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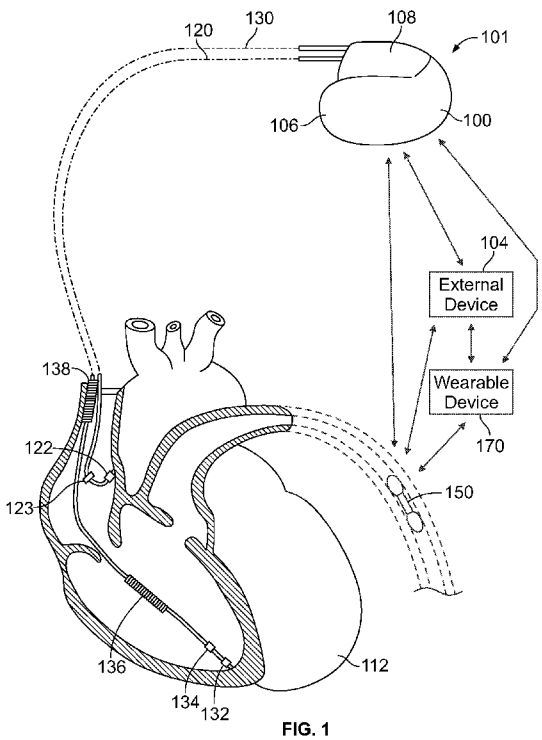

FIG. 1

(57) Abstract: System and method for determining valid heartbeats includes an external device and implantable pressure sensor (IPS) that senses pressure for a period of time and generates a pressure signal. The pressure signal is segmented into pseudo-systolic and pseudo-diastolic segments, and it is determined whether the pressure signal starts with one of the pseudo-systolic or pseudo-diastolic segments. In response to the pressure signal starting with a pseudo-diastolic segment, systolic content of at least one of the pseudo-systolic segments is modified based on diastolic content of at least one of the pseudo-diastolic segments. In response to the pressure signal starting with one of the pseudo-systolic segments, the systolic content of at least one of the pseudo-systolic segments is modified based on the systolic content of at least one of the pseudo-systolic segments, and valid heartbeats are determined based on the modified systolic content.

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SYSTEM AND METHOD FOR DIASTOLIC-ENHANCED SYSTOLIC PEAK DETECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States Provisional Application No. 63/596,402, titled "SYSTEM AND METHOD FOR DIASTOLIC-ENHANCED SYSTOLIC PEAK DETECTION" which was filed on 06-November-2023, the complete subject matter of which is expressly incorporated herein by reference in its entirety

BACKGROUND

[0002] Embodiments of the present disclosure generally relate to implantable medical devices and methods, and more particularly to identifying valid heartbeats of a patient.

[0003] Heartbeat detection is vital for diagnosing and treating various cardiovascular diseases, such as arrhythmias and heart failure. It is also important for accurately calculating heart rate variability (HRV) and cardiac output. Therefore, it is important to develop and use reliable and precise methods for heartbeat detection in different settings and scenarios.

[0004] In some cases, cardiac data can be acquired using an implantable medical device, such as a pressure sensor, that is implanted in the distal pulmonary artery and used in the treatment of heart failure patients. One example of an implantable pressure sensor is a passive pulmonary arterial (PA) pressure sensor, or passive PAP sensor. In general, a patient actively participates, such as daily or other periodic time period, to collect the physiologically relevant data and to make the data available to a clinician. For example, passive PA pressure sensors utilize an external device, outside of the patient body, for supplying energy to the sensors to power the generation and communication of the physiological data. The data may also be collected from the passive PAP sensor while the

patient is in a clinical setting. The physiologic data provides information about the hemodynamic status of the patient and helps guide their treatment.

[0005] Unfortunately, peak detection algorithms can overestimate the heart rate when the signal data includes respiratory variations, arrythmia and/or noise that can make the signal appear to include more systolic peaks than are actually present. For example, a signal transmitted wirelessly may include electronic noise, and interference can distort the signal or make it non-physiologic.

[0006] A need remains for a system and method to accurately detect normal or valid heartbeats in cardiac data while rejecting abnormal or invalid heartbeats that may introduce errors in heart rate calculations.

SUMMARY

[0007] In accordance with embodiments herein, a system for determining valid heartbeats comprises an external device and an implantable pressure sensor (IPS). The IPS comprises an IPS sensing circuit configured to sense pressure for a period of time and to generate a pressure signal based on the pressure. The IPS also includes an IPS communications circuit configured to communicate with the external device. At least one of the IPS or external device further comprises memory configured to store program instructions and one or more processors that, when executing the program instructions, are configured to segment the pressure signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length. The one or more processors determine whether the pressure signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments. In response to the pressure signal starting with one of the pseudo-diastolic segments, the one or more processors modify systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments. In response to the pressure signal starting with one of the pseudo-systolic segments, the one or

more processors modify the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments, and determine valid heartbeats based on the modified systolic content.

[0008] Optionally, the one or more processors of the system further modify the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segments. Optionally, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or more processors of the system further modify the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the at least one of the pseudo-diastolic segments. Optionally, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or more processors of the system further modify the systolic content of a first pseudo-systolic segment based on the systolic content of the first pseudo-systolic segment.

[0009] Optionally, wherein the one or more processors of the system are further configured to remove linear trends and non-linear trends from the pressure signal. Optionally, wherein the one or more processors of the system are further configured to, when segmenting the pressure signal, identify the pseudo-systolic segments based on values of the pressure signal satisfying a threshold, and identify the pseudo-diastolic segments based on the values of the pressure signal not satisfying the threshold. Optionally, wherein, in response to the pressure signal starting with one of the pseudo-diastolic segments, the one or more processors of the system are further configured to modify the systolic content of the at least one of the pseudo-systolic segments by multiplying values in the at least one of the pseudo-systolic segment with integrals of the at least one of the pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment. Optionally, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or

more processors of the system are further configured to modify the systolic content of a first pseudo-systolic segment by multiplying values in the first pseudo-systolic segment with an integral of the first pseudo-systolic segment, and modify the systolic content of at least one of the pseudo-systolic segments following the first pseudo-systolic segment by multiplying values in the at least one of the pseudo-systolic segments with integrals of a same one of the at least one pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment.

[0010] Optionally, the one or more processors of the system are further configured to determine a maximum systolic peak value for at least one of the pseudo-systolic segments, and determine a score associated with the maximum systolic peak value, the score based on i) the maximum systolic peak value, ii) integrals of the pseudo-systolic segment associated with the maximum systolic peak value, iii) integrals of the pseudo-diastolic segment associated with the pseudo-diastolic segment immediately preceding the pseudo-systolic segment associated with the maximum systolic peak value, or iv) cardiac cycle duration, wherein the valid heartbeats are further identified based on the score. Optionally, wherein the one or more processors of the system further identify valid heartbeats i) when the score satisfies a constant value, ii) when the score satisfies a dynamic threshold, iii) when the score satisfies a dynamic threshold based on non-zero values of the pseudo-systolic segments within the period of time, or iv) based on an outlier detection method.

[0011] Optionally, the system further comprises an implantable medical device comprising an IMD communications circuit configured to communicate with at least one of the IPS or the external device, memory configured to store the program instructions, and one or more processors that are configured to execute the program instructions.

[0012] In accordance with embodiments herein, a computer implemented method for determining valid heartbeats comprises sensing pressure for a period

of time at an implantable pressure sensor (IPS), generating a pressure signal based on the pressure, and, under control of one or more processors configured with executable instructions, segmenting the pressure signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length, and determining whether the pressure signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments. The method further comprises, in response to the pressure signal starting with one of the pseudo-diastolic segments, modifying systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments, in response to the pressure signal starting with one of the pseudo-systolic segments, modifying the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments, and determining valid heartbeats based on the modified systolic content.

[0013] Optionally, the method further comprises determining a score associated with the maximum systolic peak value, the score based on i) the maximum systolic peak value, ii) integrals of the pseudo-systolic segment associated with the maximum systolic peak value, iii) integrals of the pseudo-diastolic segment associated with the pseudo-diastolic segment immediately preceding the pseudo-systolic segment associated with the maximum systolic peak value, or iv) cardiac cycle duration, wherein the valid heartbeats are further identified based on the score. Optionally, the method further comprises modifying the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segments. Optionally, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the method further comprises modifying the systolic content of the at least one of the pseudo-

systolic segments based on the diastolic content of the at least one of the pseudo-diastolic segments.

[0014] Optionally, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the method further comprises modifying the systolic content of a first pseudo-systolic segment based on the systolic content of the first pseudo-systolic segment. Optionally, the method further comprises displaying at least one of a heart rate based on the valid heartbeats, cardiac output based on the valid heartbeats, a treatment notification, or a treatment recommendation. Optionally, the method further comprises transmitting, with a communications circuit associated with the IPS, at least one of the pressure signal, an indication of the valid heartbeats, a treatment notification based on the valid heartbeats, or a treatment recommendation based on the valid heartbeats.

[0015] In accordance with embodiments herein, a computer implemented method for determining valid heartbeats comprises sensing a periodic signal associated with cardiac function for a period of time at a sensor and generating a signal based on the periodic signal. The method further comprises, under control of one or more processors configured with executable instructions, segmenting the signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length, determining whether the signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments, in response to the signal starting with one of the pseudo-diastolic segments, modifying systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments, in response to the signal starting with one of the pseudo-systolic segments, modifying the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments, and determining valid heartbeats based on the modified systolic content.

[0016] Optionally, wherein the sensor of the method is i) positioned outside a body associated with the cardiac function, ii) in contact with skin of the body associated with the cardiac function, or iii) partially or entirely external to the skin of the body associated with the cardiac function.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 illustrates a system that includes an implantable medical device (IMD), an implantable pressure sensor (IPS), and an external device implemented in accordance with embodiments herein.

[0018] Figure 2 illustrates a block diagram of the system formed in accordance with embodiments herein, showing some components of the IPS, IMD, external device, and wearable device.

[0019] Figures 3A and 3B illustrate a computer-implemented method for implementing a diastolic-enhanced systolic peak detection algorithm for detecting valid systolic peaks in cardiac signals in accordance with embodiments herein.

[0020] Figure 4A shows a graph of a pulmonary pressure waveform based on a pressure signal that has been acquired by the IPS over time in accordance with embodiments herein.

[0021] Figure 4B shows a graph of a linear detrended waveform, based on the pressure waveform of Figure 4A, in accordance with embodiments herein.

[0022] Figure 4C shows a graph of a filtered waveform based on the pressure signal sensed for the period of time in accordance with embodiments herein.

[0023] Figure 4D shows a graph that combines and displays the pseudo-systolic segments and pseudo-diastolic segments identified in the signal of Figure 4C using positive values in accordance with embodiments herein.

[0024] Figure 5A shows a graph of segmented beats in accordance with embodiments herein.

[0025] Figure 5B shows a graph of enhanced or modified pseudo-systolic segments ($P_{enhanced\ systolic}$) in accordance with embodiments herein.

[0026] Figure 6A shows a graph of variability of pulse pressures over a period of time of a pressure sensor, and illustrates a comparison between systolic peaks identified using a previous peak detection algorithm and systolic peaks identified using the diastolic-enhanced systolic peak (DESP) detection algorithm in accordance with embodiments herein.

[0027] Figure 6B shows a graph of enhanced or modified systole with beat score values for each peak as determined by the diastolic-enhanced systolic peak detection algorithm in accordance with embodiments herein.

[0028] Figure 7 shows an example block diagram of the IMD formed in accordance with embodiments herein.

[0029] Figure 8 illustrates a digital healthcare system implemented in accordance with embodiments herein.

DETAILED DESCRIPTION

[0030] It will be readily understood that the components of the embodiments as generally described and illustrated in the figures herein, may be arranged and designed in a wide variety of different configurations in addition to the described example embodiments. Thus, the following more detailed description of the example embodiments, as represented in the figures, is not intended to limit the scope of the embodiments, as claimed, but is merely representative of example embodiments.

[0031] Reference throughout this specification to “one embodiment” or “an embodiment” (or the like) means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in one embodiment” or “in an embodiment” or the like in various places throughout this specification are not necessarily all referring to the same embodiment.

[0032] Furthermore, the described features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. In the following description, numerous specific details are provided to give a thorough understanding of embodiments. One skilled in the relevant art will recognize, however, that the various embodiments can be practiced without one or more of the specific details, or with other methods, components, materials, etc. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obfuscation. The following description is intended only by way of example, and simply illustrates certain example embodiments.

[0033] The methods described herein may employ structures or aspects of various embodiments (e.g., systems and/or methods) discussed herein. In various embodiments, certain operations may be omitted or added, certain operations may be combined, certain operations may be performed simultaneously, certain operations may be performed concurrently, certain operations may be split into multiple operations, certain operations may be performed in a different order, or certain operations or series of operations may be re-performed in an iterative fashion. It should be noted that, other methods may be used, in accordance with an embodiment herein. Further, wherein indicated, the methods may be fully or partially implemented by one or more processors of one or more devices or systems. While the operations of some methods may be described as performed by the processor(s) of one device, additionally, some or all of such operations may be performed by the processor(s) of another device described herein.

[0034] Embodiments may be implemented in connection with one or more implantable medical devices (IMDs). Non-limiting examples of IMDs include one or more of implantable leadless monitoring and/or therapy devices, and/or alternative implantable medical devices. For example, the IMD may represent a cardiac monitoring device, cardioverter defibrillator, pacemaker, cardiac rhythm management device, leadless pacemaker, leadless implantable medical device (LIMD), and the like.

[0035] Additionally or alternatively, the IMD may be a subcutaneous IMD that includes one or more structural and/or functional aspects of the device(s) described in U.S. Patent 10,765,860, titled "Subcutaneous Implantation Medical Device With Multiple Parasternal-Anterior Electrodes"; U.S. Patent 10,722,704, titled "Implantable Medical Systems And Methods Including Pulse Generators And Leads"; US Patent 11,045,643, titled "Single Site Implantation Methods For Medical Devices Having Multiple Leads", which are hereby incorporated by reference in their entireties. Further, one or more combinations of IMDs may be utilized from the incorporated patents and applications identified herein in accordance with embodiments herein.

[0036] In accordance with embodiments herein, the methods, devices, and systems may be implemented in connection with the systems and methods described in U.S. published application US20210020294A1, titled "METHODS DEVICE AND SYSTEMS FOR HOLISTIC INTEGRATED HEALTHCARE PATIENT MANAGEMENT" filed July 16, 2020, and U.S. patent application 18/325,147, filed on May 30, 2023, titled "System and Method for Inter-Device Arrhythmia Detection and Confirmation", which are incorporated herein by reference in their entirety. In accordance with embodiments herein, the methods, devices, and systems may be implemented in connection with the communications systems and methods described in U.S. patent application 17/820,654, filed on August 18, 2022, titled "System and Method for Intra-Body Communication of Sensed Physiologic Data", which is incorporated herein by reference in its entirety. In accordance with embodiments herein, the methods, devices, and systems may be implemented in connection with those described in US patent 11,559,241, filed on October 01, 2019, titled "Methods and Systems for Reducing False Declarations of Arrythmias", which is incorporated herein by reference in its entirety.

[0037] All references, including publications, patent applications and patents, cited herein are hereby incorporated by reference to the same extent as

if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

Terms

[0038] The terms "valid" and "normal" are used interchangeably to refer to events, features, and characteristics of, or appropriate to, a healthy functioning of the heart.

[0039] The terms "invalid", "abnormal", "arrhythmic", and "arrhythmia" are used interchangeably to refer to events, features, and characteristics of, or appropriate to, an unhealthy functioning of the heart.

[0040] The term "systolic content" shall mean content of a periodic signal that is indicative of a systolic portion of a potential heartbeat, and can include amplitude measurements over a period of time.

[0041] The term "diastolic content" shall mean content of a periodic signal that is indicative of a diastolic portion of a potential heartbeat, and can include amplitude measurements over a period of time.

[0042] The terms "cardiac activity signal", "cardiac activity signals", "CA signal" and "CA signals" (collectively "CA signals") are used interchangeably throughout to refer to measured signals indicative of cardiac activity by a region or chamber of interest. For example, the CA signals may be indicative of impedance, electrical or mechanical activity by one or more chambers (e.g., left or right ventricle, left or right atrium) of the heart and/or by a local region within the heart (e.g., impedance, electrical or mechanical activity at the AV node, along the septal wall, within the left or right bundle branch, within the purkinje fibers). The cardiac activity may be normal/healthy or abnormal/arrhythmic. An example of CA signals includes electrogram (EGM) signals. Electrical based CA signals refer to an analog or digital electrical signal recorded by two or more electrodes, where the electrical signals are indicative of cardiac activity. Heart sound (HS) based CA signals refer to signals output by a heart sound sensor such as an accelerometer, where the HS based CA signals are indicative of one or more of the S1, S2, S3 and/or S4

heart sounds. Impedance based CA signals refer to impedance measurements recorded along an impedance vector between two or more electrodes, where the impedance measurements are indicative of cardiac activity.

[0043] The term "PA" shall mean pulmonary artery. The term "PAP" shall mean pulmonary arterial pressure.

[0044] The term "pressure signal" shall refer to measured signals indicative of blood flow pressure within the body. One nonlimiting example is pulmonary arterial pressure that is measured within the pulmonary artery.

[0045] The term "signal" shall mean pressure signal, pulmonary signal, physiological signal, hemodynamic signal, periodic signal, arterial line signal, capillary blood flow signal, blood flow signal based on a sensed hemodynamic signal, and/or blood flow signal based on a sensed physiological signal.

[0046] The terms "pseudo-systolic" and "pseudo-diastolic" shall refer to waveforms based on signals that have undergone some level of signal processing and are representative of potential systolic segments and potential diastolic segments, respectively, of a heartbeat.

[0047] The term "POC" shall mean point-of-care. The terms "point-of-care" and "POC", when used in connection with medical diagnostic testing, shall mean methods and devices configured to provide medical diagnostic testing at or near a time and place of patient care. The time and place of patient care may be at an individual's home, such as when providing "at home" point of care solutions. The time and place of patient care may be at a physician's office or other medical facility, wherein one or more medical diagnostic tests may be performed on-site at a time of or shortly after a patient visit and collection of a patient sample. The POC may implement the methods, devices and systems described in one or more of the following publications, all of which are expressly incorporated herein by reference in their entireties: U.S. Patent Number 6,786,874, titled "APPARATUS AND METHOD FOR THE COLLECTION OF INTERSTITIAL FLUIDS" issued September 7, 2004; U.S. Patent Number 9,494,578, titled "SPATIAL

ORIENTATION DETERMINATION IN PORTABLE CLINICAL ANALYSIS SYSTEMS" issued November 15, 2016; and U.S. Patent Number 9,872,641, titled "METHODS, DEVICES AND SYSTEMS RELATED TO ANALYTE MONITORING" issued January 23, 2018.

[0048] The term "obtains", "obtaining", "collect", and "collecting", as used in connection with data, signals, information and the like, can be used interchangeably herein and include at least one of i) accessing memory of an external device or remote server where the data, signals, information, etc., are stored, ii) receiving the data, signals, information, etc., over a wireless communications link between the IMD and a local external device, and/or iii) receiving the data, signals, information, etc., at a remote server over a network connection. The obtaining operation, when from the perspective of an IMD and/or implantable sensor, may include sensing new signals in real-time, and/or accessing memory to read stored data, signals, information, etc., from memory within the IMD. The obtaining operation, when from the perspective of a local external device, includes receiving the data, signals, information, etc., at a transceiver of the local external device where the data, signals, information, etc., are transmitted from an IMD and/or a remote server. The obtaining operation may be from the perspective of a remote server, such as when receiving the data, signals, information, etc., at a network interface from a local external device and/or directly from an IMD. The remote server may also obtain the data, signals, information, etc., from local memory and/or from other memory, such as within a cloud storage environment and/or from the memory of a workstation or clinician external programmer. The IMD and implantable sensor may also obtain data, signals, and information from each other in response to a request or a triggering event.

[0049] The terms "processor," "a processor", "one or more processors" and "the processor" shall mean one or more processors. The one or more processors may be implemented by one, or by a combination of more than one implantable

medical device, a semi-implantable medical device, a wearable device, a local device, a remote device, a server computing device, a network of server computing devices and the like. The one or more processors may be implemented at a common location or at distributed locations. The one or more processors may implement the various operations described herein in a serial or parallel manner, in a shared-resource configuration and the like.

[0050] The term "health care system" refers to a system that includes equipment for measuring health parameters, and communication pathways from the equipment to secondary devices. The secondary devices may be at the same location as the equipment, or remote from the equipment at a different location. The communication pathways may be internal within the patient, wired, wireless, over the air, cellular, in the cloud, etc. In one example, the healthcare system provided may be one of the systems described in U.S. published application US20210020294A1, titled "METHODS DEVICE AND SYSTEMS FOR HOLISTIC INTEGRATED HEALTHCARE PATIENT MANAGEMENT" filed July 16, 2020, which is incorporated herein by reference in its entirety. Other patents that describe example monitoring systems include U.S. Pat. No. 6,572,557; titled SYSTEM AND METHOD FOR MONITORING PROGRESSION OF CARDIAC DISEASE STATE USING PHYSIOLOGIC SENSORS, filed Dec. 21, 2000; U.S. Pat. No. 6,480,733 titled METHOD FOR MONITORING HEART FAILURE filed Dec. 17, 1999; U.S. Pat. No. 7,272,443 titled SYSTEM AND METHOD FOR PREDICTING A HEART CONDITION BASED ON IMPEDANCE VALUES USING AN IMPLANTABLE MEDICAL DEVICE, filed Dec. 14, 2004; U.S. Pat. No. 7,308,309 titled DIAGNOSING CARDIAC HEALTH UTILIZING PARAMETER TREND ANALYSIS, filed Jan. 11, 2005; and U.S. Pat. No. 6,645,153 titled SYSTEM AND METHOD FOR EVALUATING RISK OF MORTALITY DUE TO CONGESTIVE HEART FAILURE USING PHYSIOLOGIC SENSORS, filed Feb. 7, 2002, the entire contents of which are incorporated in full herein by reference.

[0051] The term "real-time" shall mean a time frame contemporaneous with normal or abnormal episode occurrences. For example, a real-time process or operation would occur during or immediately after (e.g., within seconds after) a cardiac event, a series of cardiac events, an arrhythmia episode, and the like. For example, the term "real-time" may refer to a time period substantially contemporaneous with an event of interest. The term "real-time," when used in connection with collecting and/or processing data utilizing an IMD or IPS, shall refer to processing operations performed substantially contemporaneous with a physiologic event of interest experienced by a patient. By way of example, in accordance with embodiments herein, pressure and/or cardiac activity signals can be analyzed in real-time (e.g., during a cardiac event or within a few minutes after the cardiac event).

[0052] The term "on-demand" shall mean at any time that the system automatically determines that a measurement is warranted and without any need for patient action or intervention. As one example, an implantable sensor will collect pressure measurements "on-demand" automatically and in real-time in response to a data collection instruction from an IMD. As another example, an implantable sensor will collect pressure measurements "on-demand" automatically and in real-time in response to a data collection instruction from an external device such as a bedside monitor, smart phone, physician's programmer and the like. As another example, an implantable sensor will collect pressure measurements "on-demand" automatically and in real-time in response to a data collection schedule stored at the sensor, IMD or external device.

[0053] Embodiments may be implemented in connection with one or more implantable medical devices (IMDs). Non-limiting examples of IMDs include one or more of neurostimulator devices, implantable leadless monitoring and/or therapy devices, and/or alternative implantable medical devices. For example, the IMD may represent a cardiac monitoring device, pacemaker, cardioverter, cardiac rhythm management device, defibrillator, neurostimulator, leadless monitoring

device, leadless pacemaker and the like. For example, the IMD may include one or more structural and/or functional aspects of the device(s) described in U.S. Patent 9,333,351 "Neurostimulation Method And System To Treat Apnea" and U.S. Patent 9,044,610 "System And Methods For Providing A Distributed Virtual Stimulation Cathode For Use With An Implantable Neurostimulation System", which are hereby incorporated by reference.

[0054] Additionally or alternatively, the IMD may be a leadless implantable medical device (LIMD) that includes one or more structural and/or functional aspects of the device(s) described in U.S. Patent 9,216,285 "Leadless Implantable Medical Device Having Removable And Fixed Components" and U.S. Patent 8,831,747 "Leadless Neurostimulation Device And Method Including The Same", which are hereby incorporated by reference. Additionally or alternatively, the IMD may include one or more structural and/or functional aspects of the device(s) described in U.S. Patent 8,391,980 "Method And System For Identifying A Potential Lead Failure In An Implantable Medical Device" and U.S. Patent 9,232,485 "System And Method For Selectively Communicating With An Implantable Medical Device", which are hereby incorporated by reference in their entireties.

[0055] Additionally or alternatively, the IMD may be a subcutaneous IMD that includes one or more structural and/or functional aspects of the device(s) described in U.S. Patent Number 10,765,860, titled "Subcutaneous Implantation Medical Device With Multiple Parasternal-Anterior Electrodes" issued September 08, 2020; U.S. Patent Number 10,722,704, titled "Implantable Medical Systems And Methods Including Pulse Generators And Leads" issued July 28, 2020; and U.S. Patent Number 11,045,643, titled "Single Site Implantation Methods For Medical Devices Having Multiple Leads", issued June 29, 2021, which are hereby incorporated by reference in their entireties. Further, one or more combinations of IMDs may be utilized from the above incorporated patents and applications in accordance with embodiments herein.

[0056] Additionally or alternatively, the IMD may be a leadless cardiac monitor (ICM) that includes one or more structural and/or functional aspects of the device(s) described in U.S. Patent 9,949,660, titled "METHOD AND SYSTEM TO DISCRIMINATE RHYTHM PATTERNS IN CARDIAC ACTIVITY" issued April 24, 2018, which is expressly incorporated herein by reference in its entirety.

[0057] The implantable medical sensor disclosed herein may implement one or more structural and/or functional aspects of the device(s) described in U.S. patent 11,033,192, issued June 15, 2021, and titled "Wireless Sensor for Measuring Pressure;" U.S. patent 10,143,388, filed Jun. 8, 2015, titled "Method of Manufacturing Implantable Wireless Sensor for In Vivo Pressure Measurement"; U.S. patent 9,078,563, filed Nov. 4, 2009, titled "Method of Manufacturing Implantable Wireless Sensor for In Vivo Pressure Measurement"; U.S. patent 7,621,036, filed on Aug. 16, 2005, titled "Method of Manufacturing Implantable Wireless Sensor for In Vivo Pressure Measurement"; and U.S. published patent application 2006/0287602, Ser. No. 11/157,375, filed Jun. 21, 2005, titled "Implantable Wireless Sensor for In Vivo Pressure Measurement," which are expressly incorporated herein by reference in their entireties.

[0058] Embodiments may be implemented in connection with one or more PIMDs. Non-limiting examples of PIMDs may include passive wireless sensors used by themselves, or incorporated into or used in conjunction with other implantable medical devices (IMDs) such as cardiac monitoring devices, pacemakers, cardioverters, cardiac rhythm management devices, defibrillators, neurostimulators, leadless monitoring devices, leadless pacemakers, replacement valves, shunts, grafts, drug elution devices, blood glucose monitoring systems, orthopedic implants, and the like. For example, the PIMD may include one or more structural and/or functional aspects of the device(s) described in U.S. Patent No. 9,265,428 titled "Implantable Wireless Sensor", U.S. Patent No. 8,278,941 titled "Strain Monitoring System and Apparatus", U.S. Patent No. 8,026,729 titled "System and Apparatus for In-Vivo Assessment of Relative Position of an Implant",

U.S. Patent No. 8,870,787 titled "Ventricular Shunt System and Method", and U.S. Patent No. 9,653,926 titled "Physical Property Sensor with Active Electronic Circuit and Wireless Power and Data Transmission", which are all hereby incorporated by reference in their respective entireties.

[0059] The term "treatment notification" shall mean a communication and/or device command to be conveyed to one or more individuals and/or one or more other electronic devices, including but not limited to, network servers, workstations, laptop computers, tablet devices, smart phones, IMDs, electronic dispensing tool (EDT) equipment and the like. When a treatment notification is provided as a communication, the treatment notification may represent in an audio, video, vibratory or other user perceivable medium. The communication may be presented in various formats, such as to display patient information, messages, user directions and the like. The communication is presented on one or more of the various types of electronic devices described herein and may be directed to a patient, a physician, various medical personnel, various patient record management personnel and the like. The communication may represent an identification of a patient diagnosis and various treatment recommendations. The diagnosis and treatment recommendation may be provided directly to the patient. For example, in some circumstances, a diagnosis and treatment recommendation may be to modify a dosage level, in which case, the notification may be provided to the physician or medical practitioner. As another example, the diagnosis and treatment recommendation may be to begin, change or end certain physical activities, in which case, the notification may be provided to the patient, in addition to the physician or medical practitioner. As another example, the treatment notification may present an indication that a patient may or may not be a good candidate suited for implant of a ventricular assist device (e.g., LV assist device), a transplant, a valve repair procedure (e.g., a MitraClip™ valve repair to correct mitral regurgitation) and the like. Other nonlimiting examples of a communication type notification include, in part or in whole, a recommendation to schedule an

appointment with a physician, schedule an appointment for additional blood work, perform an additional at home POC blood analysis (e.g., utilizing at home EDT equipment), recommend that the patient collect additional EDT and/or IMD data. When a notification includes an action that may be performed by a patient alone, the notification may be communicated directly to the patient. Other nonlimiting examples of a communication type notification include communications sent to a patient via an electronic device, where the communication informs the patient of how a patient's lifestyle choices are directly affecting the patient's health. For example, when a patient consumes too much sugar, a notification may be sent to the patient to inform that the excessive sugar has caused a spike in the patient's glucose level. As another example, when a patient avoids exercise for a period of time, the notification may inform a patient that the patient's lack of exercise has raised a PAP trend and/or introduced an undue burden on a patient's kidneys.

[0060] When a treatment notification is provided as a device command, the treatment notification may represent an electronic command directing a computing device (e.g., IMD, EDT equipment, local external device, server) to perform an action. For example, the action may include directing the following:

1. IMD or EDT equipment to provide additional IMD data and/or EDT data already available;
2. IMD or EDT equipment to collect additional data and/or another type of data;
3. IMD to deliver a therapy and/or modify a prior therapy (e.g., a pacing therapy, neural stimulation therapy, appetite suppression therapy, drug delivery rate);
4. Local external device to provide additional information regarding past and present behavior of the patient; and
5. Server to analyze further information in the patient medical record and/or from another medical record.

[0061] The term "treatment recommendation" shall mean a recommendation for the patient, medical personnel and/or a device (e.g., an IMD, local external device, remote server, or BGA device) to take an action and/or maintain a current course of action. Non-limiting examples of treatment recommendations include dispatching an ambulance to the patient's location, instructing the patient immediately go to a hospital, instructing the patient schedule an appointment, instructing the patient change a prescription, instructing the patient undergo additional examinations (e.g., diagnostic imaging examinations, exploratory surgery and the like), instructing the patient undergo a POC test to collect new BGA data, instructing the patient take a nutritional supplement, instructing the patient start, stop or change a physical activity, or instructing the patient make no changes. The treatment recommendation may include an instruction to change, maintain, add or stop a therapy delivered by an active IMD, such as a pacing therapy, and ATP pacing therapy, a neural stimulation therapy, mechanical circulatory support and the like.

System Overview

[0062] In accordance with new and unique aspects herein, methods and devices are described that determine valid heartbeats of a patient based on a physiological signal such as pressure signals sensed, collected, and/or generated by an implantable pressure sensor. In some cases, a patient's heartbeat can be determined using periodic signals (e.g., any hemodynamic signal such as arterial line, venous blood pressure, other sensed blood pressure or blood flow signal, any physiologic signal indicative of blood pressure) sensed or obtained by a different IMD than a pressure sensor, while in other cases the patient's heartbeat can be determined using periodic signals sensed or obtained by a device outside the patient's body, such as a wearable device having a sensor that detects a periodic signal associated with cardiac function (e.g., smartwatch, optical sensor, ECG sensor), "smart" apparel, Holter monitor, transducer(s), electrode(s), and/or

circuitry affixed to the patient with adhesive, gel, pressure, etc. The methods and devices can preprocess and filter the signal and identify pseudo-systolic and pseudo-diastolic segments. The methods and devices modify at least one of the pseudo-systolic segments based on the pseudo-systolic segment and/or a previous diastolic segment. In some embodiments, all of the pseudo-systolic segments within a period of time are modified. Scores for the modified pseudo-systolic segments are determined, and the scores of the pseudo-systolic segments are compared to a threshold or evaluated using an outlier algorithm. In some embodiments, the threshold can be variable. Pseudo-systolic segments that meet, satisfy, or exceed the threshold, or meet or satisfy criteria of an outlier algorithm are declared valid heartbeats.

[0063] The methods and devices determine the heart rate accurately in signals that include noise and/or arrhythmia. Therefore, a technical advantage is realized as an accurate heart rate is important both for accessing the immediate status of the patient, as well as to provide accurate data input that is used by other algorithms to assess the patient, treat the patient, modify treatment of the patient, provide a treatment notification, provide a treatment recommendation, select an appropriate therapy for the patient, reprogram a device such as an implantable medical device, implantable sensor, implantable pressure sensor, external device, etc., and/or display information and/or recommendations related to the valid heartbeats.

[0064] Figure 1 illustrates a system 101 that includes an implantable medical device (IMD) 100, an implantable pressure sensor (IPS) 150, and an external device 104 implemented in accordance with embodiments herein. The IMD 100 and the IPS 150 are implanted within the body of a patient. The external device 104 is outside of the patient body. The external device 104 may be a programmer, an external defibrillator, a workstation, a portable computer (e.g., laptop or tablet computer), a personal digital assistant, a cell phone (e.g., smartphone), a bedside monitor, a remote care server, a wearable device (e.g.,

smart watch), EKG leads, and the like. The IMD 100 may represent a cardiac monitoring device, a pacemaker, a cardioverter, a cardiac rhythm management device, a defibrillator, a neurostimulator, a leadless monitoring device, a leadless pacemaker, and the like, implemented in accordance with embodiments herein. The IMD 100 may be a dual-chamber stimulation device capable of treating both fast and slow arrhythmias with stimulation therapy, including cardioversion, defibrillation, anti-tachycardia pacing and pacing stimulation, as well as capable of detecting heart failure, evaluating its severity, tracking the progression thereof, and controlling the delivery of therapy and warnings in response thereto.

[0065] In some embodiments, the system 101 can include the IMD 100 and/or the IPS 150 that acquire the periodic signals indicative of heart rate and/or pressure signals indicative of heart rate. In still other embodiments, the system 101 can include one or more wearable device 170 that is not fully implanted within the patient. The wearable device 170 may be partially or entirely external to the skin of the patient, including one or more device such as a smartwatch, EKG leads, Holter monitor, and smart apparel that acquire periodic signals indicative of hemodynamic function. The wearable device 170 can communicate with one or more of the IMD 100, IPS 150, the external device 104, and other remote computing device/system.

[0066] The IMD 100 includes a housing 106 that is joined to a header assembly 108 that holds receptacle connectors connected to a right ventricular lead 130 and an atrial lead 120, respectively. The atrial lead 120 includes a tip electrode 122 and a ring electrode 123. The right ventricular lead 130 includes an RV tip electrode 132, an RV ring electrode 134, an RV coil electrode 136, and an SVC coil electrode 138. The leads 120 and 130 detect intracardiac electrogram (IEGM) signals that are processed and analyzed as described herein, such as to determine valid heartbeats. The IMD 100 includes one or more processors that can process the IEGM signals and/or pressure signals acquired by the IPS 150.

[0067] The IMD 100 may be implemented as a full-function biventricular pacemaker, equipped with both atrial and ventricular sensing and pacing circuitry for four chamber sensing and stimulation therapy (including both pacing and shock treatment). Optionally, the IMD 100 may further include a coronary sinus lead with left ventricular electrodes. The IMD 100 may provide full-function cardiac resynchronization therapy. Alternatively, the IMD 100 may be implemented with a reduced set of functions and components. For instance, the IMD may be implemented without ventricular sensing and pacing.

[0068] The IPS 150 is configured to be implanted at a location remote from the electrodes of the leads 120 and 130. The IPS 150 may be implanted in a blood vessel, such as an artery or vein. In some embodiments, the IPS 150 is implanted within the pulmonary artery (PA). The IPS 150 may be anchored to the vessel wall of a blood vessel using one or more expandable loop wires. Optionally, instead of the loop wire, the IPS 150 may be attached to the end of a self-expandable stent and deployed into the blood vessel through a minimally invasive method. It should be understood that the sensor may be implanted and fixed in place utilizing other configurations. The IPS 150, when disposed within the PA or other vessel, is configured to sense pressure (e.g., blood pressure), and to generate signals indicative of the pressure.

[0069] Figure 2 illustrates a block diagram of the system 101 formed in accordance with embodiments herein, showing some components of the IPS 150, IMD 100, external device 104, and wearable device 170. The IPS 150 comprises a sensing circuit 152, one or more controller 154, an optional power source 156, a communications circuit 158 and a memory 160. By way of example, the IPS 150 may be implemented in accordance with one or more aspects of the sensors described in U.S. Published Application 2023/0109123, filed August 18, 2022 and titled "SYSTEM AND METHOD FOR INTRA-BODY COMMUNICATION OF SENSED PHYSIOLOGIC DATA", the complete subject matter of which is incorporated by reference in its entirety. The controller 154 includes one or more

processors 155. The one or more processors 155 are operably coupled to the memory 160. The IPS 150 includes a housing 151 that holds and encapsulates the sensing circuit 152, the controller 154, the power source 156, the communications circuit 158, and the memory 160, to protect these components from the harsh organic environment of the body. The housing 151 may be hermetically sealed.

[0070] In some embodiments, the IPS 150 is the CARDIOMEMS (Atlanta) heart sensor. As described by U.S. Pat. No. 9,265,428 titled "Implantable Wireless Sensor" and/or by U.S. Provisional Application No. 63/574,335, titled "Method and Device for Cardiac Pressure Sensing Using an Active Implantable Device and Near Field Communication," and incorporated herein by reference in their entireties, these sensors are MicroElectroMechanical Systems (MEMS)-based sensors that are implanted in the pulmonary artery, more particularly in the distal pulmonary artery branch and are configured to be energized with RF energy to return high-frequency, high-fidelity dynamic pressure information from a precisely-selected location within a patient's body. In some embodiments, the IPS 150 may be a passive sensor, such as the sensor 804 shown in Figure 8. The sensor 804 can have anchor loops that hold it in place within a vessel. By way of example, the sensor 804 can be a completely sealed capsule that uses the MEMS technology. As the sensor 804 is powered by radio frequency (RF) energy, it may not require a battery or other internal power source. The sensor 804 can include components and/or functionality for sensing pressure (e.g., sensing circuit 152), communicating (e.g., RF module 157), and some processing capability (e.g., microcontroller 154, processor(s) 155). In other embodiments, the sensor 804 may or may not include active circuits. As used herein, the term IPS 150 can also refer to the sensor 804.

[0071] The sensing circuit 152 is configured to sense and collect pressure data (e.g., pulse pressure) and to generate pressure signal(s) indicative of the pressure data. For example, the sensing circuit 152 of an implantable pressure sensor (e.g., IPS 150) senses pressure, on-demand and/or on a schedule, over a

period of time that includes a plurality of cardiac cycles, and generates a pressure signal based on the sensed pressure. The signals generated by the sensing circuit 152 represent electrical signals. Electrical parameters of the signals, such as voltage, current, capacitance, inductance or resistance, may vary based on a level of the pressure. The sensing circuit 152 includes one or more sensing elements that sense the pressure and circuitry that generates the electrical signals indicative of the pressure. In some embodiments, the one or more processor 155 collects multiple sensor output signals and converts such signals to meaningful information that the one or more processor then uses to build a pressure signal based on the pressure. The IPS 150 is a highly specialized component that is neither typical nor common, and as discussed herein, senses pressure within the body, and generates a pressure signal using one or more processors 155.

[0072] The controller 154 may be implemented as a microcontroller unit or another processor configuration. The controller 154 performs at least some of the operations described herein to collect real-time on-demand measurements and/or scheduled measurements by generating physiologic data and can communicate the physiologic data to at least a second device, in some cases without requiring patient interaction or external energy delivery at the time of data generation and/or communication. The controller 154 represents hardware circuitry that includes and/or is connected with the one or more processors 155 (e.g., one or more microprocessors, integrated circuits, field programmable gate arrays, etc.) In some embodiments, some or all of the functions of the IPS 150 may be powered by an external device 104 positioned outside the skin of the patient in proximity to the IPS 150.

[0073] The controller 154 includes and/or is connected to the memory 160, which is a tangible and non-transitory computer-readable storage medium. The memory 160 stores program instructions (e.g., software) that are executed by the one or more processors 155 to perform the operations of the IPS 150 described herein. The memory 160 additionally may store the physiologic data (e.g.,

pressure signals) that is generated by the sensing circuit 152. The memory 160 may store the physiologic data until the IPS 150 transmits the physiologic data to the IMD 100 and/or the external device 104, and/or operate as a memory loop by deleting the oldest data as new data is acquired. For example, the controller 154 can prepare and send pressure data collected by the IPS 150, such as over time (e.g., 10 seconds, 18, seconds, 30 seconds, one minute, etc.) to the IMD 100.

[0074] In some embodiments, an external device 104 can communicate with the IPS 150 and may optionally power the IPS 150 or passive sensor 804. In this example, the external device 104 may be a product such as a pillow, blanket, or device outside the body that is positioned in proximity to the IPS 150, 804. The patient may facilitate taking regular readings of the IPS 150, 804, such as one a day or week, and/or may conduct readings on-demand. In some cases, these readings may be 18 seconds long or longer. In other embodiments, such as during a medical procedure (e.g., catheter delivery procedure) or visit to a medical facility, the external device 104 may conduct readings on-demand that in some cases can be shorter, such as 10 seconds. The length of time the pulmonary pressure data is recorded and used for analysis may be adjusted and/or programmable, such as by a medical practitioner using an external device 104 and/or over a network.

[0075] The IPS 150 can include processing modules that are included and/or stored in the controller 154 and/or memory 160. A systolic peak analysis module 162 can include program instructions that can be stored, for example, in memory 160. The systolic peak analysis module 162 can analyze the pressure signals acquired by the IPS 150 and/or CA signals from the IMD 100, for a predetermined amount of time such as 10 seconds, 18 seconds, 20 seconds, etc., to identify valid or normal heartbeat(s) within the data. For example, the systolic peak analysis module 162 can analyze data acquired by the IPS 150 or the IMD 100 to identify and remove effects of noise and/or arrythmia from the signal. As discussed further below, the systolic peak analysis module 162 can segment the signal into pseudo-systolic and pseudo-diastolic segments and define valid

heartbeats based on modified systolic content. The systolic peak analysis module 162 determines whether the pressure signal starts with a pseudo-systolic segment or a pseudo-diastolic segment. In response to the pressure signal starting with one of the pseudo-diastolic segments, the systolic peak analysis module 162 can modify systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments, and in response to the pressure signal starting with one of the pseudo-systolic segments, the systolic peak analysis module 162 can modify the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments.

[0076] For example, in some embodiments, the systolic peak analysis module 162 can modify the systolic content of at least one of the pseudo-systolic segments based on the diastolic content of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segments. In other embodiments, if a pseudo-systolic segment is the first segment within the acquired period of time, the systolic peak analysis module 162 can modify the systolic content of at least one of the pseudo-systolic segments based on the diastolic content of the at least one of the pseudo-diastolic segments, and in some cases, if a pseudo-systolic segment is the first segment within the acquired period of time, the systolic peak analysis module 162 can further modify the systolic content of a first pseudo-systolic segment based on the systolic content of the first pseudo-systolic segment.

[0077] In still further embodiments, the systolic peak analysis module 162 can remove linear trends (such as by fitting a straight line to the signal and then subtracting from the original signal) and non-linear trends (such as by applying a band pass filter, an independent component analysis, and/or a polynomial fitting to the signal) from the pressure signal, such as prior to segmenting the pressure signal. In some embodiments, when segmenting the pressure signal, the systolic peak analysis module 162 can identify the pseudo-systolic segments based on

values of the pressure signal exceeding or satisfying a threshold, and can identify the pseudo-diastolic segments based on the values of the pressure signal being below, or not satisfying, the threshold.

[0078] In yet further embodiments, in response to the pressure signal starting with one of the pseudo-diastolic segments, the systolic peak analysis module 162 can modify the systolic content of the at least one of the pseudo-systolic segments by multiplying values in the at least one of the pseudo-systolic segment with integrals of the at least one of the pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment. In other embodiments, in response to the pressure signal starting with one of the pseudo-systolic segments, the systolic peak analysis module 162 can modify the systolic content of at least one of the pseudo-systolic segments following the first pseudo-systolic segment by multiplying values in the at least one of the pseudo-systolic segments with integrals of a same one of the at least one pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment.

[0079] In further embodiments, the systolic peak analysis module 162 can determine a score associated with the maximum systolic peak value, the score based on i) the maximum systolic peak value, ii) integrals of the pseudo-systolic segment associated with the maximum systolic peak value, iii) integrals of the pseudo-diastolic segment associated with the pseudo-diastolic segment immediately preceding the pseudo-systolic segment associated with the maximum systolic peak value, or iv) cardiac cycle duration, wherein the valid heartbeats are further identified based on the score. In still further embodiments, the systolic peak analysis module 162 can further identify valid heartbeats i) when the score exceeds or satisfies a constant value, ii) when the score exceeds or satisfies a dynamic threshold, iii) when the score exceeds or satisfies a dynamic threshold

based on non-zero values of the pseudo-systolic segments within the period of time, or iv) based on an outlier detection method.

[0080] In accordance with new and unique aspects, a technical advantage of identifying the true systolic peaks is provided, which are essential for computing mean, systolic, and pulse pulmonary artery pressures, cardiac output, and heart rate, arrhythmia detection, dicrotic notch identification, and other diagnostic algorithms, as well as improving the ability to identify other landmarks and features within the signal. A further advantage is that the true systolic peaks can be reliably detected from a small number of beats, such as may be present in 10 seconds or 18 seconds of recorded signals.

[0081] In other embodiments, a systolic peak analysis module 164 in the IMD 100, similar to the systolic peak analysis module 162 of the IPS, can process the pressure signals sensed and/or obtained by the IPS 150 and/or process CA signals to determine valid heartbeats as discussed herein. The IMD 100 can, in some cases, utilize a communications circuit 172 to wirelessly instruct the IPS 150 to acquire pressure signals for a predetermined length of time. In other cases, the IMD 100 can receive the pressure signals from the IPS 150 at random times, periodically on a schedule (e.g., once a day, twice a day), as a result of the IPS 150 detecting a predetermined condition and acquiring signals, and the like. The IMD 100 can also utilize the communications circuit 172 to send and receive data to/from the external device 104 and/or the wearable device 170.

[0082] In some embodiments, a systolic peak analysis module 166 in the external device 104, similar to the systolic peak analysis module 162 of the IPS 150, can similarly process the pressure signals sensed by the IPS 150 and/or CA signals sensed by the IMD 100. The external device 104 can utilize a communications circuit 174 to wirelessly instruct the IPS 150 to acquire pressure signals and/or the IMD 100 to acquire CA signals. The external device 104 optionally may also provide power to the IPS 150, and may communicate bidirectionally with the wearable device 170. Although not shown, the external

device 104 also includes at least one controller, at least one processor, and memory to facilitate the operations discussed herein.

[0083] The wearable device 170 may sense and/or obtain periodic data continuously, on-demand, based on a schedule, periodically, etc. Systolic peak analysis module 168, similar to the systolic peak analysis module 162 of the IPS 150, can process the periodic data of predetermined lengths (e.g., 10 seconds, 18 seconds, 30 seconds, more than 30 seconds) as the data are acquired or on-demand. In other cases, the wearable device 170 can utilize communications circuit 176 to transmit the obtained periodic data to the external device 104 for processing. In still further embodiments, the wearable device 170 may request and/or receive pressure signals from the IPS 150, CA signals from the IMD 100, or signals from another wearable device (not shown). Although not shown, the wearable device 170 also includes at least one controller, at least one processor, and memory to facilitate the operations discussed herein.

[0084] Each of the devices, IMD 100, IPS 150, external device 104, and wearable device 170 can process the sensed and/or obtained data in real-time or near real-time. Further, external devices such as the external device 104 and wearable device 170 can display a heart rate based on the valid heartbeats, cardiac output based on the valid heartbeats, treatment notification(s), and/or treatment recommendation(s). Although not shown, the external device 104 and wearable device 170 can include one or more display capable of displaying text, graphs, accepting input (e.g., touchscreen), and the like.

[0085] In still further embodiments, processing of the pressure signals and/or CA signals may be split among one or more of the IMD 100, external device 104, IPS 150, wearable device 170, and/or other remote processor.

[0086] In some embodiments, the controller 154 includes and/or is connected with an internal clock 153 or timer. The clock 153 may be used to cycle the IPS 150 between wake and sleep modes to conserve electrical energy. The controller 154 may refer to the clock 153 to determine when to activate the sensing

circuit 152 to generate the signals indicative of the pressure according to a data collection schedule. For example, if the data collection schedule in the memory 160 indicates that new physiologic data should be generated at a specific time (e.g., 6 AM) of the current day, or, for example, at intervals such as every minute, two minutes, hour, etc., then the controller 154 can utilize the clock 153 to determine when it is the specific time to activate the sensing circuit 152 according to the schedule, such that the physiologic data is generated and collected in real-time at specific prescribed times.

[0087] The communications circuit 158 is operably connected to the controller 154 via conductive elements. The communications circuit 158 communicates with the IMD 100, wearable device 170, and/or the external device 104. The communications circuit 158 may be communicatively connected to the IMD 100 via an intra-body bidirectional link, which enables the IPS 150 to transmit information (e.g., data) to the IMD 100 and receive information/requests from the IMD 100. The communications circuit 158 may include an RF module 157 and/or a conductive communication module 159. The RF module 157 includes an antenna for sending and receiving RF signals. In some cases, the processor(s) 155 can direct the IPS communications circuit 158 to transmit, to an IMD communications circuit 764 and/or communication modem 742 (both of Figure 7) a request for the CA signals, and receive the CA signals. The conductive communication module 159 includes at least two spaced-apart electrodes, connected via a conductive wire or cable, that are powered to create a polarized electric field around the IPS 150.

[0088] The optional power source 156 can supply electrical energy to power the operations of the IPS 150. The power source 156 may include one or more secondary (e.g., rechargeable) batteries, one or more primary batteries, one or more capacitors, and/or associated circuitry, such as inductive coils, charging circuits, and the like.

[0089] In other embodiments, the IPS 150 can receive power from the IMD 100, such as through a wired connection. In some cases, the wired connection can also provide at least a portion of the communications between the IPS 150 and the IMD 100. In still further embodiments, the IPS 150 can receive power wirelessly from the external device 104.

[0090] In operation, the controller 154 may directly convert, or manage conversion of, the signals from the sensing circuit 152 to digital physiologic data. The controller 154 may execute the program instructions stored in the memory 160 to activate the sensing circuit 152 to generate the signals indicative of the pressure. The controller 154 may activate the sensing circuit 152 on-demand in response to receiving a request (e.g., a data collection instruction) from another device, such as the IMD 100, or at a prescribed time according to a schedule stored in the memory 160. In other embodiments, the sensor 150 may be powered by the external device 104, triggering the activation of the sensing circuit 152. In some embodiments the controller 154 may activate the sensing circuit 152 on an on-going basis or near-on-going basis, acquiring and storing pressure data in the memory 160, such as in a loop, keeping the most recently acquired data. The controller 154 also executes the program instructions to convert the signals from the sensing circuit 152 to physiologic data indicative of the pressure. After converting, the controller 154 stores the physiologic data in the memory 160 and/or transmits the data, such as via near-field communications (NFC), to the external device 104. In an embodiment, the controller 154 (e.g., the one or more processors 155 thereof) is configured to digitize the signals generated by the sensing circuit to form the physiologic data.

[0091] In accordance with embodiments described herein, the intra-body communication between the IPS 150 and the IMD 100 provides various benefits. For example, the pressure is measured by the IPS 150 and the communications circuit 158 can transfer pressure data to the IMD 100 and receive data from the IMD 100, including CA signals and requests. In other embodiments, the IPS 150

can determine and send information concerning valid heartbeats to the IMD 100, and the IMD 100 can utilize the information concerning the valid heartbeats in analysis of data related to the patient or a larger population, provide a recommendation for treatment of the patient, provide a recommendation for adjusting a treatment of the patient, adjust a treatment of the patient based on the valid heartbeats and/or heart rate, and the like, thereby improving the patient outcome. For example, when the IMD 100 is a CRT/pacemaker, the treatment may be stimulation therapy.

[0092] Similarly, the IPS 150 can determine and send the information concerning the valid heartbeats to the external device 104 and/or wearable device 170. In some cases, the external device 104 and/or wearable device 170 receives the pressure signal and determines the valid heartbeats and/or heart rate. The external device 104 and/or wearable device 170 can utilize the information concerning the valid heartbeats in analysis of data related to the patient or a larger population, provide a recommendation for treatment of the patient, provide a recommendation for adjusting a treatment of the patient, adjust a treatment of the patient based on the valid heartbeats and/or heart rate, and the like, thereby improving the patient outcome.

[0093] In accordance with new and unique aspects, a practical application is realized as the clinician uses the measurements/data resulting from the obtaining and processing of the pressure signal, CA signals, and/or other periodic signal to prescribe/change the patient's therapy (e.g., prescribe new medication, change medication, change diet, recommend physical therapy, recommend to implant IMD, recommend to change programmed parameters of IMD and/ or IPS already implanted, reprogram the implanted IMD and/or IPS).

Diastolic-enhanced peak detection

[0094] Figures 3A and 3B illustrate a computer-implemented method for implementing a diastolic-enhanced systolic peak detection algorithm for detecting valid systolic peaks in cardiac signals in accordance with embodiments herein.

More specifically, Figure 3A illustrates a computer-implemented method for preprocessing and filtering the signal, and segmenting the processed signal into pseudo-systolic and pseudo-diastolic segments, and Figure 3B illustrates a computer-implemented method for modifying pseudo-systolic segments and differentiating between valid (normal) and invalid (abnormal) pseudo-systolic peaks. For example, the method can detect valid systolic peaks from within a signal that may also include peaks caused by noise and/or arrhythmia. The method can identify the true systolic peaks by taking into account one or more factors such as the duration of the systole (e.g., arrhythmia peaks have a short duration), the value and the end-diastole of the previous beat (e.g., respiratory variations can affect the value of systolic peaks while having pulse pressure), and the value of the systole peak itself.

[0095] The operations of Figures 3A and 3B may be implemented by hardware, firmware, circuitry and/or one or more processors housed partially and/or entirely within an IMD 100, an IPS 150, an external device 104, wearable device 170, a local external device, remote server or more generally within a health care system. Optionally, the operations of Figures 3A and 3B may be shared across devices, and thus partially implemented by one or more of an IMD 100, an IPS 150, an external device 104, a wearable device 170, a local external device, remote server or more generally within a health care system. For example, the IMD 100 includes IMD memory and one or more IMD processors, the IPS 150 includes IPS memory and one or more IPS processors, the external device 104 includes external device memory and one or more external device processors, and the wearable device 170 includes wearable memory and one or more wearable processor, and further, other of the external devices/systems (e.g., local, remote or anywhere within the health care system) that may implement the operations of Figures 3A and 3B include external device memory and one or more external device processors.

[0096] Although Figures 3A and 3B primarily discusses the detection of systolic peaks in pulmonary arterial pressure signals acquired by the IPS 150, it should be understood that the methods and systems apply equally to pressure signals acquired by a pressure sensor located in other locations within the body such as venous signals, etc., CA signals acquired by the IMD 100, as well as other periodic signals, such as those acquired by a wearable device 170 (e.g., via optical sensor). In other words, the embodiments herein apply to periodic signals indicative of cardiac function and are not limited to pressure signals.

[0097] At 302, one or more processors, such as of the IPS 150, sense (e.g., collect) pressure data, such as for 10 seconds, 18 second, etc., and generate a pressure signal that is based on the pressure data. In other embodiments, one or more processors sense (e.g., collect) cardiac activity (CA) and generate CA signals based on the CA.

[0098] At 304, one or more processors store the pressure signals in a memory in the IPS 150, such as memory 160 of Figure 2. Alternatively or additionally, one or more processors store the CA signals, such as in a memory of the IMD 100. In some embodiments, the memory can store the signals for a predetermined amount of time and/or depending upon the space available. The associated device can discard older signals in favor of storing more recently acquired signals. In some embodiments the signals can be stored in a running loop, such that older data is overwritten or otherwise deleted as more signals are collected and stored. In some embodiments, the IPS 150 can collect pressure signals and/or the IMD 100 can collect CA signals at predefined intervals, substantially in real-time by continuously sensing pressure/cardiac activity, and/or on-demand, such as upon receiving a signal or other request to sense pressure/cardiac activity, such as for a predetermined amount of time.

[0099] Optionally, at 306 the one or more processors transmit the pressure signal to another device. For example, the IPS 150 can transmit the pressure

signals to the IMD 100 and/or the external device 104. In other cases, the IMD 100 can transfer the CA signals to the external device 104 and/or IPS 150.

[00100] Figure 4A shows a graph 400 of a pulmonary pressure waveform 402 based on a pressure signal that has been acquired by the IPS 150 over time in accordance with embodiments herein. The pressure waveform 402 is periodic, having a series of peaks and valleys. Vertical axis 404 indicates a measure of pulse pressure in millimeters of mercury (mmHg), and horizonal axis 406 indicates time in seconds (s). In this example, the pressure waveform 402 has been acquired for approximately 10 seconds and is variable and/or periodic between approximately 20 mmHg to approximately 50 mmHg. In some embodiments, vertical axis 404 indicates a measure of a magnitude of a pulse portion of the pulse pressure associated with the IPS 150, and in some embodiments the magnitude can be an amplitude of the pulse portion of the pulse pressure. By way of example, for the IPS 150 that is positioned in the pulmonary artery, in some embodiments the IPS 150 measures the pulsatility that is created by the regular contraction of the left ventricle. In ventricular tachycardia (VT) and some cases of defibrillation, there is no organized contraction, so pulse pressure and thus pulsatility will diminish.

[00101] As discussed herein, the following may be accomplished in a single device, be split across more than one device, and/or processed wholly or partially by the device that acquired the signal data. For simplicity, the method will be discussed from the perspective of being processed by the external device 104.

[00102] Returning to Figure 3A, the pressure signal can be preprocessed and filtered. At 308, the one or more processors remove a linear trend from the signal. In some examples, a straight line is fit to the signal and then subtracted from the original signal, so that the resulting signal has zero mean and no linear trend.

[00103] As used herein, the term “linear trend” shall mean a statistical term that describes the tendency of a variable to change over time in a consistent and

predictable way. A linear trend can be represented by a straight line. One way to estimate the linear trend of a data set is to use linear regression, which finds the best-fitting line that minimizes the sum of squared errors between the observed data points and the line. The equation of the line is usually written as y = ax + b, where y is the variable value, x is the time point, a is the slope, and b is the intercept. The slope and the intercept are called the regression coefficients, and they can be calculated using some mathematical formulas.

[00104] Turning to Figure 4B, this figure shows a graph 420 of linear detrended waveform 422, based on the pressure waveform 402 of Figure 4A, in accordance with embodiments herein. Again, vertical axis 424 indicates a measure of pulse pressure and horizonal axis 426 indicates time. In this example, the linear detrended waveform 422 crosses zero pressure and is variable and/or periodic, extending above and below zero, between less than -10 mmHg and nearly 20 mmHg.

[00105] Returning to Figure 3A, at 310, the one or more processors remove nonlinear trends from the linear detrended waveform 422. Accordingly, the signal average is now at zero. For example, baseline wandering and high frequency noise can be removed from the linear detrended waveform 422, such as by applying a band pass filter, an independent component analysis, and/or a polynomial fitting to the signal. Low frequency content can also be subtracted. For example, the pulmonary pressure signal may include a low frequency wave that can be a respiratory artifact. It should be understood that other methods may be used.

[00106] As used herein, the term “nonlinear trend” shall mean a pattern of variation in a data set that does not follow a straight line or a simple curve. It means that the relationship between the dependent variable and the independent variable is not linear, and the rate of change is not constant. Nonlinear trends can be influenced by many factors, such as respiratory variations, activity of the patient, and the presence of arrhythmias.

[00107] Figure 4C shows a graph 440 of a filtered waveform based on the pressure signal sensed for the period of time in accordance with embodiments herein. Vertical axis 444 indicates a measure of pulse pressure (mmHg) and horizonal axis 446 indicates time (s). Portions of signal 442 that satisfy or exceed threshold 448, located in this example at approximately 0 mmHg, are identified as pseudo-systolic segments and portions of the signal 442 that do not satisfy or are below the threshold 448 are identified as pseudo-diastolic segments. In other words, the one or more processors identify the values of the pressure signal that exceed or satisfy the threshold 448 as pseudo-systolic segments and identify the values of the pressure signal that are below or do not satisfy the threshold as pseudo-diastolic segments.

[00108] Returning to Figure 3A, the signal 442 can be segmented into pseudo-systolic and pseudo-diastolic segments. At 312, the one or more processors determine the portions of the signal 442 (e.g., $\boldsymbol{P_{filtered}}$) that are pseudo-systolic segments (e.g., $\boldsymbol{P_{pseudo-systolic}}$) by identifying all positive values (e.g., above the threshold 448) and setting all negative values in the signal 442 (e.g., below the threshold 448) to zero: $\boldsymbol{P_{pseudo-systolic} = P_{filtered} > 0\ else\ P_{pseudo-systolic} = 0}$.

[00109] At 314, the one or more processors determine the portions of the signal 442 that are pseudo-diastolic segments (e.g., $\boldsymbol{P_{pseudo-diastolic}}$) by inverting the signal 442 shown in Figure 4C, such as by multiplying values of the waveform by -1. All positive values of the inverted signal are identified as pseudo-diastolic (e.g., values that were previously below the threshold 448 are now positive values). The negative values in the inverted signal are set to zero: $\boldsymbol{P_{pseudo-diastolic} = -P_{filtered} > 0\ else\ P_{pseudo-diastolic} = 0}$. Therefore, in 312 and 314 the method eliminates the negative values by setting them to zero, and all values in $\boldsymbol{P_{pseudo-systolic}}$ and $\boldsymbol{P_{pseudo-diastolic}}$ are positive. It should be understood that other methods can be used by the one or more processors to identify the pseudo-systolic and pseudo-diastolic segments in 312 and 314.

Accordingly, the one or more processors have identified which values in the period of time are associated with the pseudo-systolic segments and which values are associated with the pseudo-diastolic segments.

[00110] Referring to Figure 4D, this figure shows a graph 460 that combines and displays the pseudo-systolic segments 462 and pseudo-diastolic segments 464 identified in the signal 442 using positive values in accordance with embodiments herein. Not all of the pseudo-systolic segments 462 and pseudo-diastolic segments 464 are individually indicated. Vertical axis 466 indicates a measure of pulse pressure (mmHg) and horizonal axis 468 indicates time (s). Portions of the signal 442 that were above the threshold 448 in Figure 4C form the pseudo-systolic segments 462, and portions of the signal 442 that were below the threshold 448 have been inverted to extend above the 0.0 pressure line and form the pseudo-diastolic segments 464. Therefore, the pseudo-systolic segments and the pseudo-diastolic segments that were calculated at 312 and 314, respectively, are displayed together in Figure 4D.

[00111] Although discussed together herein, in some embodiments, 316–324 of Figure 3A discussed below are accomplished for the pseudo-systolic segments 462 separately from the pseudo-diastolic segments 464. In some embodiments, the method uses the element-wise difference of a vector, excluding the time vector, to find the first non-zero element of each pseudo-systolic/diastolic beat. A pseudo-systolic/diastolic beat is a sequence of zero values in the vector, followed by a non-zero value. The element-wise difference of a vector is calculated by subtracting each element from the next one. For example, if `v = [a, b, c, d]`, then `diff(v) = [b-a, c-b, d-c]`.

[00112] In this context, a value of 1 in the difference vector indicates that two adjacent elements in the original vector are both zero. By replacing these values with 0, the algorithm ensures that only the first zero in each beat is marked as the start of the pseudo-systolic/diastolic beat.

[00113] For example, if the original vector is `v = [0, 0, 0, 15, 23, 18, 0, 0, 0, 7, 10, 13, 9, 0, 0]`, then the index of zero elements is `i = [1, 2, 3, 7, 8, 9, 14, 15]`, and the difference of the index vector is `diff(i) = [1, 1, 4, 1, 1, 5, 1]`. The values of 1 in `diff(i)` mean that there are consecutive zeros in `v`. By setting these values to 0, the result is `diff(i) = [0, 0, 4, 0, 0, 5, 0]`. The non-zero values in `diff(i)` are at index `[3, 6]`, which correspond to the first non-zero elements in `v` at index `[4, 10]`. These are the start of the pseudo-systolic/diastolic beats.

[00114] For example, the unit of the difference, between the elements of the array depends on the unit of the elements themselves. If the elements of the array represent a physical quantity with a specific unit, then the unit of the difference between the elements of the array will be the same as the unit of the elements. For example, if the elements of the array represent mmHg, then the unit of the difference between the elements will be mmHg.

[00115] At 316, the one or more processors determine the positions (e.g., along the horizontal axis 468 of time) of the zero values of the pseudo-systolic segments 462 and the pseudo-diastolic segments 464.

[00116] At 318, the one or more processors determine the differences between the zero value positions that are adjacent in time. For example, the difference is measured between a first zero value of a pseudo-systolic segment 462 and the next zero value in time.

[00117] At 320, the one or more processors ignore differences that are equal to one. Differences that are equal to one indicate that there are two consecutive zero values in the signal.

[00118] At 322, the one or more processors determine the segment lengths of the pseudo-systolic segments 462 and pseudo-diastolic segments 464.

[00119] At 324, the one or more processors determine the starting and ending points of the pseudo-systolic segments 462 and pseudo-diastolic segments 464, such as by using the first positions of the zero values and the segment lengths. It should be understood that other methods may be implemented

to determine the starting and ending points of the pseudo-systolic segments 462 and pseudo-diastolic segments 464.

[00120] Returning to Figure 4D, starting point 470a represents a start of pseudo-systolic segment 462a and ending point 472a represents the end of pseudo-systolic segment 462a. Starting point 474a and ending point 476a represent the start and end of pseudo-diastolic segment 464b. Similarly, starting point 474b and ending point 476b indicate the start and end of the pseudo-diastolic segment 464c, and starting point 470b and ending point 472b indicate the start and end of the pseudo-systolic segment 462c. The points 470, 472, 474, and 476 indicate some of the zero points that were determined. In some embodiments, the starting point 470 that represents a start of a pseudo-systolic segment 462 can be located at the same position along the horizontal axis 468 as the ending point 476 that indicates an end of a pseudo-diastolic segment 464, and the ending point 472 that represents an end of a pseudo-systolic segment 462 can be located at the same position along the horizontal axis 468 as the starting point 474 that represents a start of a pseudo-diastolic segment 464. In some embodiments, an estimated number of heartbeats can be determined based on the number of pseudo-systolic segments 462, such as those shown in Figure 4D.

[00121] Figure 5A shows a graph 500 of segmented beats in accordance with embodiments herein. Vertical axis 502 indicates a measure of pulse pressure (mmHg) and horizonal axis 504 indicates time (s). The pseudo-systolic segments 462 and pseudo-diastolic segments 464 are shown. The pseudo-diastolic segment 464d has a starting point 506a and ending point 508a. The pseudo-diastolic segments 464e and 464f have starting points 506b and 506c, respectively, and ending points 508b and 508c, respectively. Similarly, the pseudo-systolic segments 462d, 462e, and 462f have starting points 510a, 510b, and 510c, respectively, and ending points 512a, 512b, and 512c, respectively. Not all of the starting and ending points are indicated.

[00122] Segment lengths are defined between respective starting and ending points. Segment lengths L2, L4, and L6 of the pseudo-systolic segments 462d, 462e, and 462f, respectively, and segment lengths L1, L3, and L5 of the pseudo-diastolic segments 464d, 464e, and 464f, respectively, are also indicated. Not all of the segment lengths are indicated.

[00123] Turning to Figure 3B, the one or more processors modify (e.g., enhance) the systolic content of the pseudo-systolic segments 462, such as by modifying the systolic content with diastolic content of a pseudo-diastolic segment 464 and/or with systolic content of the same pseudo-systolic segment 462. It should be understood that not all of the pseudo-systolic segments 462 may be modified.

[00124] At 326 the one or more processors determine whether the waveform starts with a pseudo-systolic segment 462 or pseudo-diastolic segment 464. In the example of Figure 5A, the represented waveform starts with pseudo-diastolic segment 464a. If the waveform starts with a pseudo-systolic segment 462, the method passes to 328. In some embodiments, the starting segment may be a partial or incomplete segment that does not include a starting point 506, 510.

[00125] At 328, for the first pseudo-systolic segment 462, the one or more processors modify the systolic content of the first pseudo-systolic segment 462 based on the systolic content of the same pseudo-systolic segment 462. For example, the systolic content of the first pseudo-systolic segment 462 can be modified or enhanced by multiplying the values (e.g., amplitude of the waveform) in the first pseudo-systolic segment 462 with twice the integral of the first pseudo-systolic segment 462 to calculate $P_{enhanced\ systolic}$. In other cases, the systolic content can be modified by one, three, or N times the integral of the first pseudo-systolic segment 462.

[00126] At 330, for the pseudo-systolic segments 462 following the first pseudo-systolic segment 462, the one or more processors modify the systolic content of the pseudo-systolic segments 462 based on the diastolic content of the

immediately preceding pseudo-diastolic segment 464 and in some cases, also the systolic content of the same pseudo-systolic segment 462. For example, the one or more processors multiply the values in the pseudo-systolic segment 462 with the integrals of that pseudo-systolic segment 462 and the integrals of the previous pseudo-diastolic segment 464 to calculate $P_{enhanced\ systolic}$. For example, for the pseudo-systolic segment 462b as indicated in Figure 5A, the one or more processors multiply the values of the pseudo-systolic segment 462b with the integrals of pseudo-systolic segment 462b and the integrals of pseudo-diastolic segment 464b. In some embodiments, the systolic content can be modified based on two, three, or N times the content of the same pseudo-systolic segment 462 and/or the systolic content can be modified based on two, three, or N times the content, integrals, etc., of the previous pseudo-diastolic segment 464. In still further embodiments, only a portion of the pseudo-systolic segments 462 within the period of time may be modified.

[00127] Returning to 326, if the waveform starts with a pseudo-diastolic segment 464, the method passes to 332. At 332, for at least a portion of the pseudo-systolic segments 462, the one or more processors modify the systolic content as discussed in 330.

[00128] The processing at 328, 330, and 332 amplifies or exaggerates the beats compared to noise, arrythmia, etc., based on diastolic content of the associated beat and/or the systolic content of the same beat. It should be understood that other modifications may be used.

[00129] From 330 and 332, the method flows to 334 and the one or more processors determine a maximum value in each enhanced or modified pseudo-systolic segment, as a peak of each modified pseudo-systolic segment, which is referred to as a pseudo-systolic peak (PSP).

[00130] At 336, the one or more processors calculate and/or determine a score that is assigned to each PSP. The scoring further magnifies the difference between the peaks to be kept (actual heartbeats) and peaks to be rejected (false

peaks resulting from arrhythmia, noise, etc.). An advantage of the scoring process is that abnormalities such as premature contraction, etc., can be detected. Also, in some embodiments content of the diastole is being used to score the systole, in comparison with previous methods of peak detection that merely look at the zero crossing points to determine where potential systolic peaks may start.

[00131] In some embodiments, the score can be calculated as: $Score_{PSP} = |PSP|_{beat} \times \int P_{pseudo-systole}{}_{beat} \times \int P_{pseudo-diastole}{}_{previous\ beat}$, or the absolute value of the maximum value of the enhanced pseudo-systolic segment, multiplied times the integral of the pseudo-systolic segment 462 and the integral of the previous pseudo-diastolic segment 464. In this example, the elements of the $Score_{PSP}$ algorithm are all to the power of one. The calculation of the score is not limited to this algorithm, and in other embodiments, the score can be any combination of $|PSP|^a$, $\int P_{pseudo-systole}{}^b$, $\int P_{pseudo-diastole}{}^c$, $and\ \ cardiac\ cyles\ duration^d$, for calculating the |PSP| that cardiac duration varies for each beat. In other words, the score can be other combinations of the PSP, the integral of the pseudo-systole, the integral of the pseudo-diastole, and the cardiac cycle duration (e.g., the segment length L of the previous pseudo-diastolic segment 464 and the segment length L of the associated pseudo-systolic segment 462), and in other cases, one or more of the elements in the algorithm can be multiplied by any power. In some embodiments, different powers can be applied to enhance certain aspects of the signals, such as enhancement of the diastolic content at a different power than the systolic content.

[00132] In some embodiments, the power of the scoring algorithm can be adjusted based on the mean difference of the pseudo systolic peaks, or pseudo-RR peaks. The mean difference of the pseudo systolic peaks is the average distance between them. If the mean difference is larger than a threshold, the heart rate is low and the cardiac cycles are long. In this case, the value of the constant "d" in the scoring algorithm equation can be increased to better detect the arrhythmic beats that have a short duration. On the other hand, if the mean

difference is smaller than a threshold, the heart rate is high, and the cardiac cycles are short. In this case, the value of the constant "d" in the scoring algorithm can be decreased to reduce the influence of the cardiac cycles length on identifying the abnormal beats. In cases such as these, the scoring algorithm needs to run twice, a first time for detecting the pseudo-RR peaks and a second time for re calculating the PSP score based on the "d" value.

[00133] At 338, the one or more processors differentiate normal (e.g., valid) and abnormal (e.g., invalid) PSPs. For example, valid PSPs are associated with normal or valid heartbeats and invalid PSPs are associated with signals such as noise, arrythmia, motion, etc., and should not be counted as a normal heartbeat when determining heart rate, estimating cardiac output, etc. A number of differentiation methods can be used, including but not limited to: i) any PSP and/or score associated with the PSP that is smaller than a constant threshold can be considered as an invalid PSP and be excluded, ii) any PSP and/or score associated with the PSP that is smaller than a dynamic threshold, e.g., 25th percentile of the nonzero values of pseudo-systole or any other subset of cardiac pressure (or amplitude for waveforms not based on pressure) that includes baseline wandering and respiratory signal can be used as a threshold to exclude invalid PSP, iii) any PSP and/or score associated with the PSP that detects as a lower bound by outlier detection method including but not limited to Z-Score, k-nearest neighbors, local outlier factor, SVM, etc., and/or iv) based on one or more determined scores associated with different peaks. Additionally, the threshold can be determined based on the signal that is acquired, personalized based on a patient and/or condition (e.g., particular type of arrythmia), etc. In other embodiments, the threshold can be optimized based on an application that will use the heart rate data. In still further embodiments, the threshold can be set to accept all detected beats as valid.

[00134] In some embodiments, the constant threshold can be chosen independently of the enhanced systolic value. For example, the mean diastolic

pressure of the original signal can be used as the constant threshold. Alternatively, any other subset of the pressure signal that contains baseline wandering and respiratory signal can be used as the constant threshold. This means that the same dynamic thresholding method that was used for the enhanced systolic signal can be applied to the original signal or any other subset of the pressure signal, and the resulting value can be used as the threshold for detecting the abnormal beats.

[00135] Figure 5B shows a graph 550 of enhanced or modified pseudo-systolic segments ($P_{enhanced\ systolic}$) in accordance with embodiments herein. Vertical axis 552 indicates a score (e.g., Pressure x Impulse^2(mmHg^{3}s^2)) and horizonal axis 554 indicates time (s). As discussed above, other algorithms can be used to determine the score. A score 556 is determined for each PSP of each modified pseudo-systolic segment 558. For example, the modified pseudo-systolic segment 558a has an associated score 556a of 104.6, the modified pseudo-systolic segment 558b has an associated score 556b of 88.5, and so on.

[00136] By way of example only, if a threshold 560a is defined at a score of approximately 25, the one or more processors determine that the beat associated with the modified pseudo-systolic segment 558g, that has a score 556g of 11.3, should not be counted as a normal or valid heartbeat. The remaining modified pseudo-systolic segments 558a–f, 558h–j would be counted as valid heartbeats because they satisfy or exceed the threshold 560a. If a threshold 560b is defined at a score of approximately 45, the one or more processors determine that the beats associated with the modified pseudo-systolic segments 558c and 558g, that have a score 556c of 32.2 and a score 556g of 11.3, respectively, should not be counted as valid heartbeats. The remaining modified pseudo-systolic segments 558a, 558b, 558d–f, and 558h–j would be counted as valid heartbeats because they satisfy or exceed the threshold 560b. It should be understood that the thresholds 560a, 560b are defined in Figure 5B for description purposes only.

[00137] Returning to Figure 3B, at 340, the one or more processors determine heart rate metrics such as an estimated heart rate, heart rate variability, cardiac output, etc., based on the valid PSPs. In the example of threshold 560a, wherein the modified pseudo-systolic segment 558g is excluded, the sample 10 seconds includes 9 heartbeats, and thus the estimated heart rate based on the normal PSPs would be 54 beats per minute. In the example of threshold 560b, wherein the modified pseudo-systolic segments 558c and 558g are excluded, the sample 10 seconds includes 8 heartbeats, and thus the estimated heart rate based on the normal PSPs would be 48 beats per minute.

[00138] At 342, the one or more processors utilize the heart rate metrics to treat and/or monitor a patient condition, such as to activate circuitry, components, algorithms, and/or processes to treat arrhythmia, use the heart rate metrics in algorithms directed to treat, diagnose, and/or analyze, prevent the overtreatment of arrhythmia, modify dosage of medication(s), propose medication adjustments, modify treatment settings and protocols, propose modifications to treatment settings and protocols, display information related to the heartbeat data, treatment notifications, etc., transmit information related to the heartbeat data to other devices, and the like.

[00139] In accordance with new and unique aspects herein, the method provides the particular treatment and prophylaxis of determining an accurate estimated heart rate prior to treating the patient, and thus the patient is spared unnecessary and/or painful treatment, and/or the patient receives improved treatment. Further, as the diagnostic-enhanced systolic peak detection algorithm accurately detects valid heartbeats, the patient can be spared additional exams and time spent in clinic, preventing unnecessary patient stress and anxiety, and saving time and money for the patient, the medical staff, insurance companies and/or government agencies.

[00140] Further, the IMD 100, IPS 150, external device 104, and/or wearable device 170 deliver the particular treatment and prophylaxis for at least the medical

condition of arrhythmia (e.g., MVT, SVT, PVT, etc.). Noise and arrhythmia can result in an erroneously high heart rate, and thus result in erroneous and/or unnecessary treatment. The one or more processors, using all or portions of the diastolic-enhanced systolic peak detection algorithm, determine the estimated heart rate by determining valid heartbeats and not including beats associated with an arrhythmia and/or noise. Therefore, invalid heartbeats can be eliminated before treatment is administered to the patient, and thus appropriate treatment can be delivered to the patient, improving patient outcomes.

[00141] Technical advantages of the diastolic-enhanced systolic peak detection algorithm include an accurate heart rate determined using a signal that has a relatively short length of time. Further, the calculations do not require any derivatives of the signal, do not rely on any external reference or calibration, can distinguish between various types of noise and artifacts in the signal and the true systolic peaks, can adapt to different signal characteristics and patient conditions, and thus provide accurate and reliable identification and detection of normal systolic peaks.

[00142] In contrast, using only peak detection to determine the heart rate does not distinguish when beats are erroneous, such as peaks caused by noise or certain arrhythmias, which may appear to be systole but are not. Therefore, in the presence of arrythmia and/or noise, peak detection results in an estimated heart rate that is higher than the actual heart rate, leading to over-treatment and/or unnecessary treatment.

[00143] Figure 6A shows a graph 600 of variability of pulse pressures over a period of time of a pressure sensor, and illustrates a comparison between systolic peaks identified using a previous peak detection algorithm and systolic peaks identified using the diastolic-enhanced systolic peak (DESP) detection algorithm in accordance with embodiments herein. In some embodiments the pressure sensor can be a pulmonary arterial pressure sensor. Vertical axis 602 indicates pressure (mmHg) (e.g., a measure of a magnitude of a pulse portion of the pulse

pressure associated with the IPS 150), and horizonal axis 604 indicates time (s). In some embodiments the magnitude can be an amplitude of the pulse portion of the pulse pressure. A waveform 606 associated with the pulse pressures includes both larger beats (e.g., upper peak at a relatively higher pressure) and smaller beats (e.g., upper peak at a relatively lower pressure). The smaller beats can be associated with arrhythmia and/or noise, for example.

[00144] Systolic peaks 608a-608e, indicated using open circles (not all are individually indicated), indicate systolic peaks identified using a previous peak detection algorithm, such as by taking a derivative of the waveform to find zero crossing points of slope that are either on the up stroke or down stroke of pressure (e.g., peaks and valleys of the signal). Systolic peaks 610a, 610b, indicated using open triangles (not all are individually indicated), indicate systolic peaks identified using the diastolic-enhanced systolic peak detection algorithm discussed herein. End diastole 612a, 612b, indicated using solid circles (not all are individually indicated), indicate end diastole identified using a peak detection algorithm, and end diastole 614a, 614b, indicated using solid triangles (not all are individually indicated), indicate end diastole identified using the diastolic-enhanced systolic peak detection algorithm discussed herein.

[00145] The waveform 606 and the systolic peaks 608 of Figure 6A show an example of a signal wherein the heart rate was estimated to be approximately double (e.g., heart rate of 164 bpm) compared to the actual heart rate because of arrhythmias and/or noise in the waveform. The smaller beats, such as those indicated as systolic peaks 608a, 608b, and 608e, can be arrythmia such as premature ventricular contractions and/or premature atrial contractions where the heart is beating but not effectively, noise, etc. In some embodiments, these smaller beats should not be counted as a true beat.

[00146] Figure 6B shows a graph 650 of enhanced or modified systole with beat score values for each peak as determined by the diastolic-enhanced systolic peak detection algorithm in accordance with embodiments herein. Vertical axis

652 indicates a score (e.g., Pressure x Impulse^2(mmHg^{3}s^2)) and horizonal axis 654 indicates time (s). The modified pseudo-systolic segments are shown along line 656. Circles indicate modified pseudo-systolic peaks 658 that are counted as actual, valid heartbeats, and Xs indicate the modified pseudo-systolic peaks 660 that were rejected as being associated with invalid heartbeats. Each of the accepted and rejected modified pseudo-systolic peaks has an associated score.

[00147] A threshold 662 is set, in this example, at approximately the pseudo-systole lower quartile. When the score of an enhanced or modified pseudo-systolic peak satisfies or exceeds the threshold 662, this indicates that the heart is doing real work, while if the score does not satisfy or exceed the threshold 662, this indicates that the associated peak is not an actual heartbeat and should not be counted when determining the heart rate.

[00148] Referring to Figure 6A, calculating the heart rate based on the systolic peaks 608 would result in an exceedingly high heart rate measurement due to the inaccurate detection of systolic peaks by the previous peak detection algorithm. For example, the heart rate based on the systolic peaks 608 would be 164 bpm. In contrast, the heartbeat, as determined by the diastolic-enhanced systolic peak detection algorithm and shown in Figure 6B, is 84 bpm.

[00149] In some cases, it is possible to have a peak with a relatively large amplitude that may be near or even exceed the amplitude of a regular heartbeat, such as systolic peak 620 of Figure 6A, which was identified using peak detection. However, when detecting peaks using the diastolic-enhanced systolic peak detection algorithm, the integration of time associated with the systolic peak 620 and preceding diastolic content is small, resulting in rejected enhanced pseudo-systolic peak 664 of Figure 6B. As can be seen by the complexity of the waveform 606 (Figure 6A) that results from a patient experiencing arrhythmia and/or from noise corrupting the signal, the valid heartbeats of the waveform 606 can only accurately be determined using the one or more processor and the method described herein.

[00150] Figure 7 shows an example block diagram of the IMD 100 formed in accordance with embodiments herein. The IMD 100 may treat both fast and slow arrhythmias, including VA (e.g., further including VF/VT, etc.), with stimulation therapy, including cardioversion, pacing stimulation, suspend tachycardia detection, tachyarrhythmia therapy, and/or the like. In some embodiments, the IMD 100 can be one of an implantable cardioverter defibrillator, pacemaker, cardiac rhythm management device, defibrillator, or leadless pacemaker but is not so limited.

[00151] The IMD 100 has a housing 740 to hold the electronic/computing components. The housing 740 (which is often referred to as the "can," "case," "encasing," or "case electrode") may be programmably selected to act as an electrode for certain sensing modes. Housing 740 further includes a connector (not shown) with at least one terminal 700 and optionally additional terminals 702, 704, 706, 708, 710. The terminals 700, 702, 704, 706, 708, 710 may be coupled to sensing electrodes that are provided upon or immediately adjacent the housing 740. Optionally, more or less than six terminals 700, 702, 704, 706, 708, 710 may be provided in order to support more or less than six sensing electrodes. Additionally or alternatively, the terminals 700, 702, 704, 706, 708, 710 may be connected to one or more leads having one or more electrodes provided thereon, where the electrodes are located in various locations about the heart. The type and location of each electrode may vary. The lead can be positioned in one of a transvenous, subcutaneous, or subxiphoid position. In some embodiments, the IMD 100 can be a subcutaneous IMD coupled to an extravascular lead having a first electrode disposed along a distal segment of the lead and a second electrode disposed along a proximal segment of the lead.

[00152] The IMD 100 includes a programmable microcontroller 720 that controls various operations of the system 101, including cardiac monitoring. Microcontroller 720 includes a microprocessor (or equivalent control circuitry, one or more processors, etc.), RAM and/or ROM memory, logic and timing circuitry

732, state machine circuitry, and I/O circuitry. The timing circuitry 732 can control the timing of the stimulation pulses (e.g., pacing rate, atrio-ventricular (AV) delay, atrial interconduction (A-A) delay, or ventricular interconduction (V-V) delay, etc.). Microcontroller 720 includes an arrhythmia analysis module 734 that is configured to analyze the cardiac activity (CA) signals over one or more cardiac beats to identify the existence of a candidate arrhythmia. The microcontroller 720 and/or arrhythmia analysis module 734 can declare a candidate arrhythmia episode (e.g., VT or VF arrhythmia) based on the CA signals.

[00153] In some embodiments, the arrhythmia analysis module 734 can include morphology detection to review and analyze one or more features of the morphology of cardiac signals. In other embodiments, the arrhythmia analysis module 734 can compare CA signals and/or pressure signals to one or more templates (e.g., stored in memory 760) associated with normal sinus rhythm. The arrhythmia analysis module 734 can analyze the cardiac signals indicative of cardiac events that are sensed by electrodes located proximate to one or more atrial and/or ventricular sites.

[00154] Also, the microcontroller 720 further controls a shocking circuit 780 by way of a control signal 782. The shocking circuit 780 generates shocking pulses that are applied to the heart of the patient to terminate the detected arrhythmia through various configurations such as less than a full shock strength of one or more electrode through full shock strength with two or more electrodes, etc. The shocking circuit 780 can generate high-voltage and/or medium-voltage and the shocking electrodes, such as the electrodes as discussed in Figure 1, can be configured to deliver high-voltage or medium-voltage shocks.

[00155] The IMD 100 further includes a first chamber pulse generator 790 that generates stimulation pulses (e.g., ATP) for delivery by one or more electrodes coupled thereto. The pulse generator 790 is controlled by the microcontroller 720 via control signal 792. The pulse generator 790 is coupled to the select electrode(s) via the electrode configuration switch 726, which includes

multiple switches for connecting the desired electrodes to the appropriate I/O circuits, thereby facilitating electrode programmability.

[00156] In some embodiments, the output of a sensing circuit 744 is connected to the microcontroller 720 which, in turn, triggers or inhibits the pulse generator 790 and shocking circuit 780. The sensing circuit 744 receives a control signal 794 from the microcontroller 720 for purposes of controlling the gain, threshold, polarization charge removal circuitry (not shown), and the timing of any blocking circuitry (not shown) coupled to the inputs of the sensing circuitry.

[00157] The microcontroller 720 also includes a systolic peak analysis module 735 that includes some or all of the functionality of the systolic peak analysis module 162 described herein. The systolic peak analysis module 735 can process pressure signal data received from the IPS 150 and/or external device 104, as well as CA or other heart data acquired by the IMD 100 and/or wearable device 170. The systolic peak analysis module 735 can include program instructions that can be stored, for example, in memory 760. The systolic peak analysis module 735 can analyze the pressure signals acquired by the IPS 150 and/or CA signals from the IMD 100, for a predetermined amount of time such as 10 seconds, 18 seconds, 20 seconds, etc., to identify valid or normal heartbeat(s) within the data. For example, the systolic peak analysis module 735 can analyze data acquired by the IPS 150 or the IMD 100 to identify and remove effects of noise and/or arrythmia from the signal. As discussed herein, the systolic peak analysis module 735 can segment the signal into pseudo-systolic and pseudo-diastolic segments and define valid heartbeats based on modified systolic content. The systolic peak analysis module 735 determines whether the pressure signal starts with a pseudo-systolic segment or a pseudo-diastolic segment. In response to the pressure signal starting with one of the pseudo-diastolic segments, the systolic peak analysis module 735 can modify systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments, and in response to the pressure signal starting with

one of the pseudo-systolic segments, the systolic peak analysis module 735 can modify the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments

[00158] The IMD 100 may include one or more physiological sensor 770. For example, sensor 770 may adjust pacing stimulation rate according to the exercise state of the patient, detect changes in cardiac output, changes in the physiological condition of the heart, or diurnal changes in activity (e.g., detecting sleep and wake states). In other cases, the sensor 770 can obtain accelerometer data with respect to a global coordinate system that is defined relative to a gravitational direction that may be utilized to identify a posture of the patient, movement of the IMD 100 within the patient, etc. While shown as being included within the housing 740, the physiological sensor 770 may be external to the housing 740, yet still, be implanted within or carried by the patient.

[00159] In still further embodiments, the physiological sensor 770 may be the pressure sensor 150 and may be separate from or integrated with the IMD 100.

[00160] Although not shown, the microcontroller 720 may further include other dedicated circuitry and/or firmware/software components that assist in monitoring various conditions of the patient's heart and managing pacing therapies.

[00161] A switch 726 is optionally provided to allow selection of different electrode configurations under the control of the microcontroller 720. The electrode configuration switch 726 may include multiple switches for connecting the desired electrodes to the appropriate I/O circuits, thereby facilitating electrode programmability. The switch 726 is controlled by a control signal 728 from the microcontroller 720. Optionally, the switch 726 may be omitted and the I/O circuits directly connected to a housing electrode via terminal 700 and one or more other electrodes via terminals 702, 704, 706, 708, 710.

[00162] The IMD 100 is further equipped with a communication modem (modulator/demodulator) 742 to enable wireless communication with other

devices, implanted devices such as the IPS 150, and/or external devices 754. In one implementation, the communication modem 742 uses high frequency modulation, for example using RF, Bluetooth or Bluetooth Low Energy telemetry protocols. The signals are transmitted in a high frequency range and will travel through the body tissue in fluids without stimulating the heart or being felt by the patient. The communication modem 742 may be implemented in hardware as part of the microcontroller 720, or as software/firmware instructions programmed into and executed by the microcontroller 720. Alternatively, the modem 742 may reside separately from the microcontroller as a standalone component. The modem 742 facilitates data retrieval from a remote monitoring network. The modem 742 enables timely and accurate data transfer directly from the patient to an electronic device utilized by a physician.

[00163] The IMD 100 includes the sensing circuit 744 selectively coupled to one or more electrodes that perform sensing operations, through the switch 726, to sense cardiac activity data/signals indicative of cardiac activity. The sensing circuit 744 may include dedicated sense amplifiers, multiplexed amplifiers, or shared amplifiers. It may further employ one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and threshold detection circuit to selectively sense the features of interest. In one embodiment, switch 726 may be used to determine the sensing polarity of the cardiac signal by selectively closing the appropriate switches. The sensing circuit 744 is configured to sense CA, on-demand and in real-time, for one or more cardiac cycles and generate one or more CA signals based on the CA.

[00164] In the example of Figure 7, a single sensing circuit 744 is illustrated. Optionally, the IMD 100 may include multiple sensing circuits, similar to sensing circuit 744, where each sensing circuit is coupled to two or more electrodes and controlled by the microcontroller 720 to sense electrical activity detected at the corresponding two or more electrodes. The sensing circuit 744 may operate in a unipolar sensing configuration or a bipolar sensing configuration. Optionally, the

sensing circuit 744 may be removed entirely, and the microcontroller 720 perform the operations described herein based upon the CA signals from the A/D data acquisition system 750 directly coupled to the electrodes. The output of the sensing circuit 744 is connected to the microcontroller 720 which, in turn, determines when to store the cardiac activity data of CA signals (digitized by the A/D data acquisition system 750) in a memory 760.

[00165] In some embodiments, the A/D data acquisition system 750 is coupled to one or more electrodes via the switch 726 to sample cardiac activity signals across any pair of desired electrodes.

[00166] A communications circuit 764 can be utilized by the IMD 100 to send and receive communications and/or data between the IMD 100 and the external device 754 through communications link 765 and can utilize wireless communication protocols similar to / same as the communication modem 742.

[00167] By way of example, the external device 754 may represent a bedside monitor installed in a patient's home and utilized to communicate with the IMD 100 while the patient is at home, in bed or asleep. The external device 754 may be a programmer used in the clinic to interrogate the IMD 100, retrieve data and program detection criteria and other features. The external device 754 may be a handheld device (e.g., smartphone, tablet device, laptop computer, smartwatch and the like) that may be coupled over a network (e.g., the Internet) to a remote monitoring service, medical network and the like. The external device 754 can also act as a one-way and/or bidirectional bridge/gateway to convey messages, requests, and/or signals (e.g., CA signals, pressure signals, etc.) between the IMD 100 and the IPS 150. The external device 754 can be the IPS 150. The external device 754 may communicate with the communications circuit 764 of the IMD 100 through the communication link 765. The external device 754 facilitates access by physicians to patient data as well as permitting the physician to review real-time CA signals and/or pressure signals as collected by the IMD 100 and/or IPS 150, as well as data associated with valid heartbeats, etc.

[00168] The microcontroller 720 is coupled to a memory 760 by a suitable data/address bus 762. The memory 760 stores one or more diastolic-enhanced systolic peak detection algorithms 737 that may be selected and/or modified by a physician to personalize the treatment to the patient's particular condition. The memory 760 also stores one or more score algorithms for determining the score for each modified pseudo-systolic peak, and one or more threshold for differentiating valid and invalid peaks. The scoring algorithms and/or thresholds may be modifiable and/or customizable to personalize the treatment for the patient. It should be understood that the IPS 150, external device 104, and wearable device170 can also store one or more diastolic-enhanced systolic peak detection algorithms that may be selected and/or modified by a physician to personalize the treatment to the patient's particular condition, one or more score algorithms for determining the score for each modified pseudo-systolic peak, and one or more threshold for differentiating valid and invalid peaks, wherein the scoring algorithms and/or thresholds may be modifiable and/or customizable to personalize the treatment for the patient. The memory 760 stores the CA signals and can also store pressure signals, templates, as well as markers and other data content associated with the acquired signals. The memory 760 also stores program instructions for accomplishing the embodiments described herein.

[00169] A battery 772 provides operating power to some or all of the components in the IMD 100. The battery 772 is capable of operating at low current drains for long periods of time. The battery 772 also desirably has a predictable discharge characteristic so that elective replacement time may be detected. As one example, the housing 740 employs lithium/silver vanadium oxide batteries. The battery 772 may afford various periods of longevity (e.g., three years or more of device monitoring). In alternate embodiments, the battery 772 could be rechargeable. See, for example, U.S. Patent Number 7,294,108**,** titled "Cardiac event micro-recorder and method for implanting same", which is hereby incorporated by reference in its entirety.

[00170] The IMD 100 further includes an impedance measuring circuit 774, which can be used for many things, including: lead impedance surveillance for proper lead positioning or dislodgement; detecting operable electrodes and automatically switching to an operable pair if dislodgement occurs; measuring thoracic impedance for determining shock thresholds; detecting when the device has been implanted; measuring stroke volume; and detecting the opening of heart valves; and so forth. The impedance measuring circuit 774 is coupled to the switch 726 so that any desired electrode may be used.

[00171] Figure 8 illustrates a digital healthcare system 800 implemented in accordance with embodiments herein. The system 800 utilizes signals detected by an IMD and/or an IPS, implanted for example in a patient's pulmonary artery and/or other vessel, to analyze and determine valid heartbeats of a patient. The healthcare system 800 may include wearable devices that communicate with an IMD, IPS, external device, and/or a remote database. As a result, the healthcare system 800 may monitor health parameters of a patient, including valid heartbeats, heart rate, HRV, cardiac output, etc., and/or therapies applied utilizing the health parameters, and provide a diagnosis and/or recommendations for the patient based on the monitored health parameters.

[00172] The system 800 may be implemented with various architectures, that are collectively referred to as a healthcare system 820. By way of example, the healthcare system 820 may be implemented as described herein. The healthcare system 820 is configured to receive data, including IMD data, from a variety of external and implantable sources including, but not limited to, active IMDs 802 capable of delivering therapy to a patient, passive IMDs (e.g., cardiac monitors) or sensors 804 (e.g., IPS), wearable devices/sensors 808, and point-of-care (POC) devices 810 (e.g., at home or at a medical facility). Any of the IMD 802, sensor 804, sensor 808, and/or POC device 810 may analyze a signal acquired for a period of time to determine the valid heartbeats as described herein. The data from one or more of the external and/or implantable sources is collected and

communicated to one or more secure databases within the healthcare system 820. Optionally, the patient and/or other users may utilize a device, such as a smart phone, tablet device, etc., to enter data.

Closing

[00173] It should be clearly understood that the various arrangements and processes broadly described and illustrated with respect to the Figures, and/or one or more individual components or elements of such arrangements and/or one or more process operations associated of such processes, can be employed independently from or together with one or more other components, elements and/or process operations described and illustrated herein. Accordingly, while various arrangements and processes are broadly contemplated, described and illustrated herein, it should be understood that they are provided merely in illustrative and non-restrictive fashion, and furthermore can be regarded as but mere examples of possible working environments in which one or more arrangements or processes may function or operate.

[00174] As will be appreciated by one skilled in the art, various aspects may be embodied as a system, method or computer (device) program product. Accordingly, aspects may take the form of an entirely hardware embodiment or an embodiment including hardware and software that may all generally be referred to herein as a "circuit," "module" or "system." Furthermore, aspects may take the form of a computer (device) program product embodied in one or more computer (device) readable storage medium(s) having computer (device) readable program code embodied thereon.

[00175] Any combination of one or more non-signal computer (device) readable media may be utilized. The non-signal media may be a storage medium. A storage medium may be, for example, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples of a storage medium

would include the following: a portable computer diskette, a hard disk, a random access memory (RAM), a dynamic random access memory (DRAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing.

[00176] Program code for carrying out operations may be written in any combination of one or more programming languages. The program code may execute entirely on a single device, partly on a single device, as a stand-alone software package, partly on single device and partly on another device, or entirely on the other device. In some cases, the devices may be connected through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made through other devices (for example, through the Internet using an Internet Service Provider) or through a hard wire connection, such as over a USB connection. For example, a server having a first processor, a network interface, and a storage device for storing code may store the program code for carrying out the operations and provide this code through its network interface via a network to a second device having a second processor for execution of the code on the second device.

[00177] Aspects are described herein with reference to the figures, which illustrate example methods, devices and program products according to various example embodiments. The program instructions may be provided to a processor of a general-purpose computer, special purpose computer, or other programmable data processing device or information handling device to produce a machine, such that the instructions, which execute via a processor of the device implement the functions/acts specified. The program instructions may also be stored in a device readable medium that can direct a device to function in a particular manner, such that the instructions stored in the device readable medium produce an article of manufacture including instructions which implement the function/act specified. The

program instructions may also be loaded onto a device to cause a series of operational steps to be performed on the device to produce a device implemented process such that the instructions which execute on the device provide processes for implementing the functions/acts specified.

[00178] The units/modules/applications herein may include any processor-based or microprocessor-based system including systems using microcontrollers, reduced instruction set computers (RISC), application specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs), logic circuits, and any other circuit or processor capable of executing the functions described herein. Additionally, or alternatively, the modules/controllers herein may represent circuit modules that may be implemented as hardware with associated instructions (for example, software stored on a tangible and non-transitory computer readable storage medium, such as a computer hard drive, ROM, RAM, or the like) that perform the operations described herein. The above examples are exemplary only, and are thus not intended to limit in any way the definition and/or meaning of the term "controller." The units/modules/applications herein may execute a set of instructions that are stored in one or more storage elements, in order to process data. The storage elements may also store data or other information as desired or needed. The storage element may be in the form of an information source or a physical memory element within the modules/controllers herein. The set of instructions may include various commands that instruct the modules/applications herein to perform specific operations such as the methods and processes of the various embodiments of the subject matter described herein. The set of instructions may be in the form of a software program. The software may be in various forms such as system software or application software. Further, the software may be in the form of a collection of separate programs or modules, a program module within a larger program or a portion of a program module. The software also may include modular programming in the form of object-oriented programming. The processing of input data by the processing machine may be in

response to user commands, or in response to results of previous processing, or in response to a request made by another processing machine.

[00179] It is to be understood that the subject matter described herein is not limited in its application to the details of construction and the arrangement of components set forth in the description herein or illustrated in the drawings hereof. The subject matter described herein is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” or “having” and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[00180] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. In addition, many modifications may be made to adapt a particular situation or material to the teachings herein without departing from its scope. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the embodiments should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Moreover, in the following claims, the terms "first," "second," and "third," etc., are used merely as labels, and are not intended to impose numerical requirements on their objects or order of execution on their acts.

WHAT IS CLAIMED IS:

1. A system for determining valid heartbeats, comprising:

an external device; and

an implantable pressure sensor (IPS) comprising:

an IPS sensing circuit configured to sense pressure for a period of time, and to generate a pressure signal based on the pressure; and

an IPS communications circuit configured to communicate with the external device;

wherein at least one of the IPS or external device further comprises:

memory configured to store program instructions; and

one or more processors that, when executing the program instructions, are configured to:

segment the pressure signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length;

determine whether the pressure signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments;

in response to the pressure signal starting with one of the pseudo-diastolic segments, modify systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments;

in response to the pressure signal starting with one of the pseudo-systolic segments, modify the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments; and

determine valid heartbeats based on the modified systolic content.

2. The system of claim 1, wherein the one or more processors further modify the systolic content of the at least one of the pseudo-systolic segments

based on the diastolic content of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segments.

3. The system of claim 1, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or more processors further modify the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the at least one of the pseudo-diastolic segments.

4. The system of claim 1, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or more processors further modify the systolic content of a first pseudo-systolic segment based on the systolic content of the first pseudo-systolic segment.

5. The system of claim 1, wherein the one or more processors are further configured to remove linear trends and non-linear trends from the pressure signal.

6. The system of claim 1, wherein the one or more processors are further configured to, when segmenting the pressure signal:

identify the pseudo-systolic segments based on values of the pressure signal satisfying a threshold; and

identify the pseudo-diastolic segments based on the values of the pressure signal not satisfying the threshold.

7. The system of claim 1, wherein, in response to the pressure signal starting with one of the pseudo-diastolic segments, the one or more processors are further configured to modify the systolic content of the at least one of the pseudo-systolic segments by multiplying values in the at least one of the pseudo-

systolic segment with integrals of the at least one of the pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment.

8. The system of claim 1, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the one or more processors are further configured to:

modify the systolic content of a first pseudo-systolic segment by multiplying values in the first pseudo-systolic segment with an integral of the first pseudo-systolic segment; and

modify the systolic content of at least one of the pseudo-systolic segments following the first pseudo-systolic segment by multiplying values in the at least one of the pseudo-systolic segments with integrals of a same one of the at least one pseudo-systolic segment and integrals of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segment.

9. The system of claim 1, the one or more processors further configured to:

determine a maximum systolic peak value for at least one of the pseudo-systolic segments; and

determine a score associated with the maximum systolic peak value, the score based on i) the maximum systolic peak value, ii) integrals of the pseudo-systolic segment associated with the maximum systolic peak value, iii) integrals of the pseudo-diastolic segment associated with the pseudo-diastolic segment immediately preceding the pseudo-systolic segment associated with the maximum systolic peak value, or iv) cardiac cycle duration, wherein the valid heartbeats are further identified based on the score.

10. The system of claim 9, wherein the one or more processors further identify valid heartbeats i) when the score satisfies a constant value, ii) when the score satisfies a dynamic threshold, iii) when the score satisfies a dynamic threshold based on non-zero values of the pseudo-systolic segments within the period of time, or iv) based on an outlier detection method.

11. The system of claim 1, further comprising an implantable medical device comprising:

an IMD communications circuit configured to communicate with at least one of the IPS or the external device;

memory configured to store the program instructions; and

one or more processors that are configured to execute the program instructions.

12. A computer implemented method for determining valid heartbeats, comprising:

sensing pressure for a period of time at an implantable pressure sensor (IPS);

generating a pressure signal based on the pressure; and

under control of one or more processors configured with executable instructions:

segmenting the pressure signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length;

determining whether the pressure signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments;

in response to the pressure signal starting with one of the pseudo-diastolic segments, modifying systolic content of at least one of the pseudo-

systolic segments based on diastolic content of at least one of the pseudo-diastolic segments;

in response to the pressure signal starting with one of the pseudo-systolic segments, modifying the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments; and

determining valid heartbeats based on the modified systolic content.

13. The method of claim 12, further comprising determining a score associated with the maximum systolic peak value, the score based on i) the maximum systolic peak value, ii) integrals of the pseudo-systolic segment associated with the maximum systolic peak value, iii) integrals of the pseudo-diastolic segment associated with the pseudo-diastolic segment immediately preceding the pseudo-systolic segment associated with the maximum systolic peak value, or iv) cardiac cycle duration, wherein the valid heartbeats are further identified based on the score.

14. The method of claim 12, further comprising modifying the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the pseudo-diastolic segment immediately preceding the at least one of the pseudo-systolic segments.

15. The method of claim 12, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the method further comprises modifying the systolic content of the at least one of the pseudo-systolic segments based on the diastolic content of the at least one of the pseudo-diastolic segments.

16. The method of claim 12, wherein, in response to the pressure signal starting with one of the pseudo-systolic segments, the method further comprises

modifying the systolic content of a first pseudo-systolic segment based on the systolic content of the first pseudo-systolic segment.

17. The method of claim 12, further comprising displaying at least one of a heart rate based on the valid heartbeats, cardiac output based on the valid heartbeats, a treatment notification, or a treatment recommendation.

18. The method of claim 12, further comprising transmitting, with a communications circuit associated with the IPS, at least one of the pressure signal, an indication of the valid heartbeats, a treatment notification based on the valid heartbeats, or a treatment recommendation based on the valid heartbeats.

19. A computer implemented method for determining valid heartbeats, comprising:

sensing a periodic signal associated with cardiac function for a period of time at a sensor;

generating a signal based on the periodic signal; and

under control of one or more processors configured with executable instructions:

segmenting the signal, for the period of time, into pseudo-systolic segments and pseudo-diastolic segments, each of the pseudo-systolic segments and the pseudo-diastolic segments having an associated segment length;

determining whether the signal starts with one of the pseudo-systolic segments or the pseudo-diastolic segments;

in response to the signal starting with one of the pseudo-diastolic segments, modifying systolic content of at least one of the pseudo-systolic segments based on diastolic content of at least one of the pseudo-diastolic segments;

in response to the signal starting with one of the pseudo-systolic segments, modifying the systolic content of at least one of the pseudo-systolic segments based on the systolic content of at least one of the pseudo-systolic segments; and

determining valid heartbeats based on the modified systolic content.

20. The method of claim 19, wherein the sensor is i) positioned outside a body associated with the cardiac function, ii) in contact with skin of the body associated with the cardiac function, or iii) partially or entirely external to the skin of the body associated with the cardiac function.

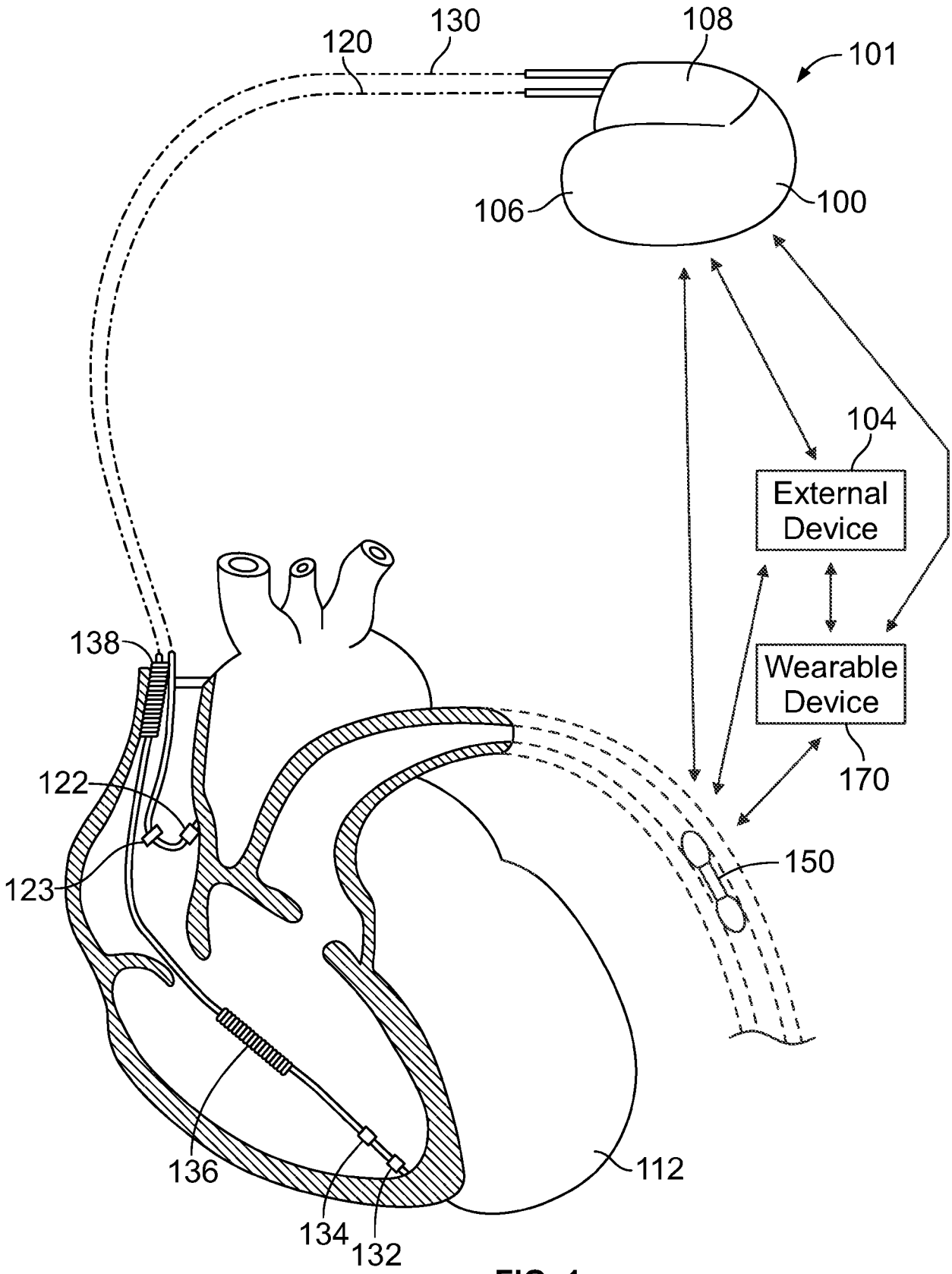
120
130
108
101
106
100
104
External Device
Wearable Device
170
150
138
122
123
136
134
132
112

FIG. 1

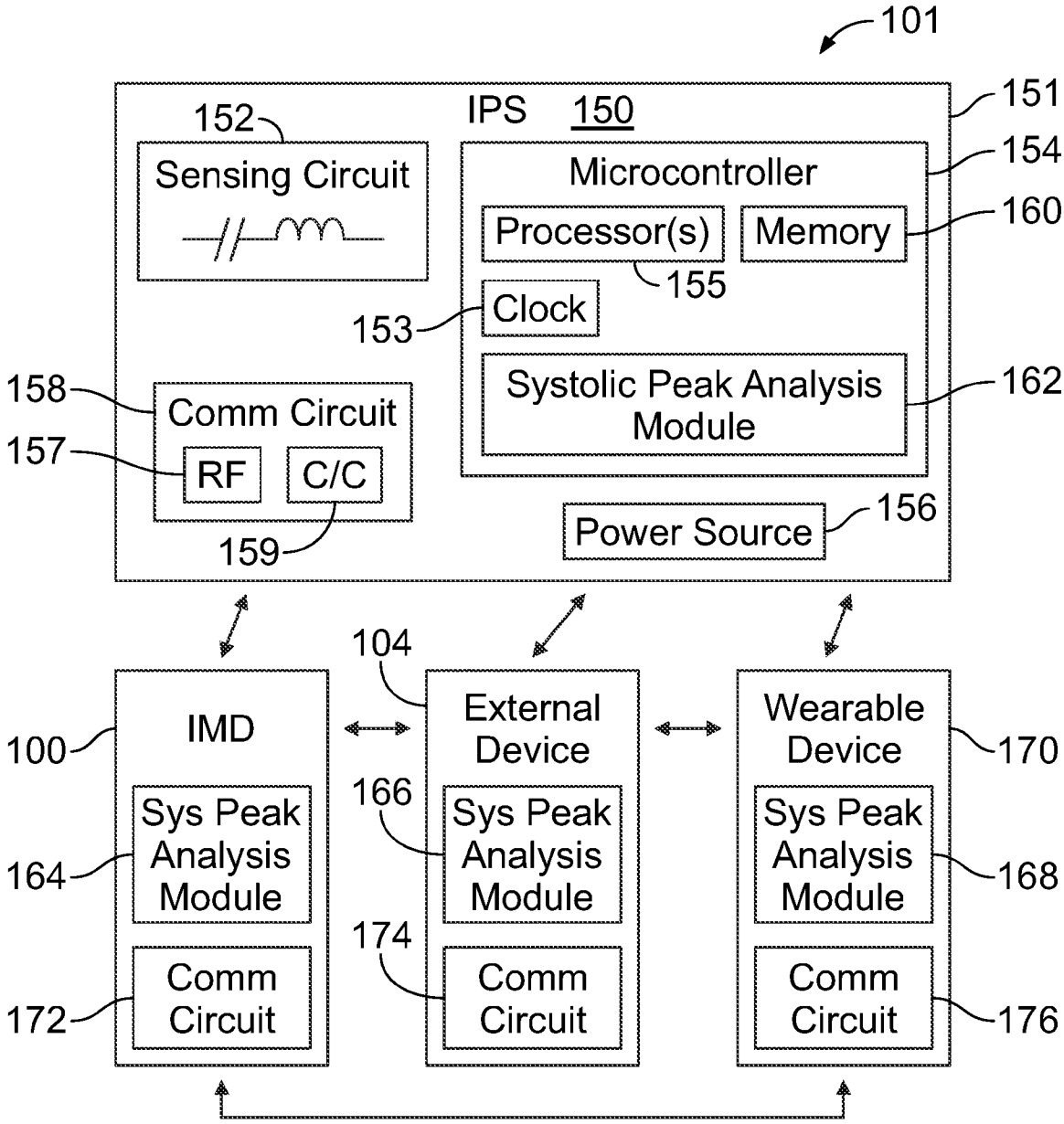
101
IPS 150
151
152
Sensing Circuit
Microcontroller
154
Processor(s)
Memory
160
155
Clock
153
Systolic Peak Analysis Module
162
158
Comm Circuit
157
RF
C/C
159
Power Source
156
104
IMD
External Device
Wearable Device
100
170
166
Sys Peak Analysis Module
Sys Peak Analysis Module
Sys Peak Analysis Module
164
168
174
Comm Circuit
Comm Circuit
Comm Circuit
172
176

FIG. 2

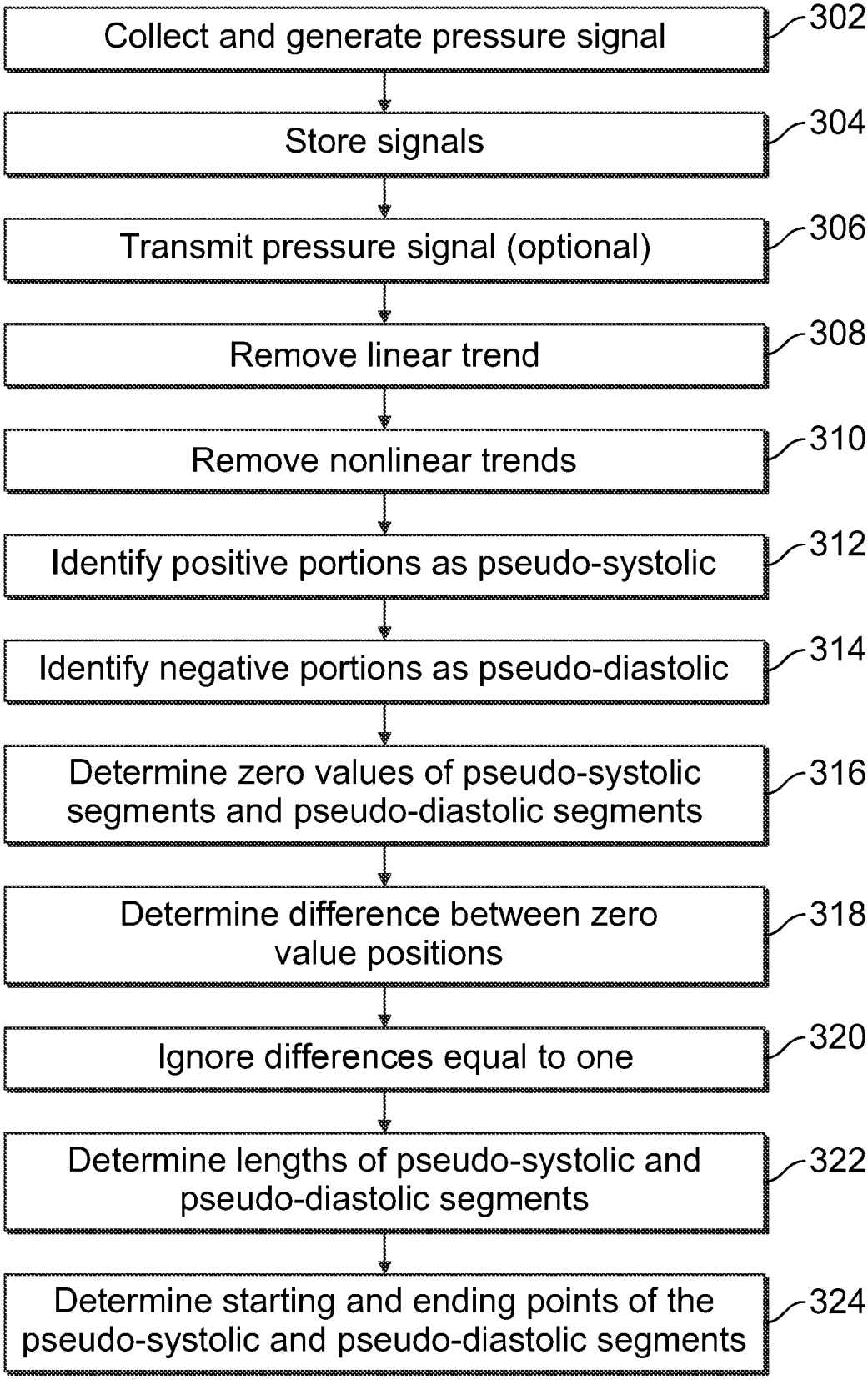
Collect and generate pressure signal
302
Store signals
304
Transmit pressure signal (optional)
306
Remove linear trend
308
Remove nonlinear trends
310
Identify positive portions as pseudo-systolic
312
Identify negative portions as pseudo-diastolic
314
Determine zero values of pseudo-systolic segments and pseudo-diastolic segments
316
Determine difference between zero value positions
318
Ignore differences equal to one
320
Determine lengths of pseudo-systolic and pseudo-diastolic segments
322
Determine starting and ending points of the pseudo-systolic and pseudo-diastolic segments
324

FIG. 3A

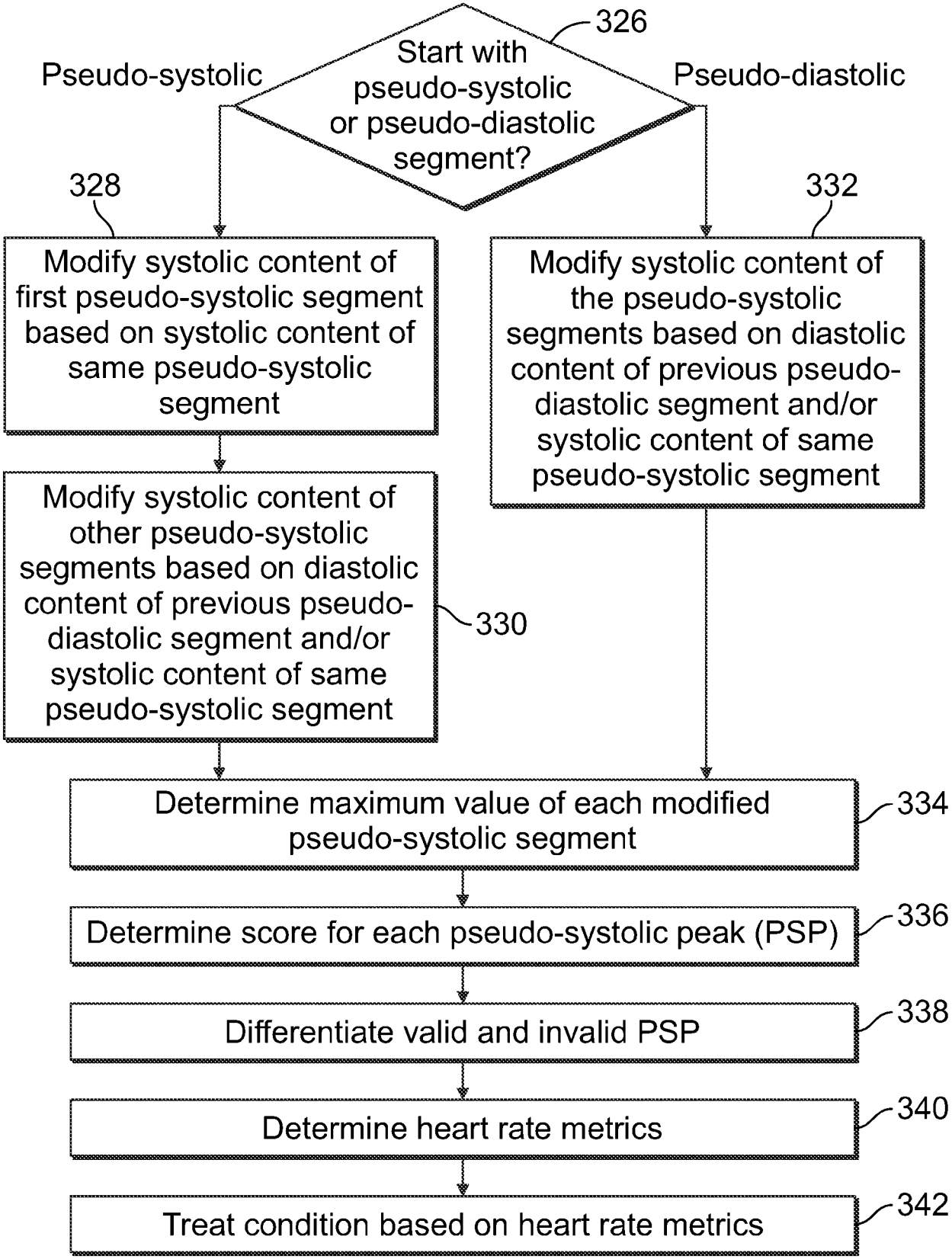
Start with pseudo-systolic or pseudo-diastolic segment?
326
Pseudo-systolic
Pseudo-diastolic
328
332
Modify systolic content of first pseudo-systolic segment based on systolic content of same pseudo-systolic segment
Modify systolic content of the pseudo-systolic segments based on diastolic content of previous pseudo-diastolic segment and/or systolic content of same pseudo-systolic segment
Modify systolic content of other pseudo-systolic segments based on diastolic content of previous pseudo-diastolic segment and/or systolic content of same pseudo-systolic segment
330
Determine maximum value of each modified pseudo-systolic segment
334
Determine score for each pseudo-systolic peak (PSP)
336
Differentiate valid and invalid PSP
338
Determine heart rate metrics
340
Treat condition based on heart rate metrics
342

FIG. 3B

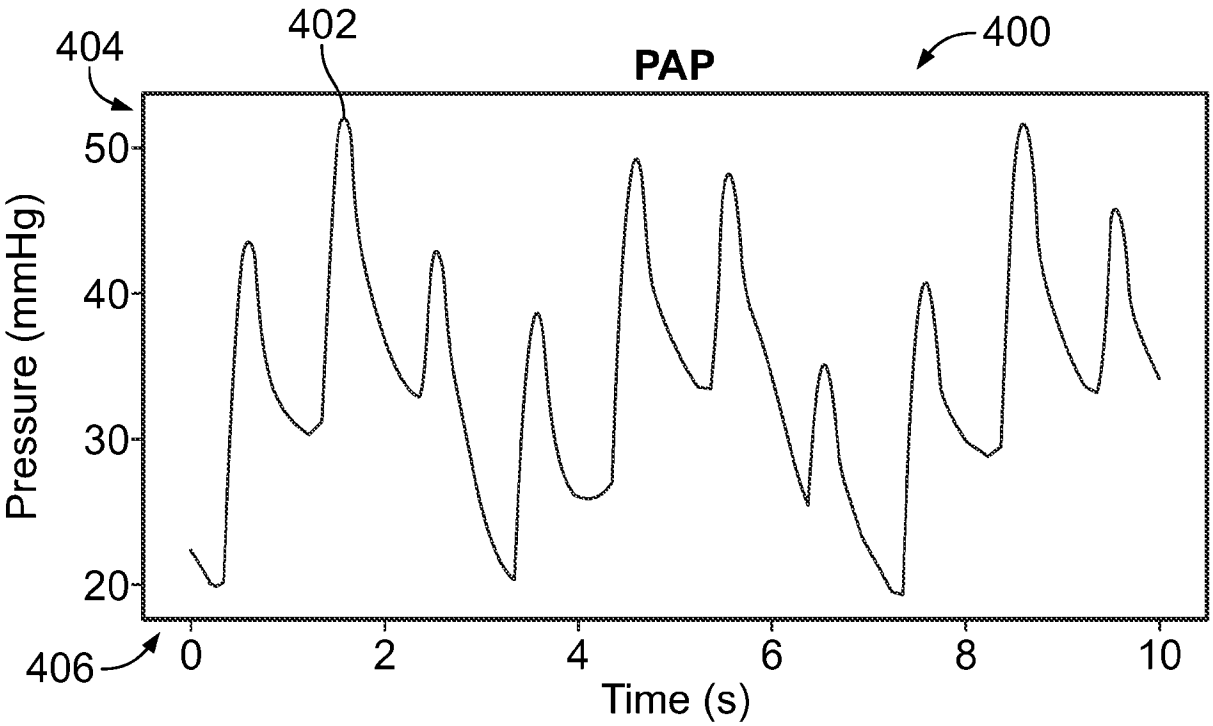
402
404
PAP
400
50
40
30
20
Pressure (mmHg)
406
0
2
4
6
8
10
Time (s)

FIG. 4A

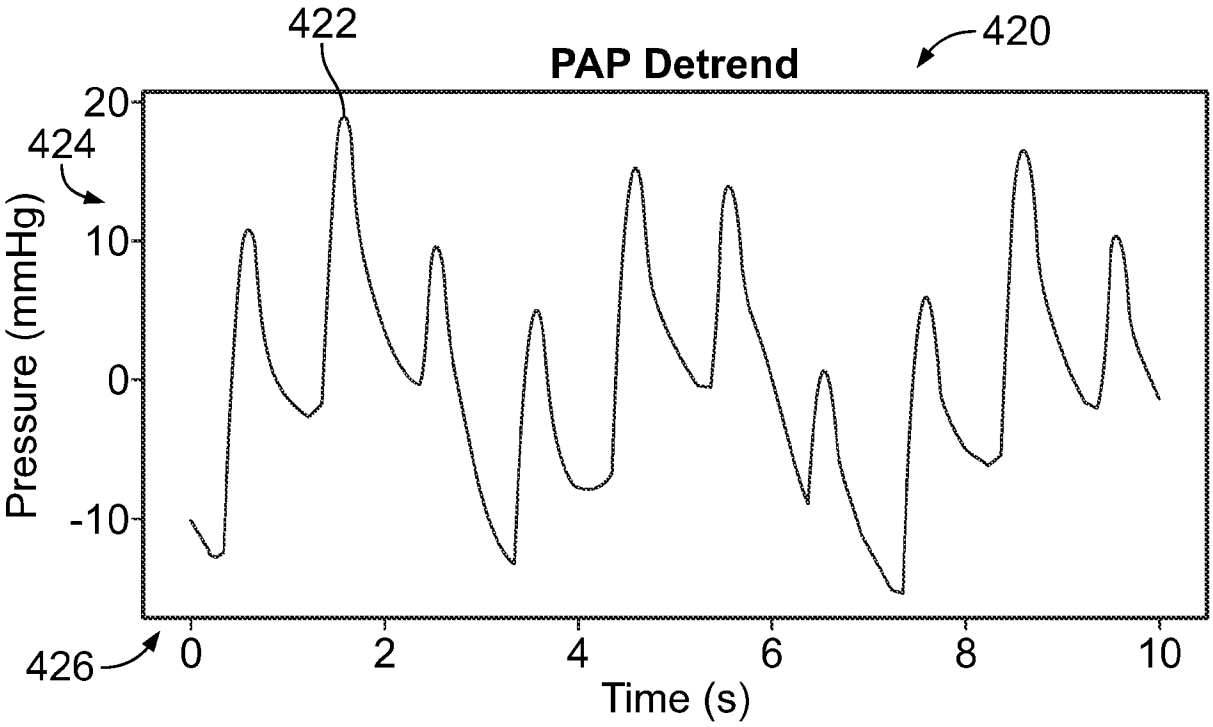
422
PAP Detrend
420
20
424
10
0
-10
Pressure (mmHg)
426
0
2
4
6
8
10
Time (s)

FIG. 4B

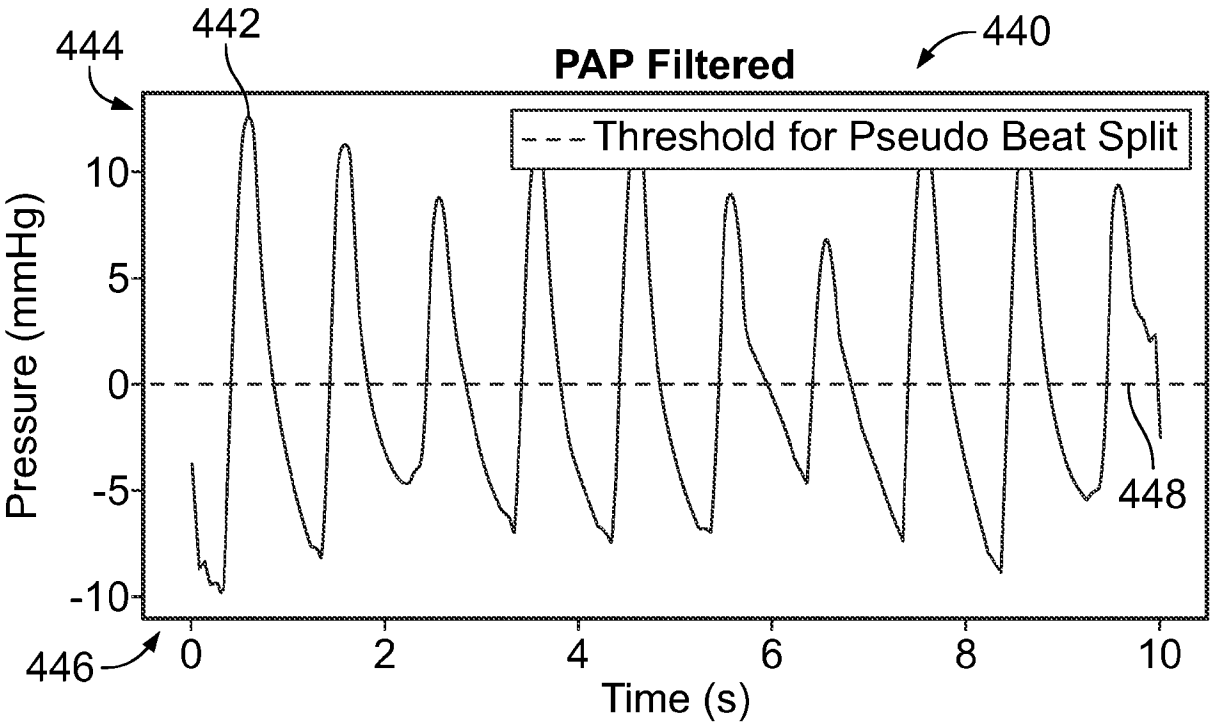
444
442
440
PAP Filtered
Threshold for Pseudo Beat Split
Pressure (mmHg)
10
5
0
-5
-10
448
446
0
2
4
6
8
10
Time (s)

FIG. 4C

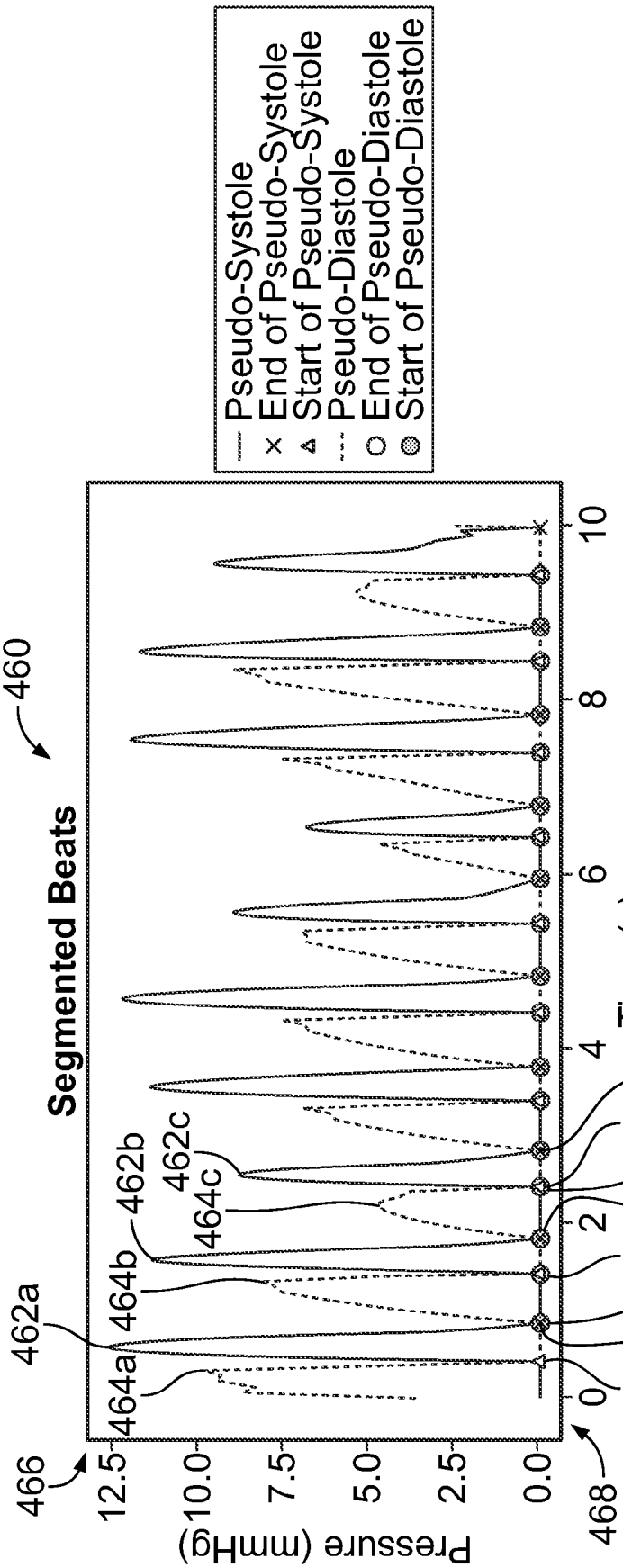
Pseudo-Systole
End of Pseudo-Systole
Start of Pseudo-Systole
Pseudo-Diastole
End of Pseudo-Diastole
Start of Pseudo-Diastole
460
Segmented Beats
462a
464a
462b
464b
462c
464c
466
468
470a
472a
474a
476a
470b
472b
474b
476b
Pressure (mmHg)
12.5
10.0
7.5
5.0
2.5
0.0
0
2
4
6
8
10
Time (s)

FIG. 4D

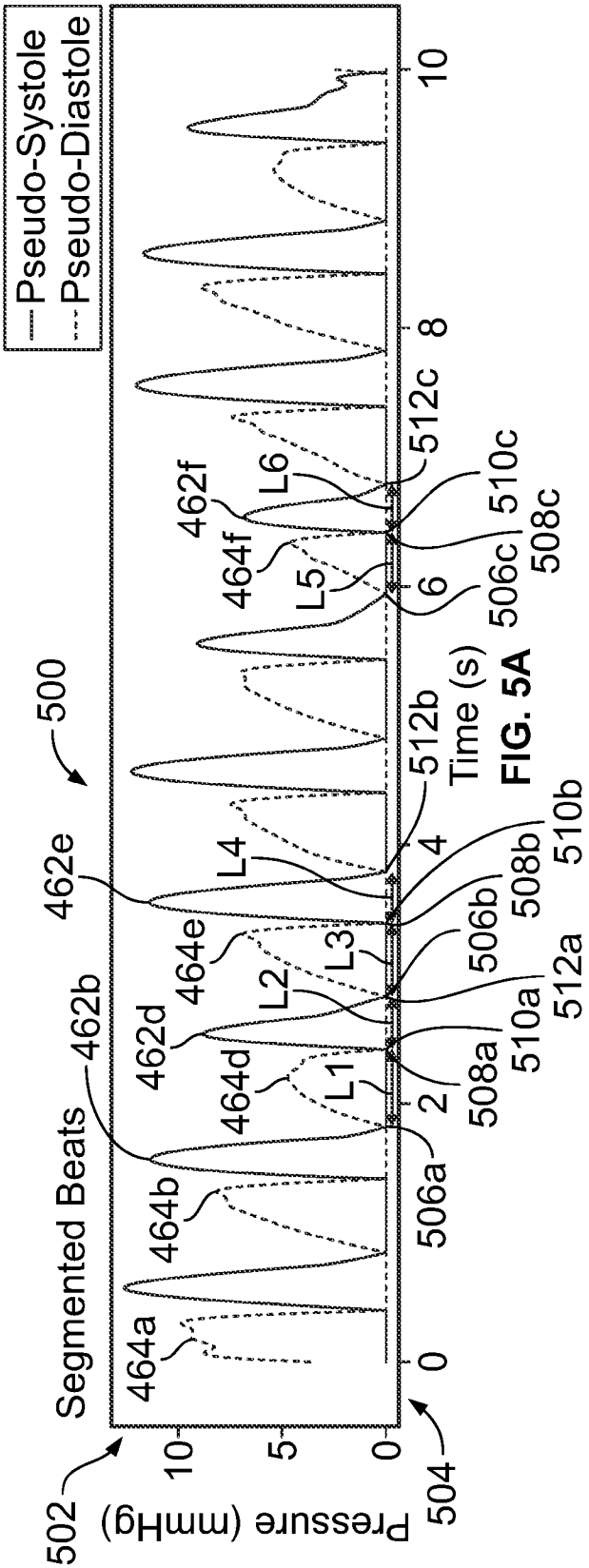
Pseudo-Systole
Pseudo-Diastole
500
Segmented Beats
462e
462b
462d
462f
464a
464b
464d
464e
464f
L1
L2
L3
L4
L5
L6
502
504
Pressure (mmHg)
Time (s)
512a
512b
512c
506a
506b
506c
508a
508b
508c
510a
510b
510c

FIG. 5A

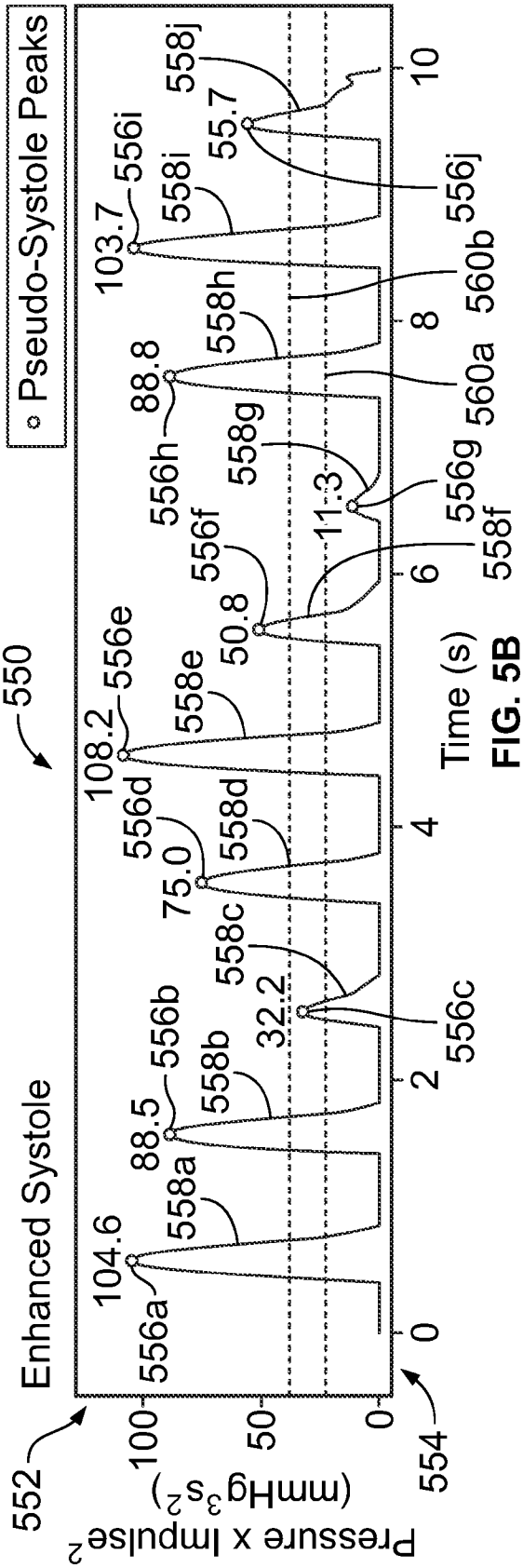
Pseudo-Systole Peaks
550
Enhanced Systole
552
554
Pressure x Impulse²
(mmHg³s²)
Time (s)
104.6
108.2
88.5
75.0
32.2
50.8
11.3
103.7
88.8
55.7
556a
556b
556c
556d
556e
556f
556g
556h
556i
556j
558a
558b
558c
558d
558e
558f
558g
558h
558i
558j
560a
560b

FIG. 5B

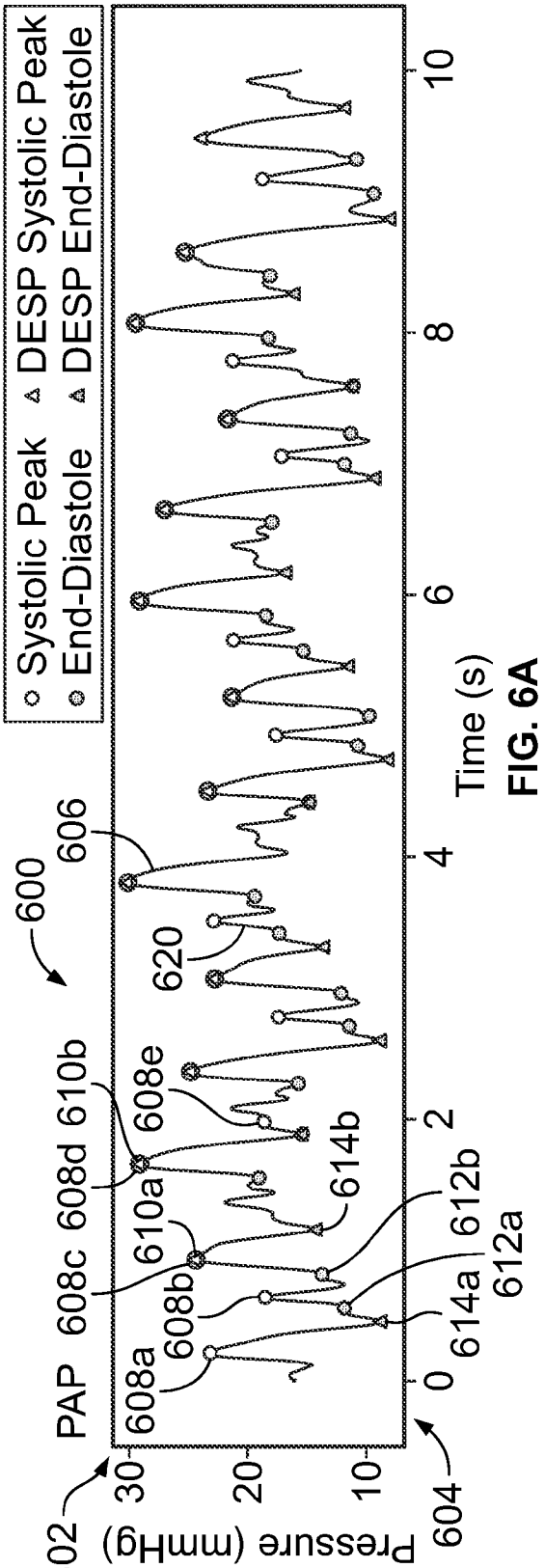
Systolic Peak
End-Diastole
DESP Systolic Peak
DESP End-Diastole
600
606
620
PAP
608a
608b
608c
608d
608e
610a
610b
614a
614b
612a
612b
602
604
Pressure (mmHg)
Time (s)

FIG. 6A

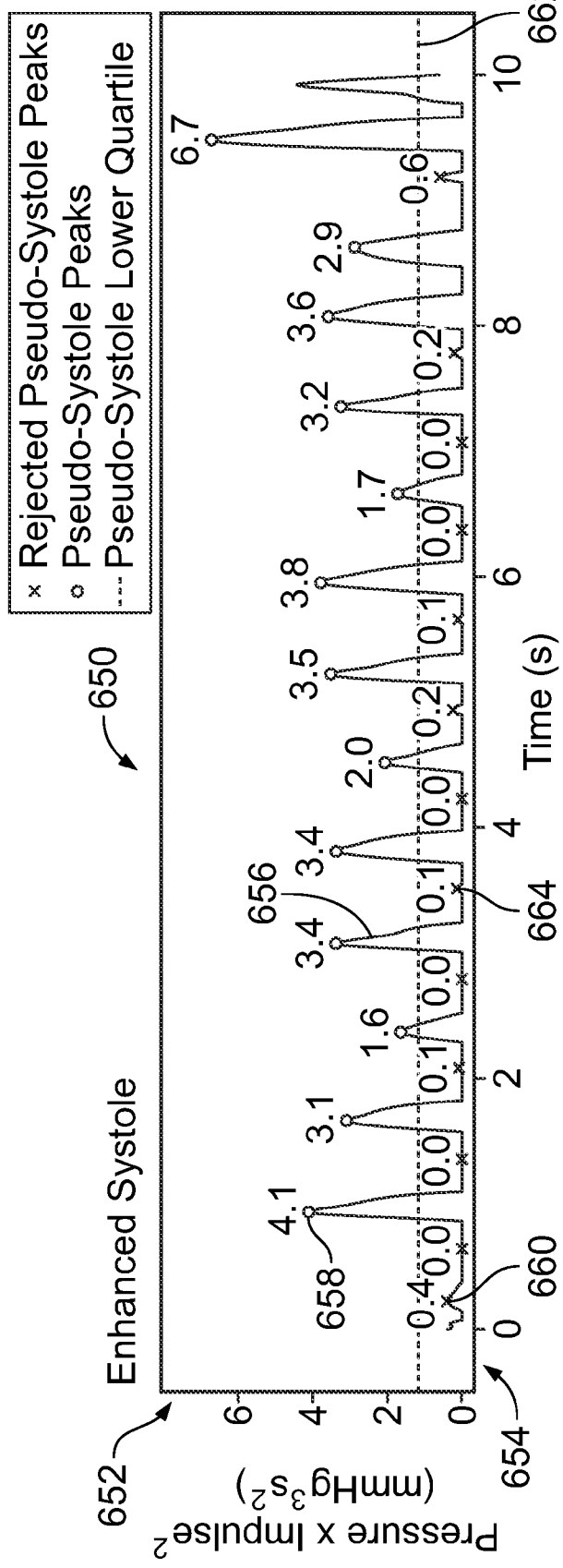
Rejected Pseudo-Systole Peaks
Pseudo-Systole Peaks
Pseudo-Systole Lower Quartile
650
662
Enhanced Systole
656
658
660
664
652
654
Pressure x Impulse²
(mmHg³s²)
Time (s)

FIG. 6B

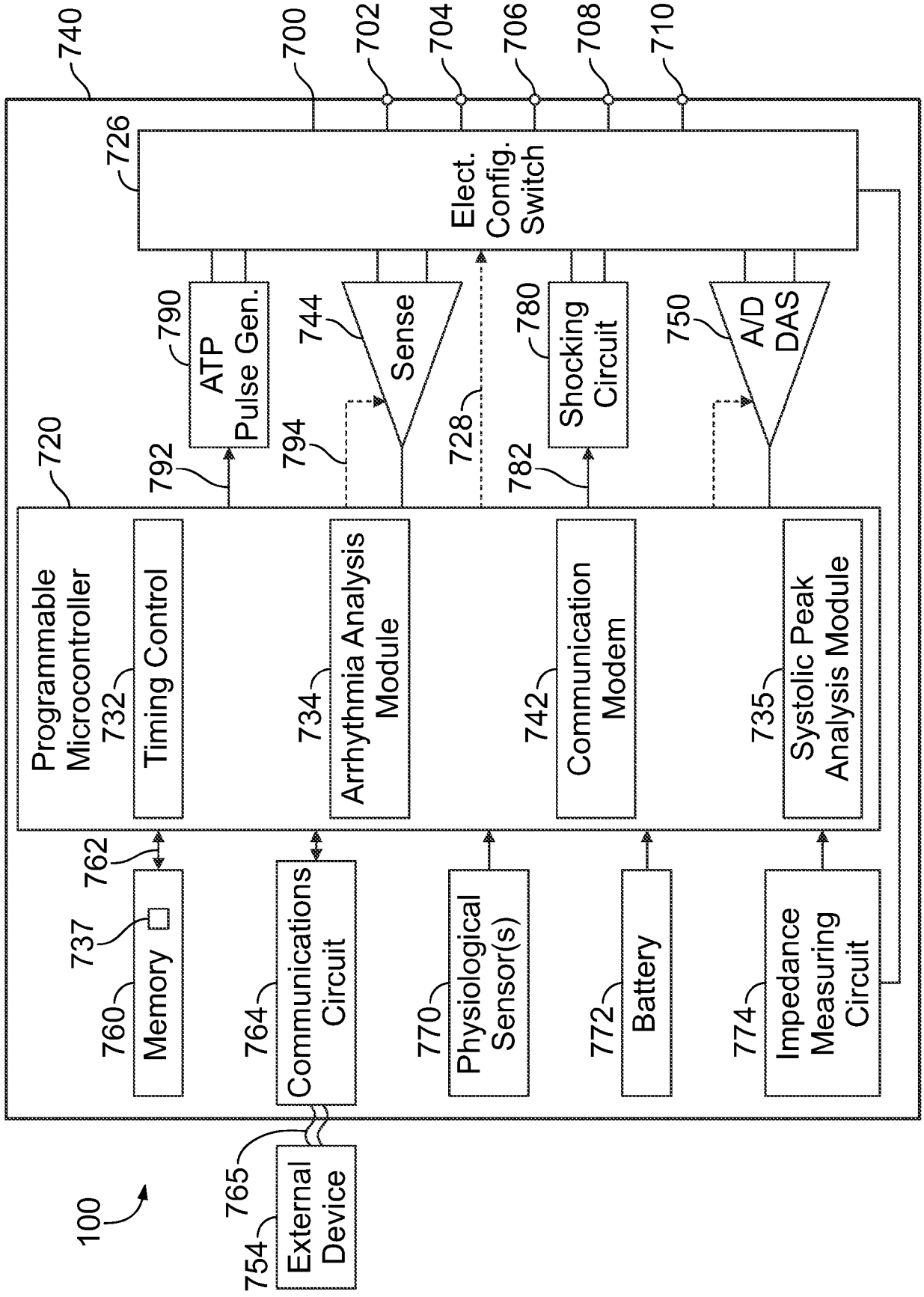
100
740
700
702
704
706
708
710
726
Elect. Config. Switch
790
ATP Pulse Gen.
744
Sense
780
Shocking Circuit
750
A/D DAS
720
792
794
728
782
Programmable Microcontroller
732
Timing Control
734
Arrhythmia Analysis Module
742
Communication Modem
735
Systolic Peak Analysis Module
762
737
760
Memory
764
Communications Circuit
770
Physiological Sensor(s)
772
Battery
774
Impedance Measuring Circuit
765
754
External Device

FIG. 7

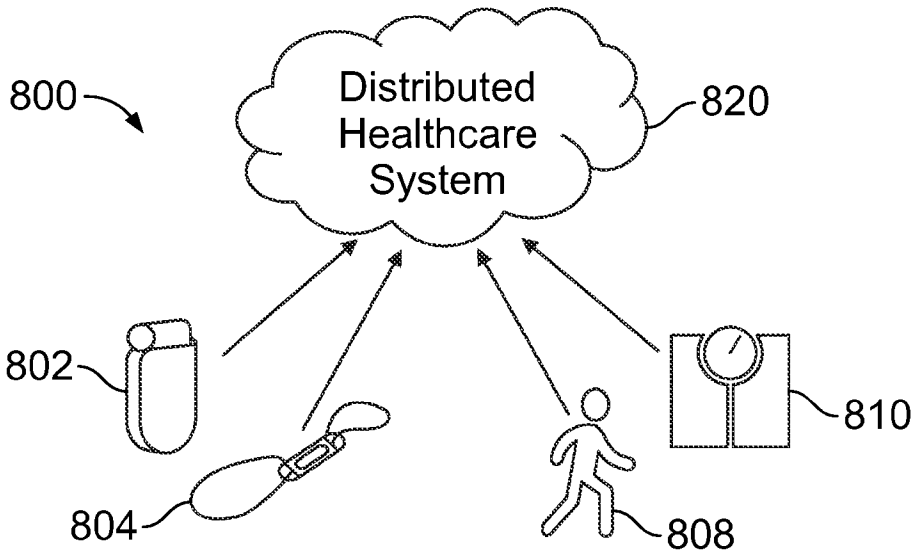

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/052734

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0215 A61B5/352 A61B5/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, INSPEC, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2010/056931 A1 (SOFFER LEAH [US] ET AL) 4 March 2010 (2010-03-04) the whole document	1-20
A	US 2009/062667 A1 (FAYRAM TIMOTHY A [US] ET AL) 5 March 2009 (2009-03-05) paragraph [0011] - paragraph [0018] paragraph [0027] - paragraph [0055] figures 1-4	1-20
A	US 2014/142443 A1 (NGO THAO [US] ET AL) 22 May 2014 (2014-05-22) paragraph [0007] - paragraph [0013] paragraph [0054] - paragraph [0059] figures 1-12	1-20
A	US 2001/034488 A1 (POLICKER SHAL [IL] ET AL) 25 October 2001 (2001-10-25) the whole document	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 January 2025	27/01/2025

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Abraham, Volkhard

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2024/052734

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		JP 2012501218 A	19-01-2012
		US 2010056931 A1	04-03-2010
		WO 2010027652 A1	11-03-2010
US 2009062667 A1	05-03-2009	EP 2030564 A2	04-03-2009
		US 2009062667 A1	05-03-2009
		US 2012108987 A1	03-05-2012
US 2014142443 A1	22-05-2014	NONE	
US 2001034488 A1	25-10-2001	AU 3403001 A	20-08-2001
		US 2001034488 A1	25-10-2001
		WO 0158517 A2	16-08-2001