiration, or edema. The processing circuitry may determine other patient parameters based on therapies delivered by ICD 10C and/or IPD 10D, such as patient parameters indicating the extent to which patient 14C or 14D is dependent on pacing, e.g., a percentage of time or other characterization of amount of pacing delivered to the patient, or the number of anti-tachyarrhythmia therapies delivered to the patient.

[0088] FIG. 7 is a functional block diagram illustrating an example configuration of an IMD 10. IMD 10 may correspond to any of ICM 10A, ICD 10B, ICD 10C, IPD 10D, or another IMD configured to implement the techniques for determining whether a physiological response crosses a threshold as described in this disclosure. In the illustrated example, IMD 10 includes processing circuitry 160 and an associated memory 170, sensing circuitry 162, therapy delivery circuitry 164, one or more sensors 166, and communication circuitry 168. However, ICD 10A, ICM 10B, ICD 10C, and IPD 10D need not include all of these components, or may include additional components. For example, ICM 10A may not include therapy delivery circuitry 164, in some examples.

**[0089]** Memory **170** includes computer-readable instructions that, when executed by processing circuitry **160**, cause IMD **10** and processing circuitry **160** to perform various functions attributed to IMD **10** and processing circuitry **160** herein (e.g., determining patient parameter values, difference metrics, scores and thresholds, and determining whether to generate an alert indicating that a physiological response crosses a threshold). Memory **170** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital or analog media. Memory **170** may store threshold(s) for physiological parameters such as maximum changes and minimum changes. Memory **170** may also store data indicating changes in physiological parameters over time in response to exertion events.

**[0090]** Processing circuitry **160** may include fixed function circuitry and/or programmable processing circuitry. Processing circuitry **160** may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), or equivalent discrete or analog logic circuitry. In some examples, processing circuitry **160** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processing circuitry **160** herein may be embodied as software, firmware, hardware or any combination thereof.

**[0091]** Sensing circuitry **162** and therapy delivery circuitry **164** are coupled to electrodes **190**. Electrodes **190** illustrated in FIG. **7** may correspond to, for example: electrodes **12**, **22**, **24**, **26**, **28**, **44**, and **44** of ICD **10**A (FIG. **1**); electrodes **64** and **66** of ICM **10**B (FIG. **3**); electrodes **106**, **108**, and one or more housing electrodes of ICD **10**C (FIGS. **4**A-**5**); or electrodes **132** and **140** of IPD **10**D (FIG. **6**).

**[0092]** Sensing circuitry **162** monitors signals from a selected two or more of electrodes **190** in order to monitor electrical activity of heart, impedance, or other electrical phenomenon. Sensing of a cardiac electrical signal may be done to determine heart rates or heart rate variability, or to detect arrhythmias (e.g., tachyarrhythmias or bradycardia) or other electrical signals. In some examples, sensing circuitry **162** may include one or more filters and amplifiers for filtering and amplifying a signal received from electrodes **190**. In some examples, sensing circuitry **162** may sense or detect physiological parameters, such as heart rate, blood pressure, respiration, and the like.

**[0093]** The resulting cardiac electrical signal may be passed to cardiac event detection circuitry that detects a cardiac event when the cardiac electrical signal crosses a sensing threshold. The cardiac event detection circuitry may include a rectifier, filter and/or amplifier, a sense amplifier, comparator, and/or analog-to-digital converter. Sensing circuitry **162** outputs an indication to processing circuitry **160** in response to sensing of a cardiac event (e.g., detected P-waves or R-waves).

**[0094]** In this manner, processing circuitry **160** may receive detected cardiac event signals corresponding to the occurrence of detected R-waves and P-waves in the respective chambers of heart. Indications of detected R-waves and P-waves may be used for detecting ventricular and/or atrial tachyarrhythmia episodes, e.g., ventricular or atrial fibrillation episodes. Some detection channels may be configured to detect cardiac events, such as P- or R-waves, and provide indications of the occurrences of such events to processing circuitry **160**, e.g., as described in U.S. Pat. No. 5,117,824 to Keimel et al., which issued on Jun. 2, 1992 and is entitled, "APPARATUS FOR MONITORING ELECTRICAL PHYSIOLOGIC SIGNALS," and is incorporated herein by reference in its entirety.

**[0095]** Sensing circuitry **162** may also include a switch module to select which of the available electrodes **190** (or electrode polarities) are used to sense the heart activity. In examples with several electrodes **190**, processing circuitry **160** may select the electrodes that function as sense electrodes, i.e., select the sensing configuration, via the switch module within sensing circuitry **162**. Sensing circuitry **162** may also pass one or more digitized EGM signals to processing circuitry **160** for analysis, e.g., for use in cardiac rhythm discrimination.

**[0096]** Processing circuitry **160** may implement programmable counters. If IMD **10** is configured to generate and deliver pacing pulses to heart, such counters may control the basic time intervals associated with bradycardia pacing (e.g., DDD, VVI, DVI, VDD, AAI, DDI, DDDR, VVIR, DVIR, VDDR, AAIR, DDIR pacing) and other modes of pacing. Intervals defined by processing circuitry **160** may include atrial and ventricular pacing escape intervals, refractory periods during which sensed P-waves and R-waves are ineffective to restart timing of the escape intervals, and the pulse widths of the pacing pulses. The durations of these intervals may be determined by processing circuitry **160** in response to pacing mode parameters stored in memory **170**.

**[0097]** Interval counters implemented by processing circuitry **160** may be reset upon sensing of R-waves and P-waves with detection channels of sensing circuitry **162**, or upon the generation of pacing pulses by therapy delivery circuitry **164**, and thereby control the basic timing of cardiac pacing functions, including bradycardia pacing, CRT, ATP, or post-shock pacing. The value of the count present in the interval counters when reset by sensed R-waves and P-waves may be used by processing circuitry **160** to measure the durations of R-R intervals, P-P intervals, P-R intervals and R-P intervals, which are measurements that may be stored in memory **170**. Processing circuitry **160** may use the count in the interval counters to detect a tachyarrhythmia event, such as atrial fibrillation (AF), atrial tachycardia (AT), VF, or VT. These intervals may also be used to detect the overall heart rate, ventricular contraction rate, and heart rate variability. A portion of memory **170** may be configured as a plurality of recirculating buffers, capable of holding series of measured intervals, which may be analyzed by processing circuitry **160** in response to the occurrence of a pace or sense interrupt to determine whether the patient's heart is presently exhibiting atrial or ventricular tachyarrhythmia.

**[0098]** In some examples, an arrhythmia detection method may include any suitable tachyarrhythmia detection algorithms. In one example, processing circuitry **160** may utilize all or a subset of the rule-based detection methods described in U.S. Pat. No. 5,545,186 to Olson et al., entitled, "PRIORITIZED RULE BASED METHOD AND APPARATUS FOR DIAGNOSIS AND TREATMENT OF ARRHYTHMIAS," which issued on Aug. 13, 1996, or in U.S. Pat. No. 5,755,736 to Gillberg et al., entitled, "PRIORITIZED RULE BASED METHOD AND APPARATUS FOR DIAGNOSIS

AND TREATMENT OF ARRHYTHMIAS," which issued on May 26, 1998. U.S. Pat. No. 5,545,186 to Olson et al. U.S. Pat. No. 5,755,736 to Gillberg et al. is incorporated herein by reference in their entireties. However, other arrhythmia detection methodologies, such as those methodologies that utilize timing and morphology of the electrocardiogram, may also be employed by processing circuitry **160** in other examples.

**[0099]** In some examples, processing circuitry **160** may determine that tachyarrhythmia has occurred by identification of shortened R-R (or P-P) interval lengths. Generally, processing circuitry **160** detects tachycardia when the interval length falls below 220 milliseconds and fibrillation when the interval length falls below 180 milliseconds. In other examples, processing circuitry **160** may detect ventricular tachycardia when the interval length falls between 330 milliseconds and ventricular fibrillation when the interval length falls below 240 milliseconds. These interval lengths are merely examples, and a user may define the interval lengths as desired, which may then be stored within memory **170**. This interval length may need to be detected for a certain number of consecutive cycles, for a certain percentage of cycles within a running window, or a running average for a certain number of cardiac cycles, as examples. In other examples, additional patient parameters may be used to detect an arrhythmia. For example, processing circuitry **160** may analyze one or more morphology measurements, impedances, or any other physiological measurements to determine that patient is experiencing a tachyarrhythmia.

**[0100]** In addition to detecting and identifying specific types of cardiac events, e.g., cardiac depolarizations, sensing circuitry **162** may also sample the detected intrinsic signals to generate an electrogram or other time-based indication of cardiac events. Sensing circuitry **162** may include an analog-to-digital converter or other circuitry configured to sample and digitize the electrical signal sensed via electrodes **190**. Processing circuitry **160** may analyze the digitized signal for a variety of purposes, including morphological identification or confirmation of tachyarrhythmia of heart. As another example, processing circuitry **160** may analyze the digitized cardiac electrogram signal to identify and measure a variety of morphological features of the signal. The morphological features of the cardiac electrogram may, in some examples, be patient parameters, and their measurements patient parameter values, used to determine whether a physiological response crosses a threshold.

**[0101]** In some examples, sensing circuitry **162** is configured to sense physiological signals of patient. For example, sensing circuitry **162** may be configured to sense signals that vary with changing thoracic impedance of patient **14**. The thoracic impedance may vary based on fluid volume or edema in patient **14**.

**[0102]** Sensing circuitry **162** may use any two or more of electrodes **190** to sense thoracic impedance. As the tissues within the thoracic cavity of patient **14** change in fluid content, the impedance between two electrodes may also change. For example, the impedance between a defibrillation coil electrode (**42**, **44**, **106**) and the housing electrode may be used to monitor changing thoracic impedance.

**[0103]** In some examples, processing circuitry **160** measured thoracic impedance values to determine a fluid index. As more fluid is retained within patient **14**, e.g., edema increases, and the thoracic impedance decreases or remains relatively high, the fluid index increases. Conversely, as the thoracic impedance increases or remains relatively low, the fluid index decreases. An example system for measuring thoracic impedance and determining a fluid index is described in U.S. Patent Publication No. 2010/0030292 to Sarkar et al., entitled, "DETECTING WORSENING HEART FAILURE BASED ON IMPEDANCE MEASUREMENTS," which published on Feb. 4, 2010 and is incorporated herein by reference in its entirety.

**[0104]** The thoracic impedance may also vary with patient respiration. In some examples, processing circuitry **160** may determine values of one or more respiration-related patient parameters based on thoracic impedance sensed by sensing circuitry **162**. Respiration-related patient parameters may include, as examples, respiration rate, respiration depth, or the occurrence or magnitude of dyspnea or apneas.

**[0105]** The magnitude of the cardiac electrogram may also vary based on patient respiration, e.g., generally at a lower frequency than the cardiac cycle. In some examples, processing circuitry **160** and/or sensing circuitry **162** may filter the cardiac electrogram to emphasize the respiration component of the signal. Processing circuitry **160** may analyze the filtered cardiac electrogram signal to determine values of respiration-related patient parameters.

**[0106]** In the example of FIG. **7**, IMD **10** includes one or more sensors **166** coupled to sensing circuitry **162**. Although illustrated in FIG. **7** as included within IMD **10**, one or more of sensors **166** may be external to IMD **10**, e.g., coupled to IMD **10** via one or more leads, or configured to wirelessly communicate with IMD **10**. In some examples, sensors **166** transduce a signal indicative of a patient parameter, which may be amplified, filtered, or otherwise processed by sensing circuitry **162**. In such examples, processing circuitry **160** determines values of patient parameters based on the signals. In some examples, sensors **166** determine the patient parameter values, and communicate them, e.g., via a wired or wireless connection, to processing circuitry **160**.

**[0107]** In some examples, sensors **166** include one or more accelerometers **167**, e.g., one or more 3-axis accelerometers. Signals generated by the one or more accelerometers **167** may be indicative of, as examples, gross body movement (e.g., activity) of patient **14**, patient posture, heart sounds or other vibrations or movement associated with the beating of the heart, or coughing, rales, or other respiration abnormalities. In some examples, sensors **166** include one or more microphones configured to detect heart sounds or respiration abnormalities, and/or other sensors configured to detect patient activity or posture, such as gyroscopes and/or strain gauges. In some examples, sensors **166** may include sensors configured to transduce signals indicative of blood flow, oxygen saturation of blood, or patient temperature, and processing circuitry **160** may determine patient parameters values based on these signals.

**[0108]** In some examples, sensors **166** include one or more pressure sensors that transduce one or more signals indicative of blood pressure, and processing circuitry **160** determines one or more patient parameter values based on the pressure signals. Patient parameter values determined based on pressure may include, as examples, systolic or diastolic pressure values, such as pulmonary artery diastolic pressure values. In some examples, a separate pressure-sensing IMD **50** includes one or more sensors and sensing circuitry configured to generate a pressure signal, and processing circuitry **160** determines patient parameter values related to blood pressure based on information received from IMD **50**.

**[0109]** Therapy delivery circuitry **164** is configured to generate and deliver electrical therapy to the heart. Therapy delivery circuitry **164** may include one or more pulse generators, capacitors, and/or other components capable of generating and/or storing energy to deliver as pacing therapy, defibrillation therapy, cardioversion therapy, other therapy or a combination of therapies. In some instances, therapy delivery circuitry **164** may include a first set of components configured to provide pacing therapy and a second set of components configured to provide anti-tachyarrhythmia shock therapy. In other instances, therapy delivery circuitry **164** may utilize the same set of components to provide both pacing and anti-tachyarrhythmia shock therapy. In still other instances, therapy delivery circuitry **164** may share some of the pacing and shock therapy components while using other components solely for pacing or shock delivery.

**[0110]** Therapy delivery circuitry **164** may include charging circuitry, one or more charge storage devices, such as one or more capacitors, and switching circuitry that controls when the capacitor(s) are discharged to electrodes **190** and the widths of pulses. Charging of capacitors to a programmed pulse amplitude and discharging of the capacitors for a programmed pulse width may be performed by therapy delivery circuitry **164** according to control signals received from processing circuitry **160**, which are provided by processing circuitry **160** according to parameters stored in memory **170**. Processing circuitry **160** controls therapy delivery circuitry **164** to deliver the generated therapy to the heart via one or more combinations of electrodes **190**, e.g., according to parameters stored in memory **170**. Therapy delivery circuitry **164** may include switch circuitry to select which of the available electrodes **190** are used to deliver the therapy, e.g., as controlled by processing circuitry **160**.

**[0111]** In some examples, IMD **10** may be configured to determine whether a physiological response, or a change or trend in physiological responses over time, crosses a threshold. For example, processing circuitry **160** may monitor the health of a subject by measuring heart rate in response to a sit-to-stand transition, which is one example of an exertion event. Processing circuitry **160** may determine a mean, median, and/or standard deviation for the heart-rate responses to sit-to-stand transitions. Processing circuitry **160** may then determine that a change in the heart-rate responses over time exceeds a threshold, such as a current increase that exceeds or falls below a threshold or threshold range of absolute or percentage changes values. The threshold may be defined in terms of a long-term mean, median, and/or heart-rate response of one or more prior responses, e.g., during a baseline or other period preceding the current transition. Processing circuitry **160** may generate an alert based on the determination that the change crosses the threshold. Processing circuitry **160** may generate the alert by causing communication circuitry **168** to transmit a signal to an external device indicating that the change in responses exceeds the threshold.

**[0112]** As another example, IMD **10** may additionally or alternatively be configured to detect a plurality of walking events, such as walking twenty steps after standing still, not moving, or sitting, which are other examples of exertion events. IMD **10** may detect the walking events based on signals from accelerometer(s) **166**. For each walking event, processing circuitry **160** may determine a respiration response based on a sensed signal from sensing circuitry **162**. Processing circuitry **160** may determine that a change in the respiration response over time crosses a threshold. The change may be a gradual trend or a single outlier measurement.

**[0113]** As another example, IMD **10** may additionally or alternatively be configured to detect a plurality of lie-sit transitions, which are another example of an exertion event, based on one or more signals from one or more accelerometers **167**. Processing circuitry **160** may determine the blood-pressure response to each lie-sit transition and determine whether a change over time crosses a threshold. Processing circuitry **160** may determine the threshold based on previous responses to lie-sit transitions, including the historical mean, median, and/or range of variability (e.g., standard deviation or variance) of the response.

**[0114]** According to the physiological-response monitoring techniques described herein, processing circuitry **160** determines values for each of one or more physiological parameters for the patient associated with the detection of an exertion event. The determined physiological parameter values are stored as physiological parameter values **174** in memory **170**.

**[0115]** The plurality of physiological parameters may include one or more parameters determined based on the cardiac electrogram, such as one or more heart rate parameters or one or more measures of heart rate variability. Other patient parameters determined based on the cardiac electrogram include morphological features of the cardiac electrogram, such as QRS width or duration, QT interval length, T-wave amplitude, R-R interval length, an interval between a peak and the end of the T-wave, a ratio between the T-wave peak to end interval and the QT interval lengths, or T-wave alternan. The presence of T-wave alternan may be detected as a periodic (e.g., beat-to-beat) variation in the amplitude or morphology of the T-wave. A T-wave alternan patient parameter value **174** may be an indication of the presence, number, frequency, or duration (total, mean, or median) of T-wave alternan episodes. Other patient parameter values **174** based cardiac electrogram morphological interval lengths may be means or medians of a plurality of measurements.

**[0116]** The plurality of physiological parameters may additionally or alternatively include at least one parameter indicative of edema, and processing circuitry **160** may determine values **174** of such physiological parameters based on sensed thoracic impedance, as described above. In some examples, a physiological parameter value **174** may be a maximum, minimum, mean, or median thoracic impedance value.

**[0117]** The plurality of physiological parameters may additionally or alternatively include at least one patient parameter indicative of cardiovascular pressure, and processing circuitry **160** may determine values **174** of such physiological parameters based on generated pressure waveform, e.g., generated by a sensor **166** or pressure-sensing IMD **50**, as described above. The physiological parameter values **174** may include a maximum, minimum, mean, and/or median of systolic pressure and/or diastolic pressure, e.g., pulmonary artery diastolic pressure.

**[0118]** The plurality of physiological parameters may additionally or alternatively include at least one patient parameter determined based on patient respiration, and processing circuitry **160** may determine values **174** of such parameters based on a generated signal that varies based on

respiration as described above, such as a signal that varies based on thoracic impedance. The physiological parameter values **174** may include a maximum, minimum, mean, and/or median of respiration rate.

**[0119]** Processing circuitry **160** may additionally or alternatively determine values **174** of one or more physiological parameters based on a generated signal that varies based on sound or other vibrations, which may indicate heart sounds, coughing, or rales. Physiological parameter values may include morphological measurements of the Si and S**2** heart sounds, the presence or frequency of occurrence of S**3** and/or S**4** heart sounds, or the presence, number, frequency, or duration (total, mean or media) of episodes or coughing or rales. Other physiological parameter values **174** that processing circuitry **160** may additionally or alternatively determine based on signals generated by sensors **166** include maximum, minimum, mean, or median values of blood flow, blood oxygen saturation, or temperature.

**[0120]** Processing circuitry **160** determines a difference metric **176** for each of the plurality physiological parameters. Processing circuitry **160** determines the difference metric **176** for each physiological parameter based on a difference between a two values **174** of the physiological parameter associated with detection of the exertion event. The two values may include a first value determined at or near, e.g., just prior to, the commencement of the exertion event, and a second value determined during the exertion event, or some predetermined period of time after or near the end of the exertion event. In this manner, difference metric **176** represents the response of the physiological parameter to the exertion event. In some examples, processing circuitry **160** determines the difference metric **176** for each of the patient parameters according to the equation, (difference metric)=(parameter value after exertion event)−(parameter value immediately before exertion event). Another possible equation for difference metric **176** calculates the percentage difference in the parameter value: (difference metric)=[(parameter value after exertion event)−(parameter value immediately before exertion event)] divided by (parameter value immediately before exertion event). The parameter value after the exertion event may be measured immediately at the end of the exertion event or a period of time after the end of the exertion event. The period of time may be five seconds, thirty seconds, several minutes, or any other period of time. Similarly, the parameter value before the exertion event may be measured immediately before the beginning of the exertion event, during the exertion event, or a period of time before the beginning of the exertion event.

**[0121]** Processing circuitry **160** compares the responses to the exertion event, e.g., difference metrics **176**, for each of the one or more patient parameters to one or more threshold values, e.g., which may define a threshold range. If the difference metric crosses the threshold, e.g., is greater than or less than (or greater than or equal to or less than or equal to) the threshold, processing circuitry **160** generates an alert that the responses to exertion events over time have crossed a threshold. Thresholds **180** may include predetermined, e.g., programmable threshold values, or values that are variable. Thresholds **180** may be determined based on one or more prior difference metrics **176** determined in response to one or more prior exertion events, e.g., a median or mean of prior difference metrics, e.g., from a fixed baseline period and/or a recently-preceding trend period. Processing circuitry may determine a threshold or threshold range by multiplying a median or mean of prior difference metrics by a coefficient value (or adding to and/or subtracting from the mean or median a value) representative of the expected or average variability of the responses.

**[0122]** In some examples, processing circuitry **160** may additionally control therapy delivery circuitry **162**, a pump included in IMD **10**, or another implanted or external medical device to deliver or modify a therapy such as a pacing therapy, a neuromodulation therapy, or a therapeutic substance based on the score crossing a threshold. In some examples, a clinician may prescribe or deliver, or control another device to deliver to modify, such a therapy based on the alert generated by processing circuitry **160**.

**[0123]** Communication circuitry **168** includes any suitable hardware, firmware, software or any combination thereof for communicating with another device, such as an external device **30** or another IMD or sensor. Under the control of processing circuitry **160**, communication circuitry **168** may receive downlink telemetry from and send uplink telemetry to external device **30** or another device with the aid of an antenna, which may be internal and/or external. In some examples, communication circuitry **168** may communicate with a local external device, and processing circuitry **160** may communicate with a networked computing device via the local external device and a computer network, such as the Medtronic CareLink® Network developed by Medtronic, plc, of Dublin, Ireland.

**[0124]** A clinician or other user may retrieve data from IMD **10** using external device **30** or another local or networked computing device configured to communicate with processing circuitry **160** via communication circuitry **168**. The clinician may also program parameters of IMD **10** using external device **30** or another local or networked computing device. In some examples, the clinician may select patient parameters used to determine if a physiological response to an exertion event crosses a threshold, select values for a coefficient used to determine threshold **180**, and receive alerts that indicate that a physiological response to an exertion event crosses a threshold.

**[0125]** FIG. **8** is a functional block diagram illustrating an example configuration of an external device **30** configured to communicate with one or more IMDs **10**. In the example of FIG. **8**, external device **30** includes processing circuitry **200**, memory **202**, user interface (UI) **204**, and communication circuitry **206**. External device **30** may correspond to any of external devices **30**A-**30**C described with respect to FIGS. **1**, **2**, and **4**A-**5**. External device **30** may be a dedicated hardware device with dedicated software for the programming and/or interrogation of an IMD **10**. Alternatively, external device **30** may be an off-the-shelf computing device, e.g., running an application that enables external device **30** to program and/or interrogate IMD **10**.

**[0126]** In some examples, a user uses external device **30** to select or program any of the values for operational parameters of IMD **10**, e.g., for patient parameter sensing, therapy delivery, and acute cardiac event prediction. In some examples, a user uses external device **30** to receive data collected by IMD **10**, such as patient parameter values **174** or other operational and performance data of IMD **10**. The user may also receive alerts generated by IMD **10** that indicate that a physiological response to an exertion event crosses a threshold. The user may interact with external device **30** via UI **204**, which may include a display to present a graphical user interface to a user, and a keypad or another

mechanism (such as a touch sensitive screen) for receiving input from a user. External device **30** may communicate wirelessly with IMD **10** using communication circuitry **206**, which may be configured for RF communication with communication circuitry **168** of IMD **10**.

**[0127]** Processing circuitry **200** may include any combination of integrated circuitry, discrete logic circuitry, analog circuitry, such as one or more microprocessors, digital signal processors (DSPs), application specific integrated circuits (ASICs), or field-programmable gate arrays (FPGAs). In some examples, processing circuitry **200** may include multiple components, such as any combination of one or more microprocessors, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry, and/or analog circuitry.

**[0128]** Memory **202** may store program instructions, which may include one or more program modules, which are executable by processing circuitry **200**. When executed by processing circuitry **200**, such program instructions may cause processing circuitry **200** and external device **30** to provide the functionality ascribed to them herein. The program instructions may be embodied in software, firmware and/or RAMware. Memory **202** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital media.

**[0129]** In some examples, processing circuitry **200** of external device **30** may be configured to provide some or all of the functionality ascribed to processing circuitry **160** of IMD **10** herein. For example, processing circuitry **200** may receive physiological signals generated by one or more IMDs **10** and determine values **174** of each of a plurality of physiological parameters associated with exertion events, and/or may receive parameter values **174** from one or more IMDs **10**. Processing circuitry **200** may determine difference metrics **176**, and thresholds **180** based on the parameter values **174** in the manner described above with respect to processing circuitry **160** of IMD **10**. Processing circuitry **200** may also compare difference metrics **176** to thresholds **180** and generate an alert and/or control delivery of therapy by one or more implanted or external medical devices in the manner described above with respect to processing circuitry **160** of IMD **10**. Processing circuitry **200** may generate an alert to a user via UI **204**, or via another device with which processing circuitry **200** communicates via communication circuitry **206**.

**[0130]** FIG. **9** is a functional block diagram illustrating an example system that includes external computing devices, such as a server **224** and one or more other computing devices **230**A-**230**N, that are coupled to IMD **10** and external device **30** via a network **222**. In this example, IMD **10** may use its communication module **168** to, e.g., at different times and/or in different locations or settings, communicate with external device **30** via a first wireless connection, and to communication with an access point **220** via a second wireless connection. In the example of FIG. **9**, access point **220**, external device **30**, server **224**, and computing devices **230**A-**230**N are interconnected, and able to communicate with each other, through network **222**.

**[0131]** Access point **220** may comprise a device that connects to network **222** via any of a variety of connections, such as telephone dial-up, digital subscriber line (DSL), or cable modem connections. In other examples, access point **220** may be coupled to network **222** through different forms of connections, including wired or wireless connections. In some examples, access point **220** may be co-located with patient **14**. Access point **220** may interrogate IMD **10**, e.g., periodically or in response to a command from patient **14** or network **222**, to retrieve physiological signals, patient parameter values **174**, difference metrics **176**, scores **178**, thresholds **180**, alerts of crossed thresholds, and/or other operational or patient data from IMD **10**. Access point **220** may provide the retrieved data to server **224** via network **222**.

**[0132]** In some cases, server **224** may be configured to provide a secure storage site for data that has been collected from IMD **10** and/or external device **30**. In some cases, server **224** may assemble data in web pages or other documents for viewing by trained professionals, such as clinicians, via computing devices **230**A-**230**N. The illustrated system of FIG. **9** may be implemented, in some aspects, with general network technology and functionality similar to that provided by the Medtronic CareLink® Network developed by Medtronic plc, of Dublin, Ireland.

**[0133]** In some examples, one or more of access point **220**, server **224**, or computing devices **230** may be configured to perform, e.g., may include processing circuitry configured to perform, some or all of the techniques described herein, e.g., with respect to processing circuitry **160** of IMD **10** and processing circuitry **200** of external device **30**, relating to physiological responses that cross a threshold. In the example of FIG. **9**, server **224** includes a memory **226** to store physiological signals or patient parameter values **174** received from IMD **10** and/or external device **30**, and processing circuitry **228**, which may be configured to provide some or all of the functionality ascribed to processing circuitry **160** of IMD **10** and processing circuitry **200** of external device **30** herein. For example, processing circuitry **228** may determine values **174** of each of a plurality of physiological parameters, and/or may receive parameter values **174** from one or more IMDs **10**. Processing circuitry **228** may determine difference metrics **176** and thresholds **180** based on the parameter values **174** in the manner described above with respect to processing circuitry **160** of IMD **10**. Processing circuitry **227** may also compare difference metrics **176** to thresholds **180** and generate an alert and/or control delivery of preventative therapy by one or more implanted or external medical devices in the manner described above with respect to processing circuitry **160** of IMD **10**. Processing circuitry **228** may generate an alert to a user via network **222**, e.g., via external device **30** or one of computing devices **170**.

**[0134]** FIG. **10** is a conceptual diagram **240** illustrating a sagittal axis **242**, a vertical axis **244** and transverse axis **246** in a three-dimensional coordinate system. As described above, an accelerometer **167** of an IMD **10** that is oriented along a depth (D) of the IMD may be oriented substantially along sagittal axis **242** when the IMD is implanted within a patient **14**.

**[0135]** FIG. **11** is a timing diagram illustrating a chart of three accelerometer signals **260**-**262**, where the three signals represent vertical acceleration, transverse acceleration, and sagittal acceleration. IMD **10** may comprise one or more accelerometers **167**, e.g., one or more three-axis accelerometers. Signals generated by the one or more accelerometers, such as one or more of a sagittal axis signal, a vertical axis

signal and a transverse axis signal, may be indicative of, as examples, gross body movement (e.g., activity) of a patient, patient posture, heart sounds or other vibrations or movement associated with the beating of the heart, or coughing, rales, or other respiration abnormalities. Three-axis accelerometers, as well as techniques for detecting sit-to-stand transitions or other posture transitions based on signals generated by three-axis accelerometers, are described in commonly-assigned U.S. Provisional Patent Application No. 62/370,138, titled, "ACCELEROMETER SIGNAL CHANGE AS A MEASURE OF PATIENT FUNCTIONAL STATUS," bearing Attorney Docket Number C00012555. USP1, filed Aug. 2, 2016, the entire content of which is incorporated by reference herein.

**[0136]** Sagittal signal **260** may exhibit the largest amplitude swings during a posture transition **250** such as a sit-to-stand transition or a lay-sit transition. Transverse signal **261** may exhibit a negative amplitude swing during the posture transition **250**, and vertical signal **262** may exhibit moderate variation during the posture transition **250**. The posture transition may begin at approximately time **252** and end at approximately time **254**. The peak **266** of the sagittal acceleration signal **260** during posture transition is also illustrated.

**[0137]** FIG. **11** also illustrates a marker channel chart showing detected heart beats (e.g., depolarizations) before, during, and after posture transition **250**, which is an example of an exertion event. Intervals **270** (one of which is labeled for clarity) may indicate a time between beats, e.g., R-waves, and may be an R-R interval. Heart rate may be represented by or determined from, and is inversely proportional, to intervals **270**. Shorter intervals **170** may indicate a faster heart rate, and longer intervals **170** may indicate a slower heart rate.

**[0138]** Time period **272** may be a time during which an IMD can measure the physiological parameter before its response to the exertion event. Time period **272** may occur before or during the exertion event. The IMD may continually store data indicating the physiological parameter in a memory buffer. When the IMD detects an exertion event, such as at approximately time **250**, the IMD may move the data from time period **272** into data memory to preserve the data for comparison with data from time period **274**. Time period **274** may be a time during which an IMD can measure the response of the physiological parameter to the exertion event. Time period **274** may occur after or during the exertion event.

**[0139]** FIG. **11** depicts the heart rate during time period **274** as faster than the rate during time period **272**. An IMD and/or other device may determine the response to an exertion event, e.g., sit-to-stand transition or other postural transition, by determining the difference in heart rate between time period **274** and time period **272**. An excessive or inadequate increase in heart rate in response to a postural transition may indicate declining patient health.

**[0140]** For example, when a person stands up, baroreceptor reflexes are rapidly activated to restore arterial pressure so that mean arterial pressure is not reduced by more than a few mmHg when a person is standing compared to lying down. However, in order to maintain this normal mean arterial pressure, the person who is standing upright has increased systemic vascular resistance (sympathetic mediated), decreased venous compliance (due to sympathetic activation of veins), decreased stroke volume (due to decreased preload), and increased heart rate (baroreceptor-mediated tachycardia). Patients with autonomic nerve dysfunction or hypovolemia will not be able to effectively utilize these compensatory mechanisms and therefore will display orthostatic hypotension. Consequently, such patients may have relatively lower changes in heart rate and higher decreases in pressure in response to posture transitions.

**[0141]** On the other hand, postural tachycardia syndrome (POTS) is an excessive increase in heart rate on assuming an upright posture from an initial sitting posture. POTS is associated with symptoms of orthostatic intolerance and sympathetic over-activity. POTS may be associated with brain hypoperfusion, usually in the absence of hypotension. POTS is described in Wieling et al., "Testing for Autonomic Neuropathy: Heart Rate Changes After Orthostatic Manoeuvres and Static Muscle Contractions," Clinical Science (London), 64(6):581-6, 1983.

**[0142]** FIG. **12** is a flowchart illustrating an example technique **300** for determining whether a change in responses of a physiological parameter to an exertion event crosses a threshold, in accordance with this disclosure. Technique **300** may be implemented by any one of the implantable medical devices (IMDs) discussed above in connection with FIGS. **1-9**, because each one of the IMDs is configured to include at least one accelerometer (i.e., accelerometer circuitry), as well as communication and processing circuitry (see FIG. **7** and corresponding description) to facilitate determining patient movements. More generally, technique may be performed, at least in part, by processing circuitry of any IMD and/or other device described herein.

**[0143]** The technique of FIG. **12** includes monitoring, e.g., by processing circuitry, a signal that varies as a function of movement of a subject as well as one or more other signals that vary as a function of a physiological parameter (**302**). The processing circuitry may monitor first sensed signals that vary as a function of movement of the subject using accelerometers. The first sensed signals may indicate exertion events such as posture transitions. The processing circuitry may monitor second sensed signals that vary as a function of a physiological parameter such as heart rate or blood pressure. The processing circuitry may monitor the second sensed signals through electrodes and/or sensing circuitry.

**[0144]** The technique of FIG. **12** further includes detecting an exertion event based on the signals (**304**). The processing circuitry may detect an exertion event by analyzing the patterns, amplitude, and duration of the first sensed signals. If the processing circuitry does not detect an exertion event, the processing circuitry may continue to monitor signals. In order to improve the accuracy of the measurements, technique **300** may require that the subject has not been physically active for the previous thirty minutes before the exertion event. Physical activity during the previous thirty minutes may substantially alter the response of the physiological parameter to the exertion event. Technique **300** may define "physical activity" by using the first sensed signals from the accelerometers.

**[0145]** If the processing circuitry detects an exertion event, the technique of FIG. **12** further includes determining the response of the physiological parameter to the exertion event (**306**). The physiological parameter, such as heart rate, blood pressure, or respiration, may increase in response to, e.g., during or immediately after, the exertion event. The response may comprise a difference or percentage difference

in a measurement before the exertion event and a measurement after the exertion event. Technique **300** may comprise selecting a measurement before the exertion event with a minimum value and selecting a measurement during or after the exertion event with a maximum value.

**[0146]** The technique of FIG. **12** further includes determining whether a change in the responses over time crosses, e.g., exceeds and/or falls below, a threshold (**308**). The change in the responses over time may be a trend, or a difference and/or ratio between a measurement for a current exertion event and one or more prior measurements for one or more prior exertion events, e.g., a mean or median of prior measurements. The threshold may be a fixed value, or may vary over time. In some examples, the threshold may be determined based on one or more prior measurements, such that determining whether a change in response over time crosses a threshold comprises comparing a current response to a threshold determined based on prior responses.

**[0147]** If the IMD determines that a change in the responses crosses a threshold, the technique of FIG. **12** further includes generating an alert to a user (**310**). The alert may be an audible or visual alert, and may include an IMD transmitting a signal to an external device. The signal may indicate that the change in the responses crosses a threshold, along with pertinent details of the change in the responses.

**[0148]** FIG. **13** is a flowchart illustrating an example technique **320** for determining whether a change in heartbeat responses to a sit-to-stand transition crosses a specific threshold, in accordance with this disclosure. Technique **320** may be a specific example of technique **300**. Technique **320** may be implemented by any one of the implantable medical devices (IMDs) discussed above in connection with FIGS. **1-9**, because each one of the IMDs is configured to include at least one accelerometer (i.e., accelerometer circuitry), as well as communication and processing circuitry (see FIG. **7** and corresponding description) to facilitate determining patient movements. More generally, technique may be performed, at least in part, by processing circuitry of any IMD and/or other device described herein.

**[0149]** The technique of FIG. **13** includes monitoring one or more accelerometer signals and one or more cardiac electrogram signals (**322**). The accelerometer signal may indicate the movement of the subject. The accelerometer signal may comprise three signals from an accelerometer, such as sagittal, vertical, and transverse. The cardiac electrogram signal may indicate the heart rate of the subject.

**[0150]** The technique of FIG. **13** further includes detecting a sit-to-stand transition based on the accelerometer signal (**324**). Processing circuitry may detect a sit-stand transition by analyzing the patterns, amplitude, and duration of the accelerometer signal. If the processing circuitry does not detect a sit-to-stand transition, the processing circuitry may continue to monitor the accelerometer signal.

**[0151]** In some examples, to detect sit-to-stand transitions, processing circuitry identifies a baseline of an accelerometer signal, e.g., sagittal signal **260**. Identifying the baseline may include assigning a value of a current sample of the signal to value "0" by determining whether the current sample of the sagittal axis signal **1202** is within a certain number of units (e.g., 0.1 g) of baseline (e.g., 0 g) for at least a certain number (e.g., 15) of seconds. The processing circuitry also identifies the start **252** and end **254** of standing up by, for example, determining whether the amplitude of the accelerometer signal increases over a threshold (e.g. 0.2 g) and then decreases to less than the baseline within a certain time period (e.g. within 0.5 s-5 s). In some examples, processing circuitry also identifies a peak **266** of the accelerometer signal as a maximum value occurring between the start and end of the transition.

**[0152]** If the processing circuitry detects a sit-to-stand transition, the technique of FIG. **13** further includes determining the heart-rate response to the sit-to-stand transition (**326**). The heart rate of the subject may increase immediately after the sit-stand transition. The heart-rate response may comprise the difference between a heart rate during after the exertion event, e.g., a difference between a maximum heart rate during this period, and a heart rate before the exertion event.

**[0153]** The technique of FIG. **13** further includes determining whether a change in the heart-rate responses over time crosses a threshold (**328**). The change in the responses over time may be a trend, or a difference and/or ratio between heart rate response for a current sit-to-stand transition and one or more prior measurements for one or more prior exertion sit-to-stand transition, e.g., a mean or median of prior measurements. The threshold may be a fixed value, or may vary over time. In some examples, the threshold may be determined based on one or more prior measurements, such that determining whether a change in response over time crosses a threshold comprises comparing a current response to a threshold determined based on prior responses. For example, the threshold may be determined based on a mean or median of baseline or other prior sit-to-stand transition heart rate response measurements, modified by a value representative of an expected (predetermined and possibly programmed) or observed variability of the sit-to-stand transition heart rate response measurements.

**[0154]** In some examples, processing circuitry tracks median and variability (e.g., coefficient of variability (CV)) of sit-to-stand transition heart rate response measurements over time, and issues an alert of one of the sit-to-stand transition heart rate response measurements is an outlier. In some examples, the expected variability of sit-to-stand transition heart rate response measurements may be 15% to 40% increase in heart in response to the sit-to-stand transition. In some examples, the threshold range may have other percentage increase values, which may be determined based on observed variability. In some examples, a sit-to-stand transition heart rate change that is less than or falls below a lower threshold or threshold range bound, and/or that is greater than or exceeds an upper threshold or threshold range bound, is considered an outlier than crosses a threshold. The processing circuitry may generate an alert in response to the threshold being crossed.

**[0155]** If the IMD determines that the change in the heart-rate responses crosses the threshold, the technique of FIG. **13** further includes generating an alert to a user (**330**). The alert may be an audible or visual alert, or an IMD may transmit a signal to an external device. The signal may indicate that the change in the responses crosses a threshold, along with pertinent details of the change in the responses, such as the number of beats per minute by which each heart rate increase exceeded the threshold.

**[0156]** The flowcharts of FIGS. **12-13** are intended to illustrate the functional operation of an IMD **10**, external device **30**, medical system **8**, and other devices and systems described herein, and should not be construed as reflective of a specific form of software or hardware necessary to

practice the methods described. Methods described in conjunction with flow diagrams presented herein may be implemented in a non-transitory computer-readable medium that includes instructions for causing a programmable processor to carry out the methods described. A non-transitory computer-readable medium includes but is not limited to any volatile or non-volatile media, such as a RAM, ROM, CD-ROM, NVRAM, EEPROM, flash memory, or other computer-readable media, with the sole exception being a transitory, propagating signal. The instructions may be implemented by processing circuitry hardware as execution of one or more software modules, which may be executed by themselves or in combination with other software.

**[0157]** The example methods illustrated by FIGS. **12-13** may be performed, by any one or more devices described herein, and may be performed, in part, by processing circuitry of any one or more devices described herein, such as by processing circuitry **160** of IMD **10** (which may correspond to any of ICD **10**A, ICM **10**B, ICD **10**C, IPD **10**D, or any other IMD), processing circuitry **200** of external device **30**, processing circuitry **228** of server **224**.

**[0158]** Various aspects of the techniques may be implemented within one or more processors, including one or more microprocessors, DSPs, ASICs, FPGAs, or any other equivalent integrated or discrete logic circuitry, as well as any combinations of such components, embodied in programmers, such as physician or patient programmers, electrical stimulators, or other devices. The term "processor" or "processing circuitry" may generally refer to any of the foregoing logic circuitry, alone or in combination with other logic circuitry, or any other equivalent circuitry.

**[0159]** In one or more examples, the functions described in this disclosure may be implemented in hardware, software, firmware, or any combination thereof. If implemented in software, the functions may be stored on, as one or more instructions or code, a computer-readable medium and executed by a hardware-based processing unit. Computer-readable media may include computer-readable storage media forming a tangible, non-transitory medium. Instructions may be executed by one or more processors, such as one or more DSPs, ASICs, FPGAs, general purpose microprocessors, or other equivalent integrated or discrete logic circuitry. Accordingly, the term "processor," as used herein may refer to one or more of any of the foregoing structure or any other structure suitable for implementation of the techniques described herein.

**[0160]** In addition, in some aspects, the functionality described herein may be provided within dedicated hardware and/or software modules. Depiction of different features as modules or units is intended to highlight different functional aspects and does not necessarily imply that such modules or units must be realized by separate hardware or software components. Rather, functionality associated with one or more modules or units may be performed by separate hardware or software components, or integrated within common or separate hardware or software components. Also, the techniques could be fully implemented in one or more circuits or logic elements. The techniques of this disclosure may be implemented in a wide variety of devices or apparatuses, including an IMD, an external programmer, a combination of an IMD and external programmer, an integrated circuit (IC) or a set of ICs, and/or discrete electrical circuitry, residing in an IMD and/or external programmer.

Exemplary Embodiments

**[0161]** Embodiment 1 is a method for monitoring health of a subject based on a physiological response to physical exertion comprising, by processing circuitry of a medical device system:

**[0162]** detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject;

**[0163]** for each of the detected exertion events, determining a response of a physiological parameter of the subject to the exertion event based on second sensed signal that varies as a function of the physiological parameter;

**[0164]** determining a trend in the responses over time crosses a threshold; and

**[0165]** generating an alert to a user based on the determination that the trend crosses the threshold.

**[0166]** Embodiment 2 is the method of embodiment 1, further comprising determining the threshold based on at least one of a mean, a median, or a range of variability of the one or more previous responses of the physiological parameter to the exertion events.

**[0167]** Embodiment 3 is the method of embodiment 2, wherein the range of variability is based on a number of standard deviations from a mean or median of the one or more previous responses of the physiological parameter to the exertion events.

**[0168]** Embodiment 4 is the method of any of embodiments 1 to 3, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a common posture transition of the subject.

**[0169]** Embodiment 5 is the method of embodiment 4, wherein each of the posture transitions comprises a sit-stand transition.

**[0170]** Embodiment 6 is the method of any of embodiments 1 to 5, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a period of activity of the subject exceeding a threshold duration.

**[0171]** Embodiment 7 is the method of any one of embodiments 1 to 6, wherein the exertion event comprises a sit-stand transition, a stand-walk transition, or a walking after sitting.

**[0172]** Embodiment 8 is the method of any of embodiments 1 to 7, wherein the second sensed signal comprises a cardiac electrogram signal, and the physiological parameter comprises a heart rate.

**[0173]** Embodiment 9 is the method of any one of embodiments 1 to 8, wherein the physiological parameter comprises a blood pressure of the subject.

**[0174]** Embodiment 10 is the method of any one of embodiments 1 to 9, wherein generating the alert to the user comprises transmitting a signal to an external device indicating the trend in the responses over time crosses the threshold.

**[0175]** Embodiment 11 is a medical device system configured to monitor health of a subject based on a physiological response to physical exertion comprising:

**[0176]** sensing circuitry configured to:

**[0177]** generate a first sensed signal that varies as a function of movement of the subject; and

**[0178]** generate a second sensed signal that varies as a function of a physiological parameter of the subject;

**[0179]** processing circuitry configured to:

[0180] detect a plurality of exertion events of the subject based on the first sensed signal;

[0181] for each of the detected exertion events, determine a response of the physiological parameter of the subject to the exertion event based on the second sensed signal;

[0182] determine that a change in the responses over time crosses a threshold; and

[0183] generate an alert to a user in response to the determination that the change crosses the threshold.

[0184] Embodiment 12 is the medical device system of embodiment 11, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a common posture transition of the subject.

[0185] Embodiment 13 is the medical device system of embodiment 12, wherein each of the posture transitions comprises a sit-stand transition.

[0186] Embodiment 14 is the medical device system of any one of embodiments 11 to 13, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a period of activity of the subject exceeding a threshold duration.

[0187] Embodiment 15 is the medical device system of any one of embodiments 11 to 14, wherein the exertion event comprises a sit-stand transition, a stand-walk transition, or a walking after sitting.

[0188] Embodiment 16 is the medical device system of any one of embodiments 11 to 15, wherein the exertion event comprises standing after sitting, walking after standing still, or walking after sitting.

[0189] Embodiment 17 is the medical device system of any one of embodiments 11 to 16, wherein the second sensed signal comprises a cardiac electrogram signal, and the physiological parameter comprises a heart rate.

[0190] Embodiment 18 is the medical device system of any one of embodiments 11 to 17, wherein the physiological parameter comprises a blood pressure of the subject.

[0191] Embodiment 19 is the medical device system of any one of embodiments 11 to 18, wherein the processor is configured to generate the alert to the user by at least transmitting a signal to an external device indicating the change in the responses over time crosses the threshold.

[0192] Embodiment 20 is a non-transitory computer-readable storage medium comprising instructions, that when executed by processing circuitry of a medical device system, cause the medical device system to perform the method of any one of the above embodiments 1 to 10.

[0193] Embodiment 21 is a medical device system comprising means for performing the method of any one of embodiments 1 to 10.

[0194] Embodiment 22 is the method of any one of embodiments 1 to 10, wherein the response of the physiological parameter of the subject to the exertion event comprises a percentage change in the physiological parameter.

[0195] Embodiment 23 is the medical device system any one of embodiments 11 to 19, wherein the response of the physiological parameter of the subject to the exertion event comprises a percentage change in the physiological parameter.

[0196] Various aspects of this disclosure have been described. These and other aspects are within the scope of the following claims.

What is claimed is:

**1**. A method for monitoring health of a subject based on a physiological response to physical exertion comprising, by processing circuitry of a medical device system:

detecting a plurality of exertion events of the subject based on a first sensed signal that varies as a function of movement of the subject;

for each of the detected exertion events, determining a response of a physiological parameter of the subject to the exertion event based on second sensed signal that varies as a function of the physiological parameter;

determining that a change in the responses over time crosses a threshold; and

generating an alert to a user based on the determination that the change crosses the threshold.

**2**. The method of claim **1**, further comprising determining the threshold for a current response of the physiological parameter to the exertion event based on one or more previous responses of the physiological parameter to the exertion event.

**3**. The method of claim **2**, wherein determining the threshold comprises determining the threshold based on at least one of a mean, a median, or a range of variability of the one or more previous responses of the physiological parameter to the exertion events.

**4**. The method of claim **3**, wherein the range of variability is based on a number of standard deviations from a mean or median of the one or more previous responses of the physiological parameter to the exertion events.

**5**. The method of claim **1**, wherein each of the responses comprises a metric quantifying a change in the physiological parameter in response to a respective one of the exertion events.

**6**. The method of claim **1**, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a common posture transition of the subject.

**7**. The method of claim **6**, wherein each of the posture transitions comprises a sit-stand transition.

**8**. The method of claim **1**, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a period of activity of the subject exceeding a threshold duration.

**9**. The method of claim **1**, wherein the exertion event comprises a sit-stand transition, a stand-walk transition, or a walking after sitting.

**10**. The method of claim **1**, wherein the second sensed signal comprises a cardiac electrogram signal, and the physiological parameter comprises a heart rate.

**11**. The method of claim **1**, wherein the physiological parameter comprises a blood pressure of the subject.

**12**. The method of claim **1**, wherein generating the alert to the user comprises transmitting a signal to an external device indicating the change in the responses over time crosses the threshold.

**13**. A medical device system configured to monitor health of a subject based on a physiological response to physical exertion comprising:

sensing circuitry configured to:

generate a first sensed signal that varies as a function of movement of the subject; and

generate a second sensed signal that varies as a function of a physiological parameter of the subject;

processing circuitry configured to:

detect a plurality of exertion events of the subject based on the first sensed signal;

for each of the detected exertion events, determine a response of the physiological parameter of the subject to the exertion event based on the second sensed signal;

determine that a change in the responses over time crosses a threshold; and

generate an alert to a user in response to the determination that the change crosses the threshold.

**14**. The medical device system of claim **13**, further comprising a housing containing the sensing circuitry and the processing circuitry wherein the housing is configured for implantation in a human body.

**15**. The medical device system of claim **13**, further comprising a memory configured to store the threshold and data indicating the change in responses over time the baseline change.

**16**. The medical device system of claim **13**, wherein the processor is further configured to determine the threshold for a current response of the physiological parameter to the exertion event based on one or more previous responses of the physiological parameter to the exertion event.

**17**. The medical device system of claim **16**, wherein the processor is configured to determine the threshold by at least determining the threshold based on at least one of a mean, a median, or a range of variability of the one or more previous responses of the physiological parameter to the exertion events.

**18**. The medical device system of claim **17**, wherein the range of variability is based on a number of standard deviations from a mean or median of the one or more previous responses of the physiological parameter to the exertion events.

**19**. The medical device system claim **13**, wherein each of the responses comprises a metric quantifying a change in the physiological parameter in response to a respective one of the exertion events.

**20**. The medical device system of claim **13**, wherein the first sensed signal comprises an accelerometer signal, and each of the exertion events comprises a common posture transition of the subject.

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摘要(译)

描述了一种用于通过医疗设备系统的处理电路基于对体力消耗的生理反应来监测对象的健康状况的方法，该方法包括基于作为功能而变化的第一感测信号来检测对象的多个运动事件主体的运动。该方法还包括基于作为生理参数的函数而变化的第二感测信号来确定对于每个检测到的运动事件的运动事件的生理参数对运动事件的响应。该方法进一步包括确定响应随时间的变化超过阈值，并且基于确定变化跨越阈值来向用户生成警报。