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(54) **MEASUREMENT OF CARDIAC CYCLE LENGTH AND PRESSURE METRICS FROM PULMONARY ARTERIAL PRESSURE**

(52) **U.S. Cl.**
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(71) Applicant: **Medtronic, Inc.**, Minneapolis, MN (US)

(72) Inventor: **Saul E. Greenhut**, Denver, CO (US)

(21) Appl. No.: **16/524,360**

(57) **ABSTRACT**

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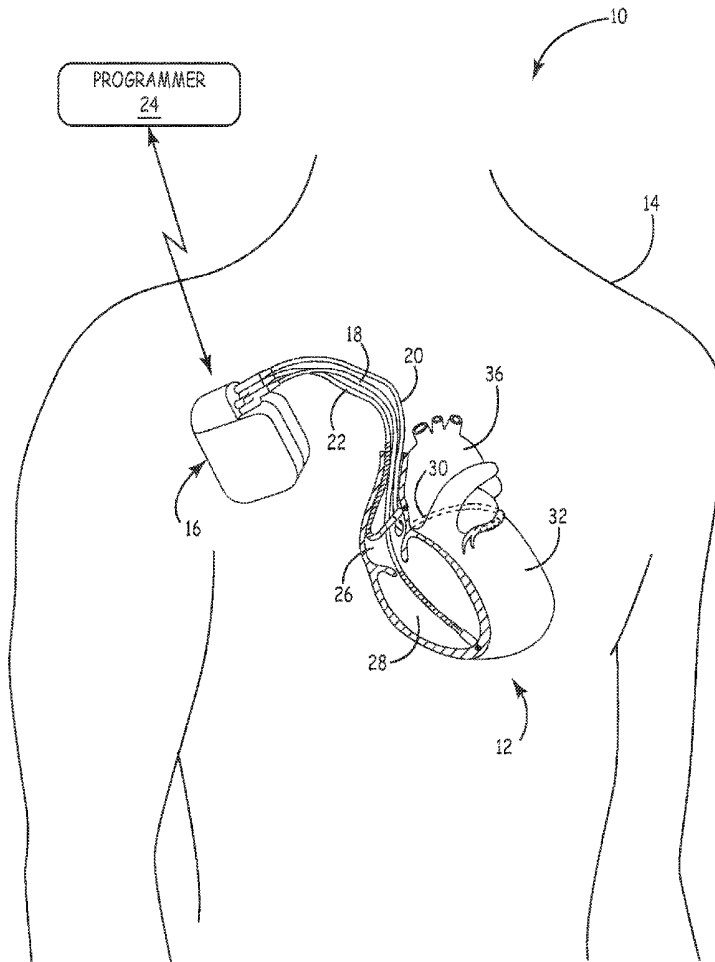
A method and apparatus for monitoring a cardiovascular pressure signal in a medical device that includes determining whether the sensed pressure signal is greater than a first pressure threshold, determining a first metric of the pressure signal in response to the sensed pressure signal being greater than the first pressure threshold, determining whether the sensed pressure signal is greater than a second pressure threshold not equal to the first pressure threshold, determining a second metric of the pressure signal in response to the sensed pressure signal being greater than the first pressure threshold, and determining at least one of a systolic pressure or a diastolic pressure, wherein the at least one of a systolic pressure or a diastolic pressure is determined based on the first metric in response to the pressure signal not being greater than the second threshold, and based on the second metric in response to the pressure signal being greater than the second threshold.

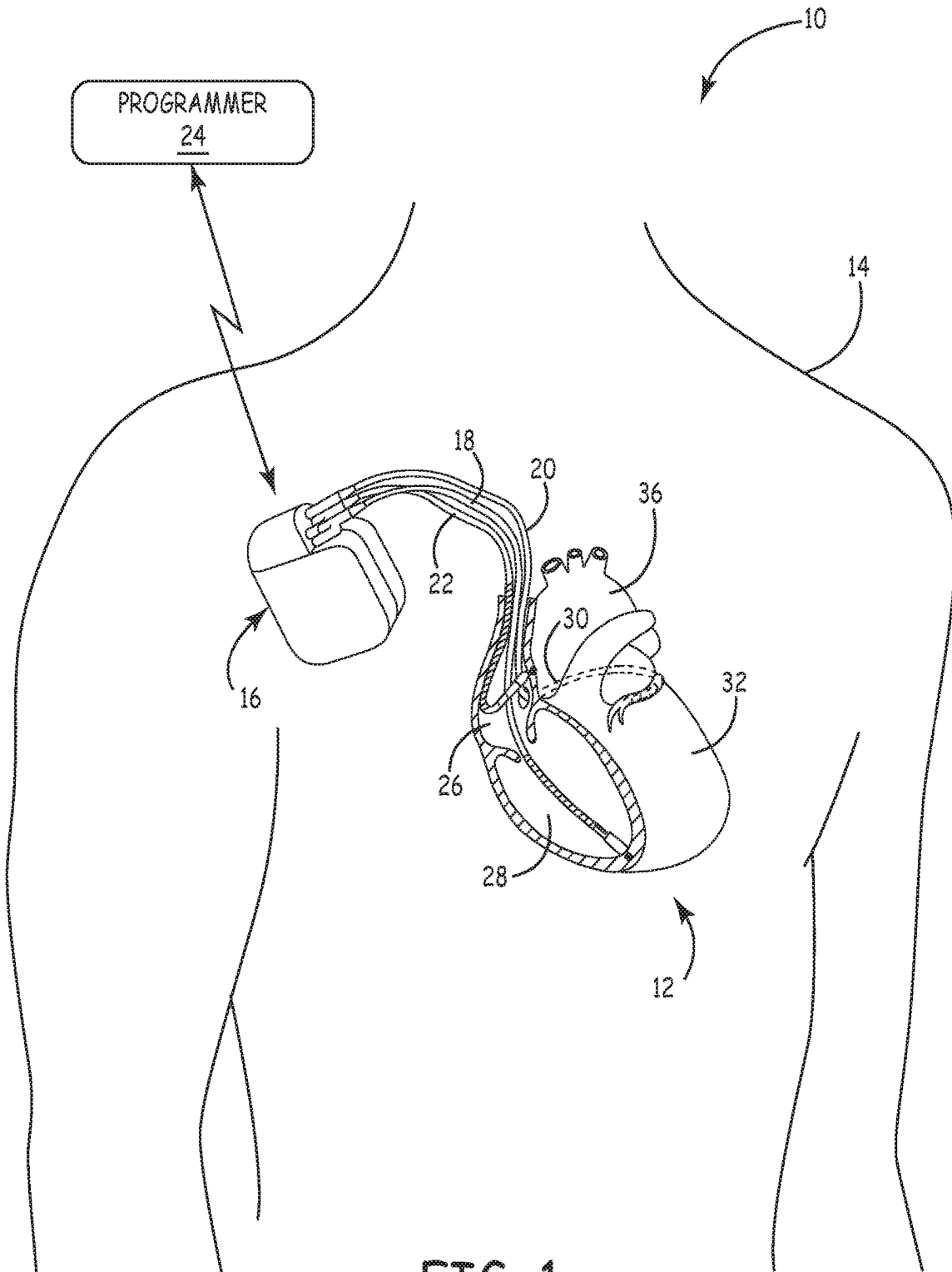
Related U.S. Application Data

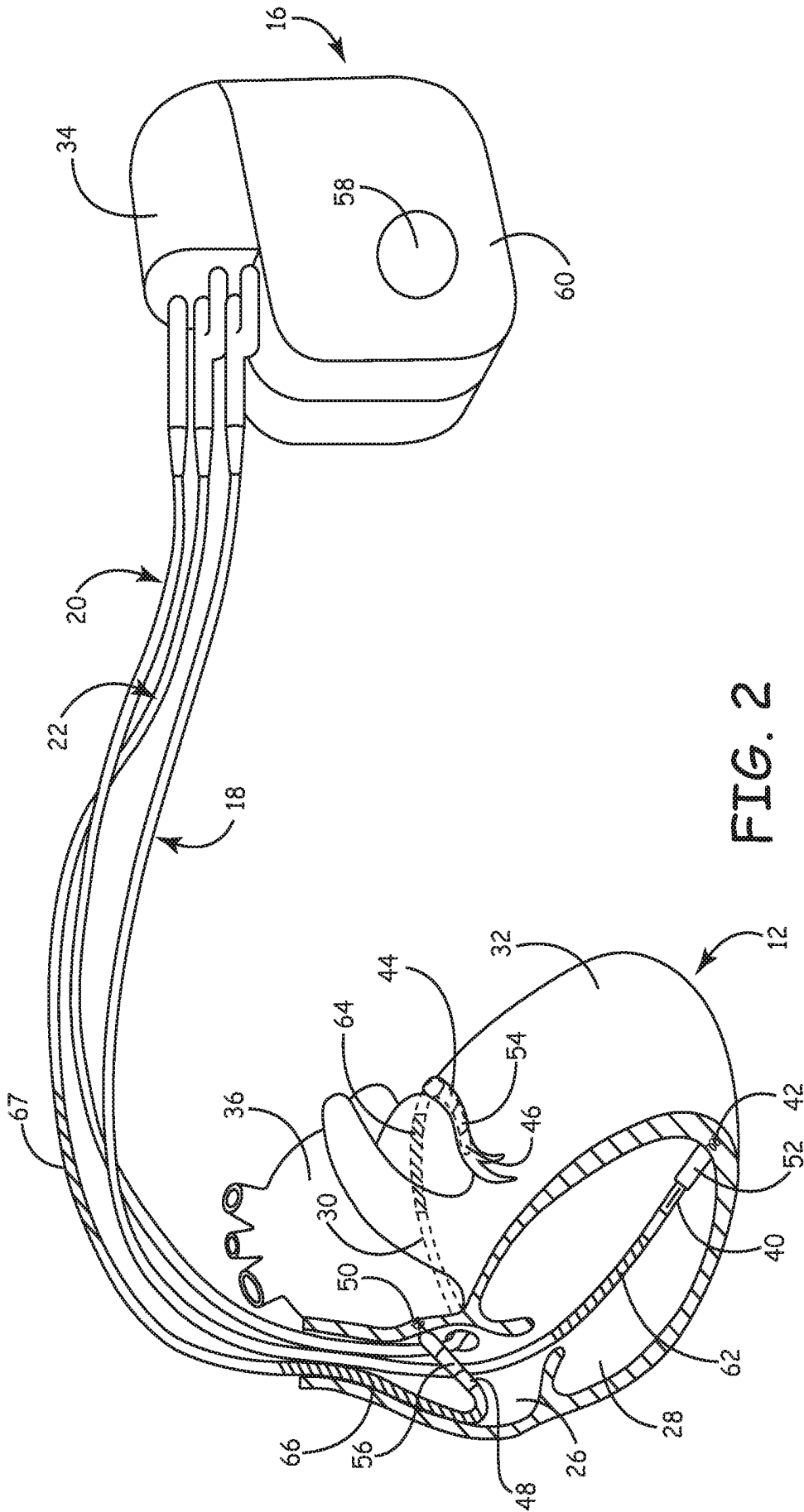
(60) Division of application No. 15/131,770, filed on Apr. 18, 2016, now Pat. No. 10,362,946, which is a continuation of application No. 13/096,012, filed on Apr. 28, 2011, now Pat. No. 9,314,205.

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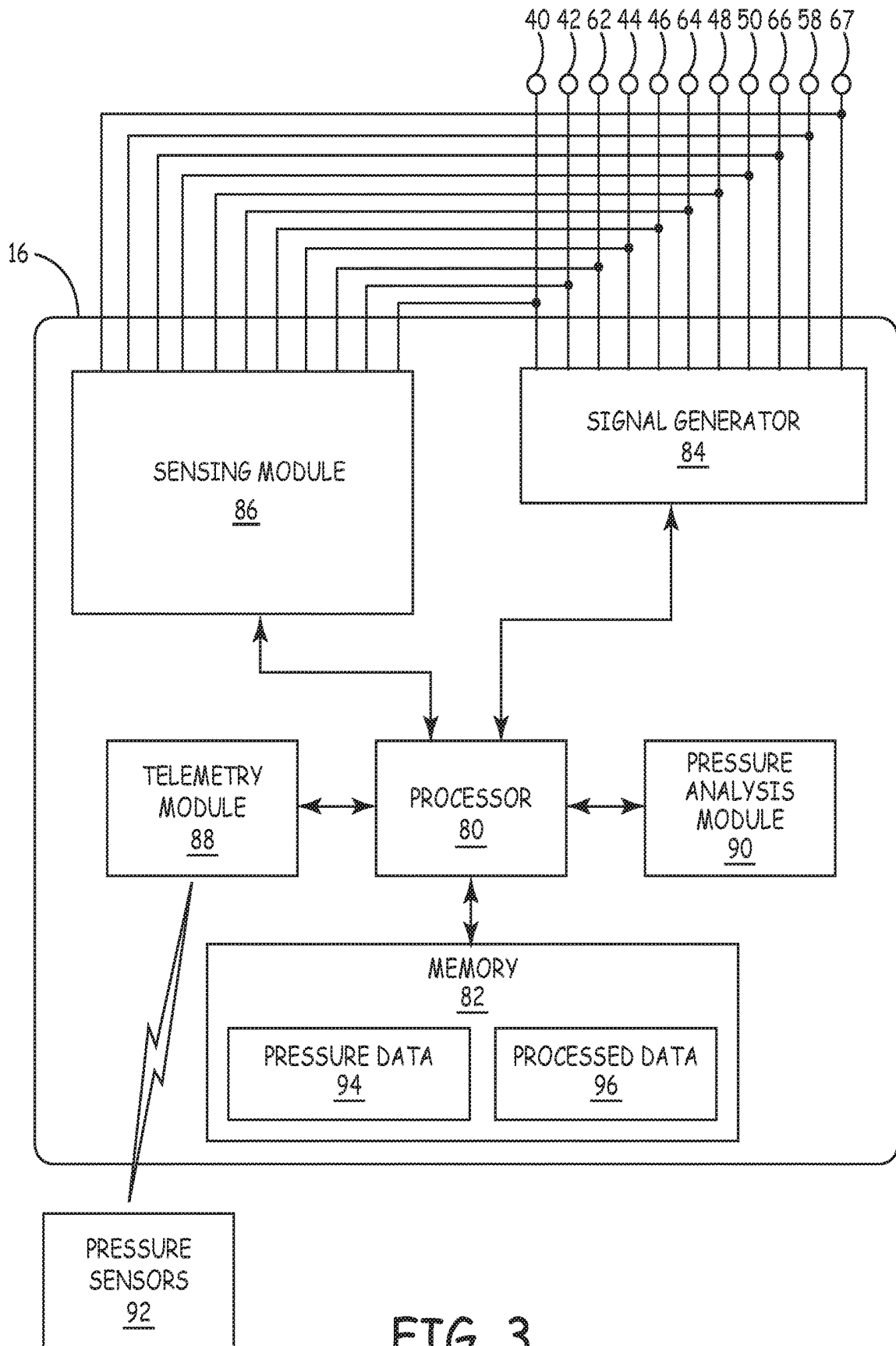


FIG. 3

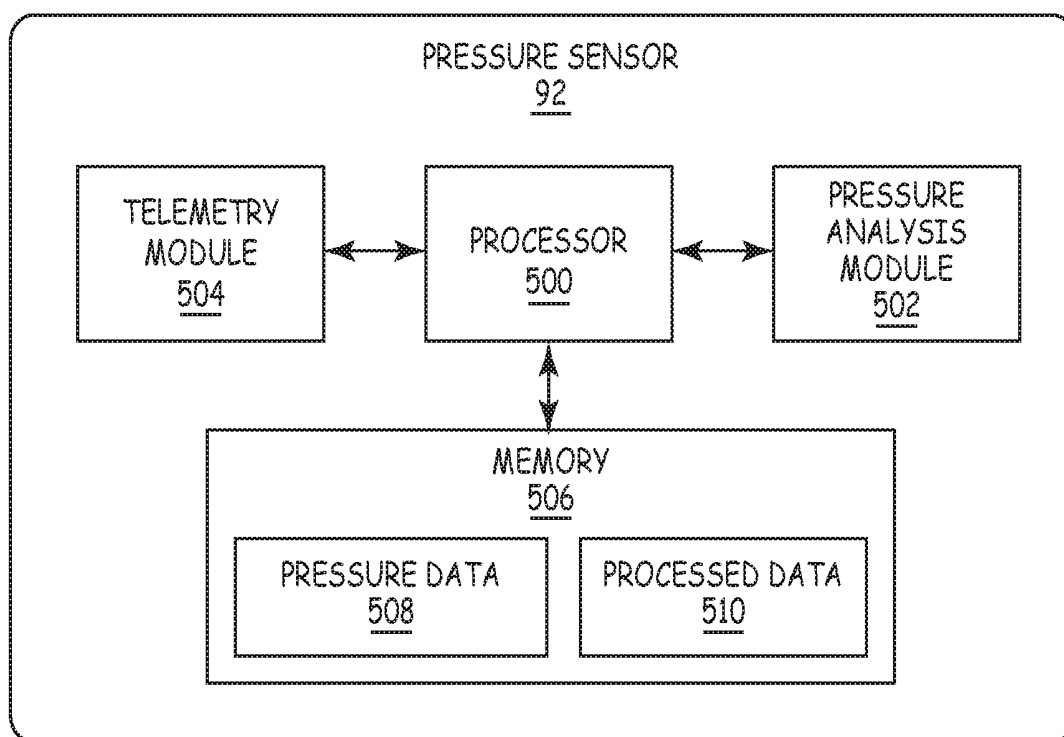


FIG. 4

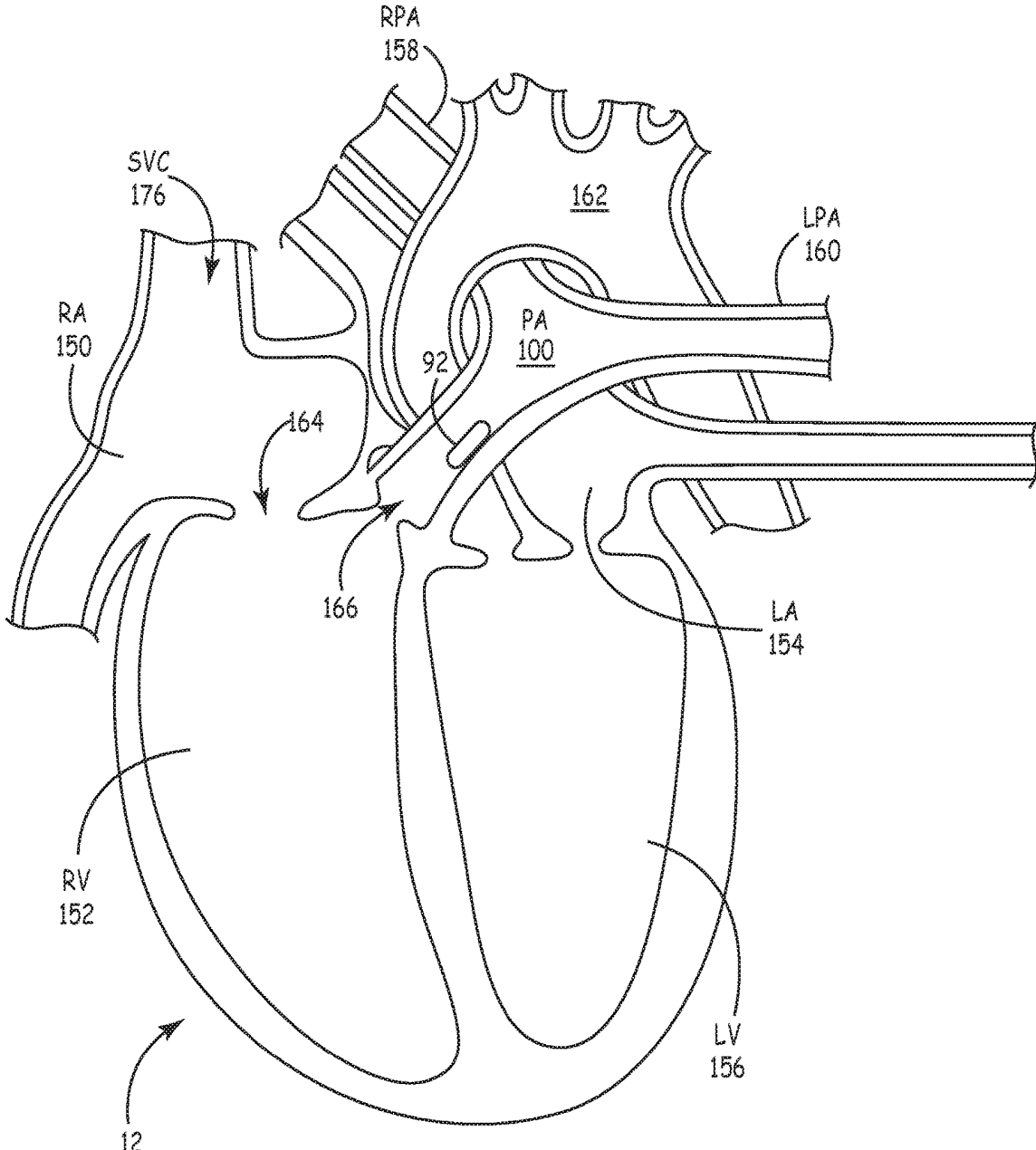


FIG. 5

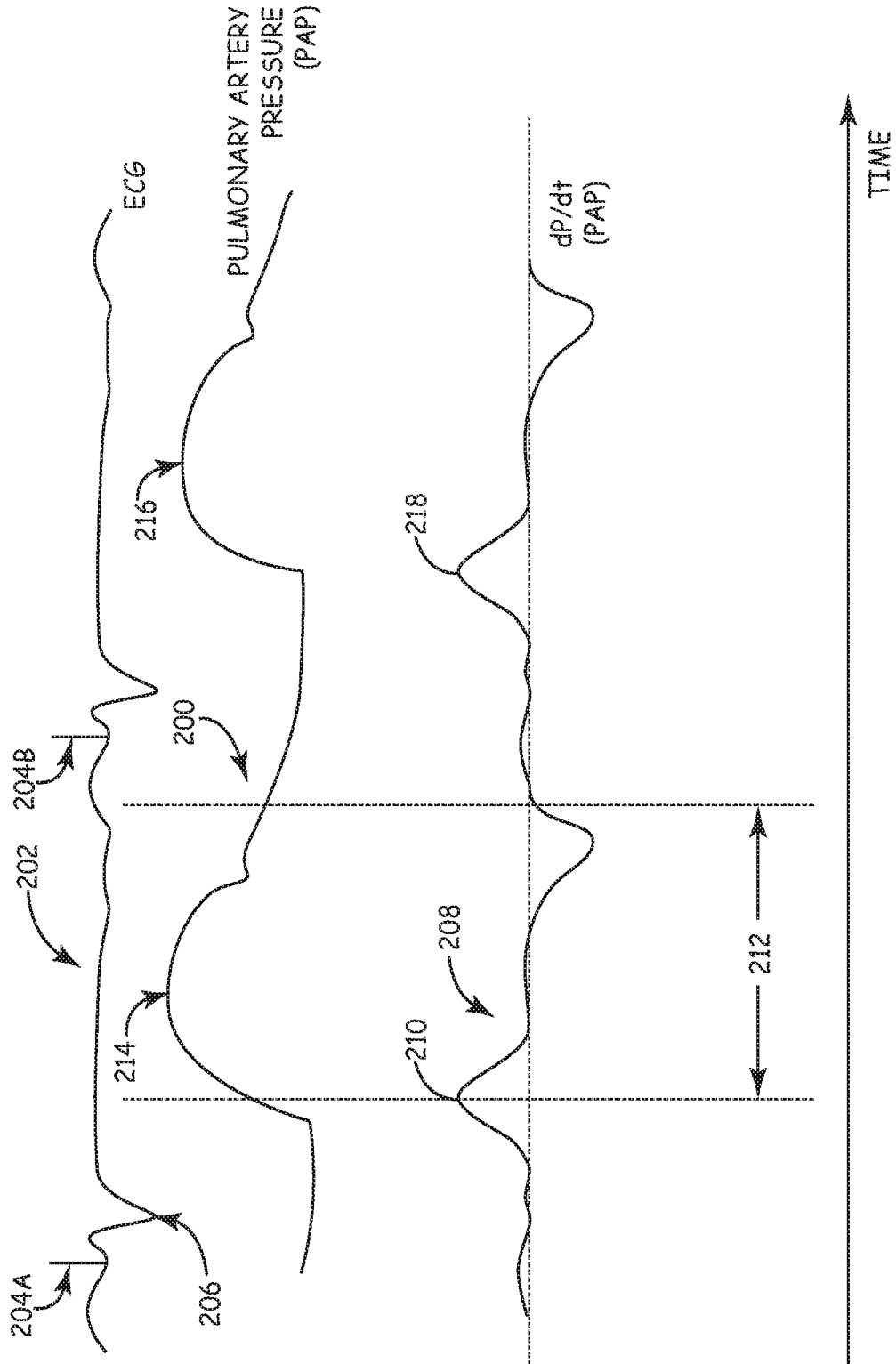


FIG. 6

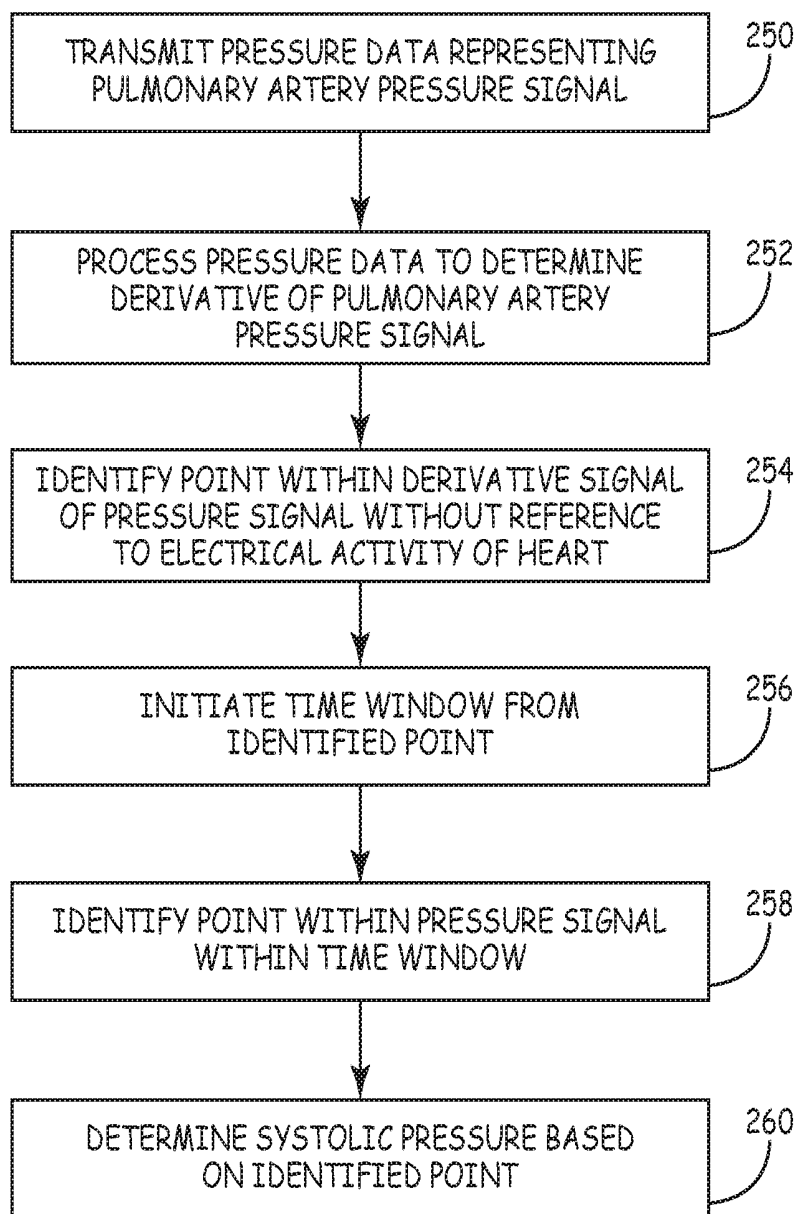


FIG. 7

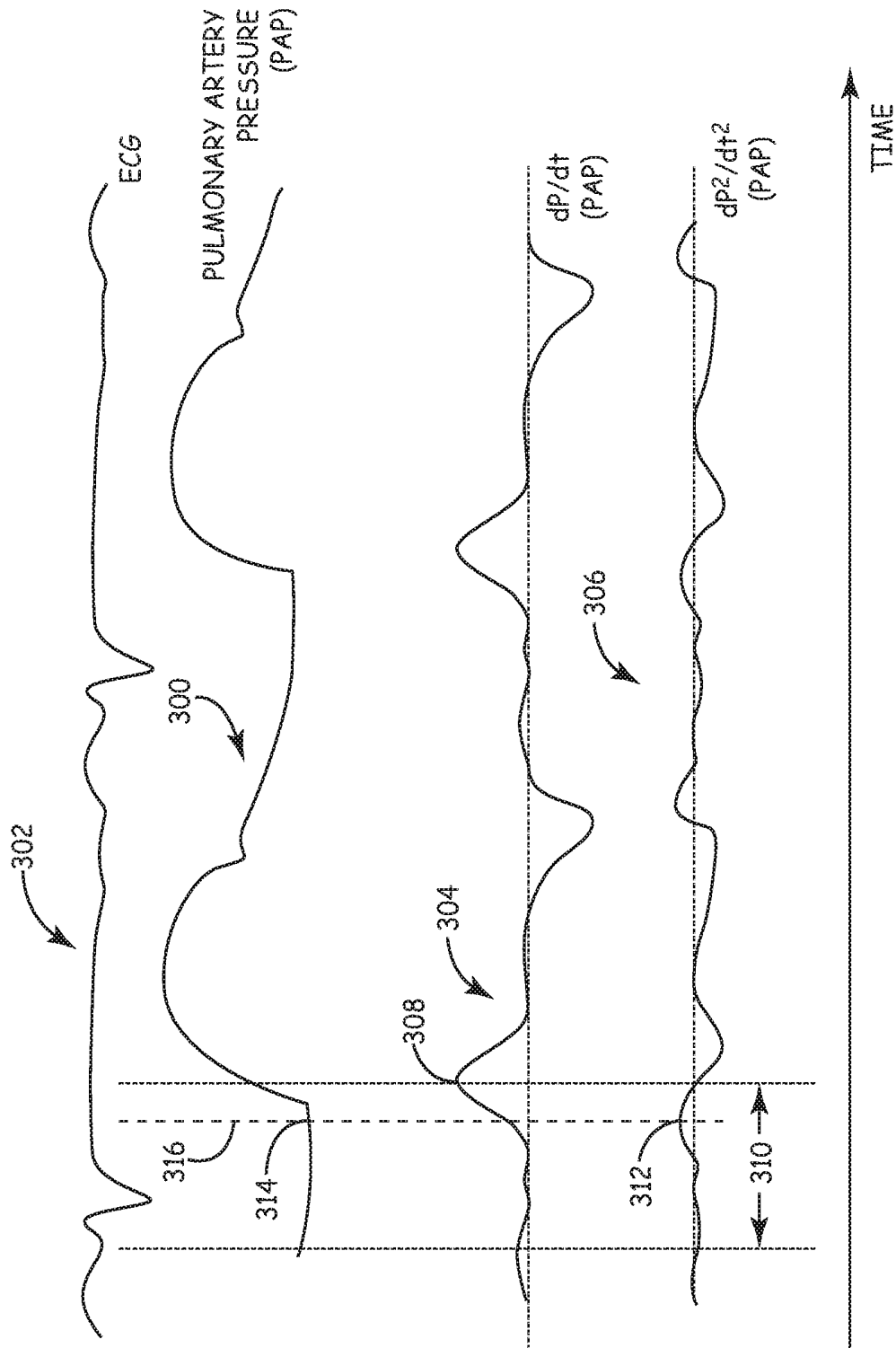


FIG. 8

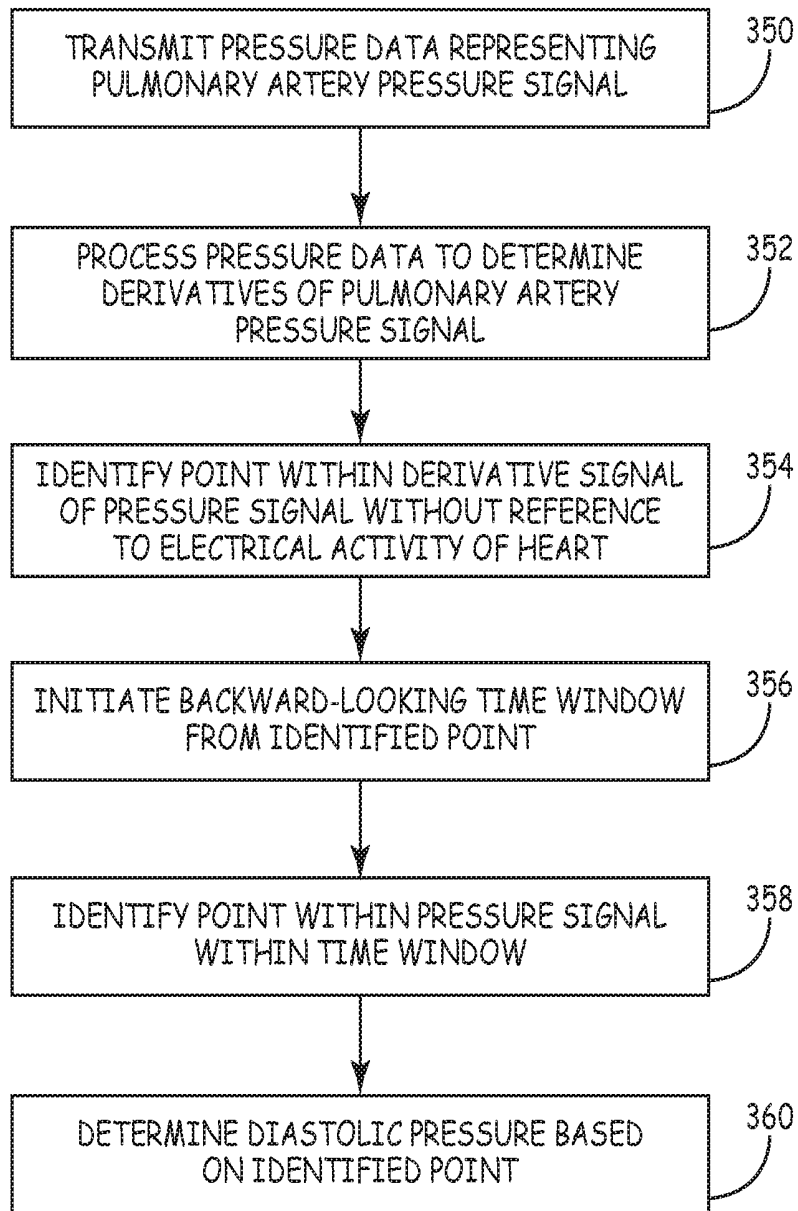


FIG. 9

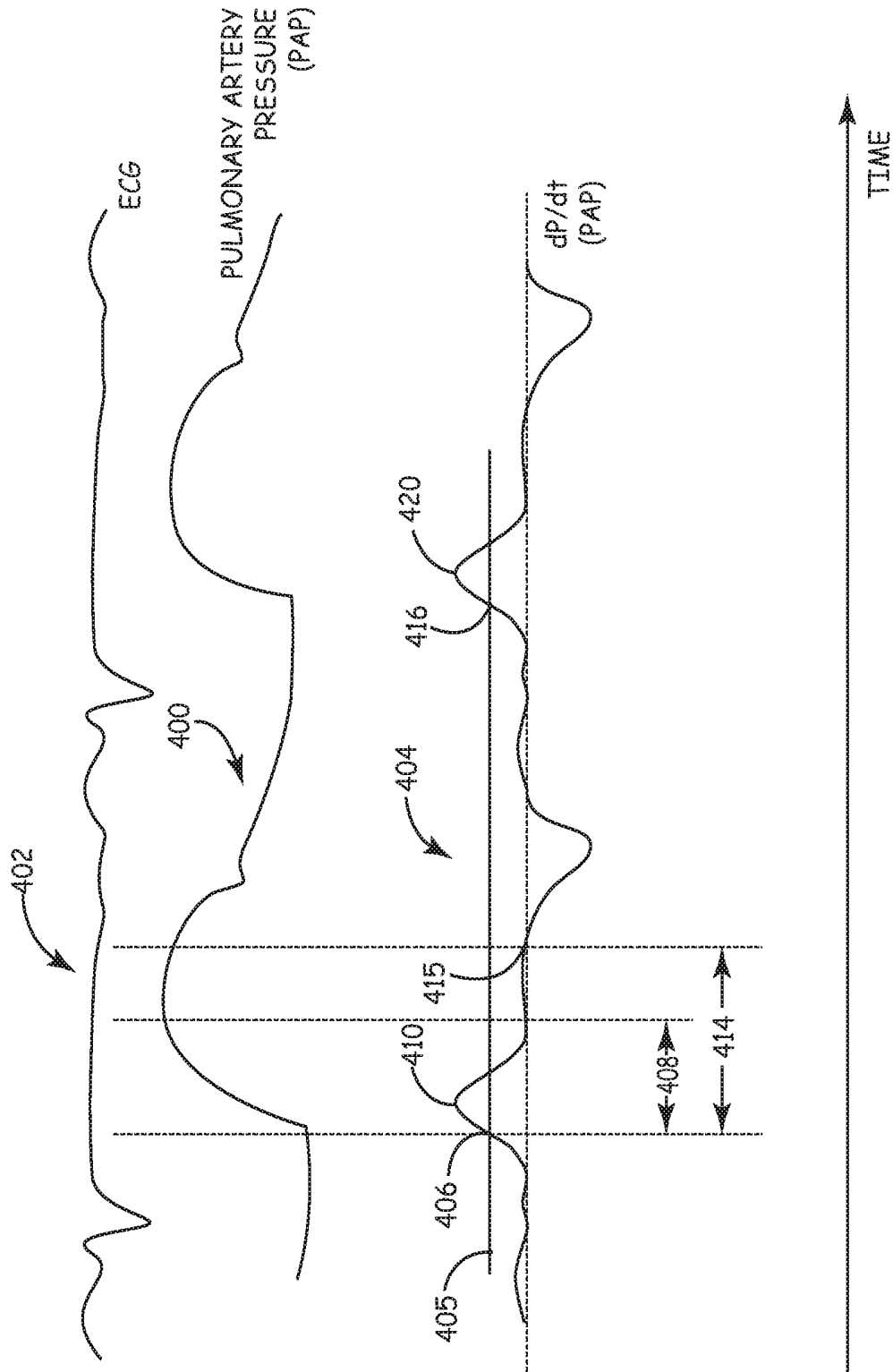


FIG. 10

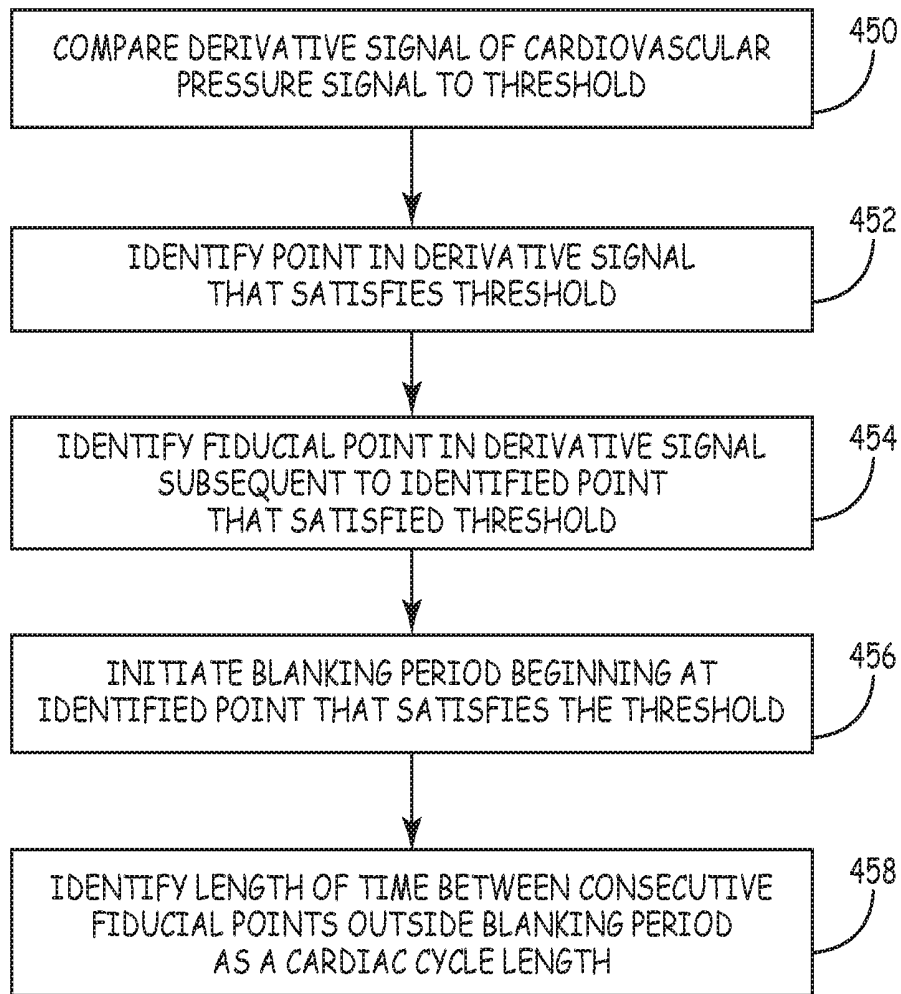


FIG. 11

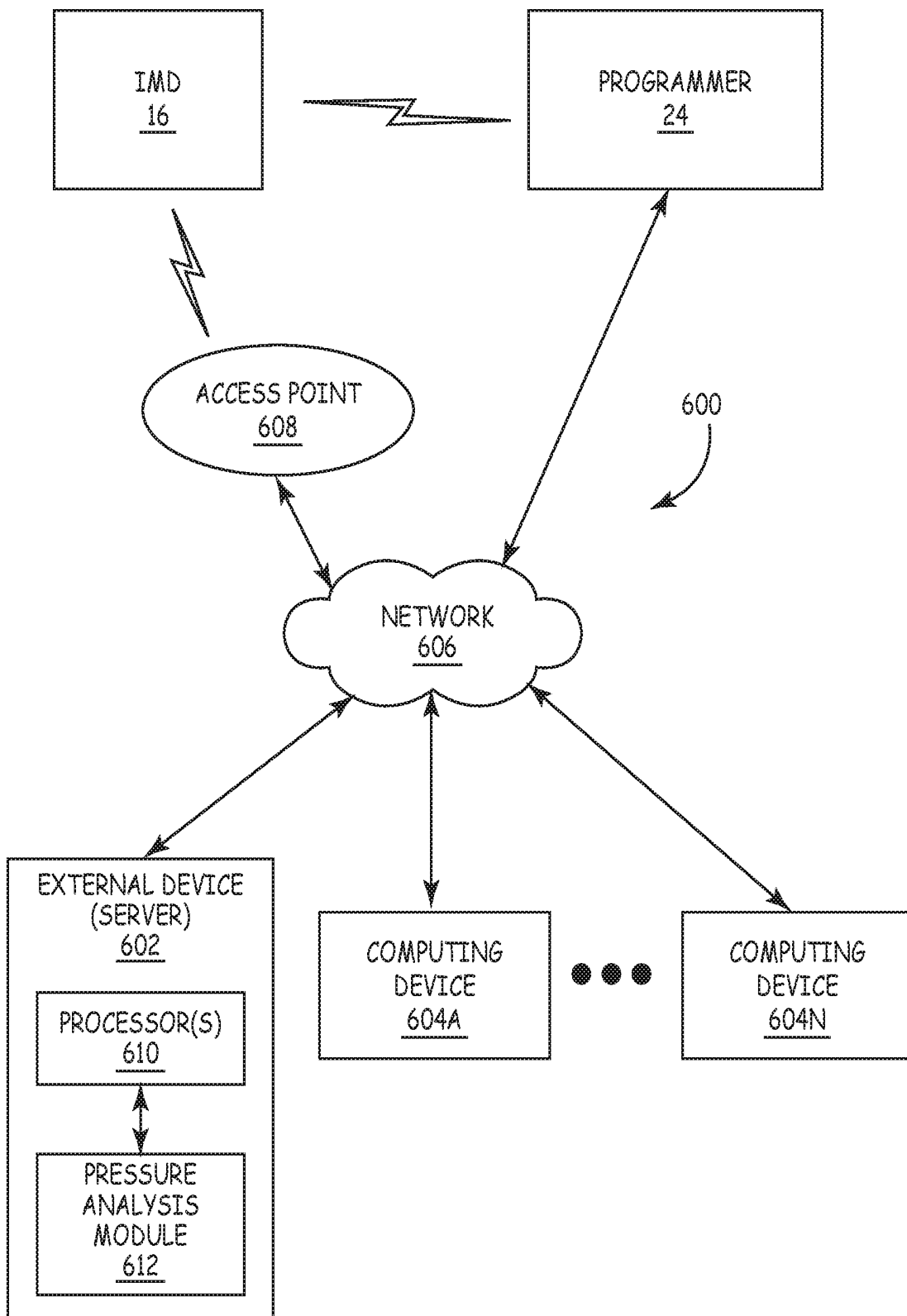


FIG. 12

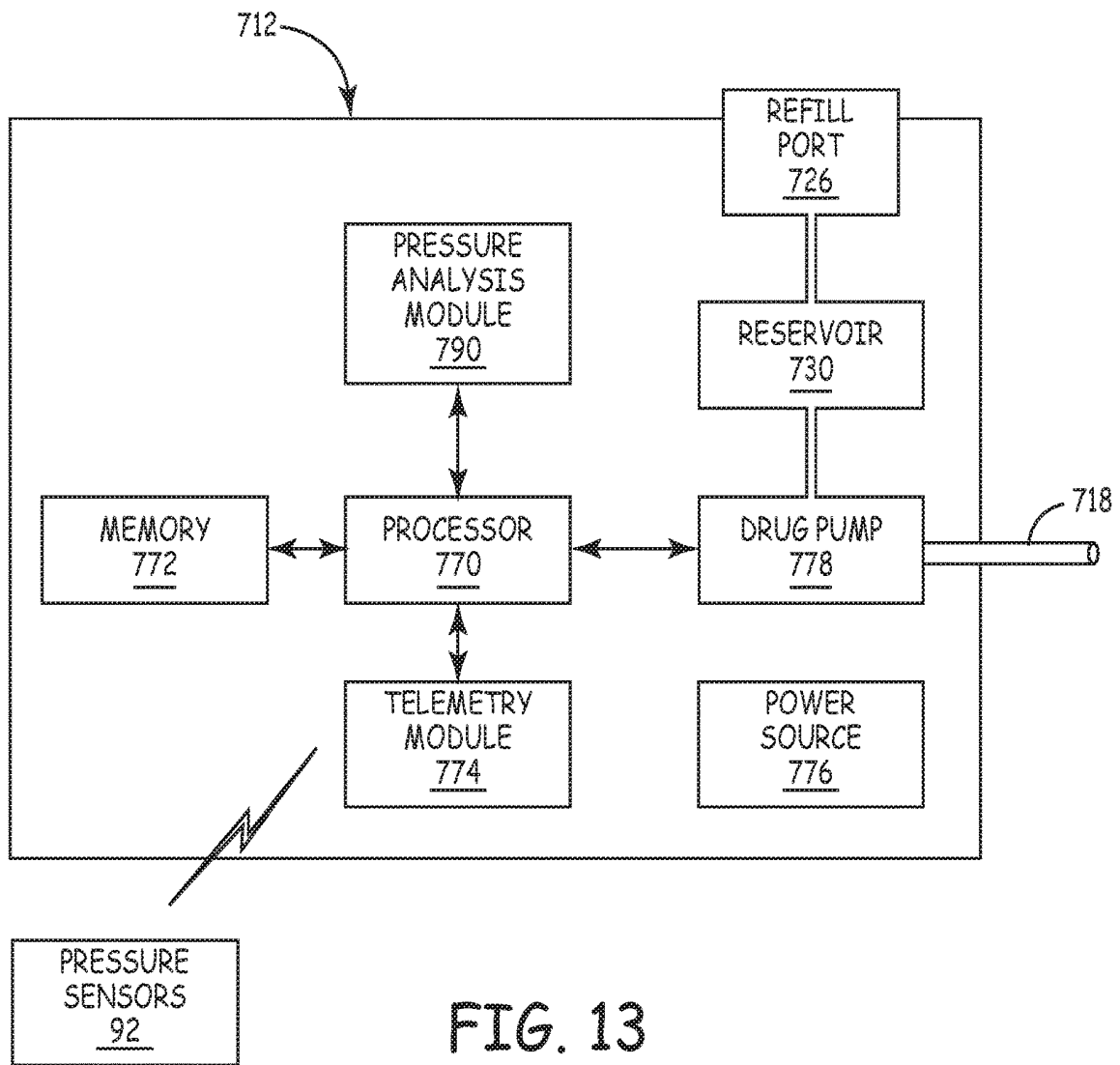


FIG. 13

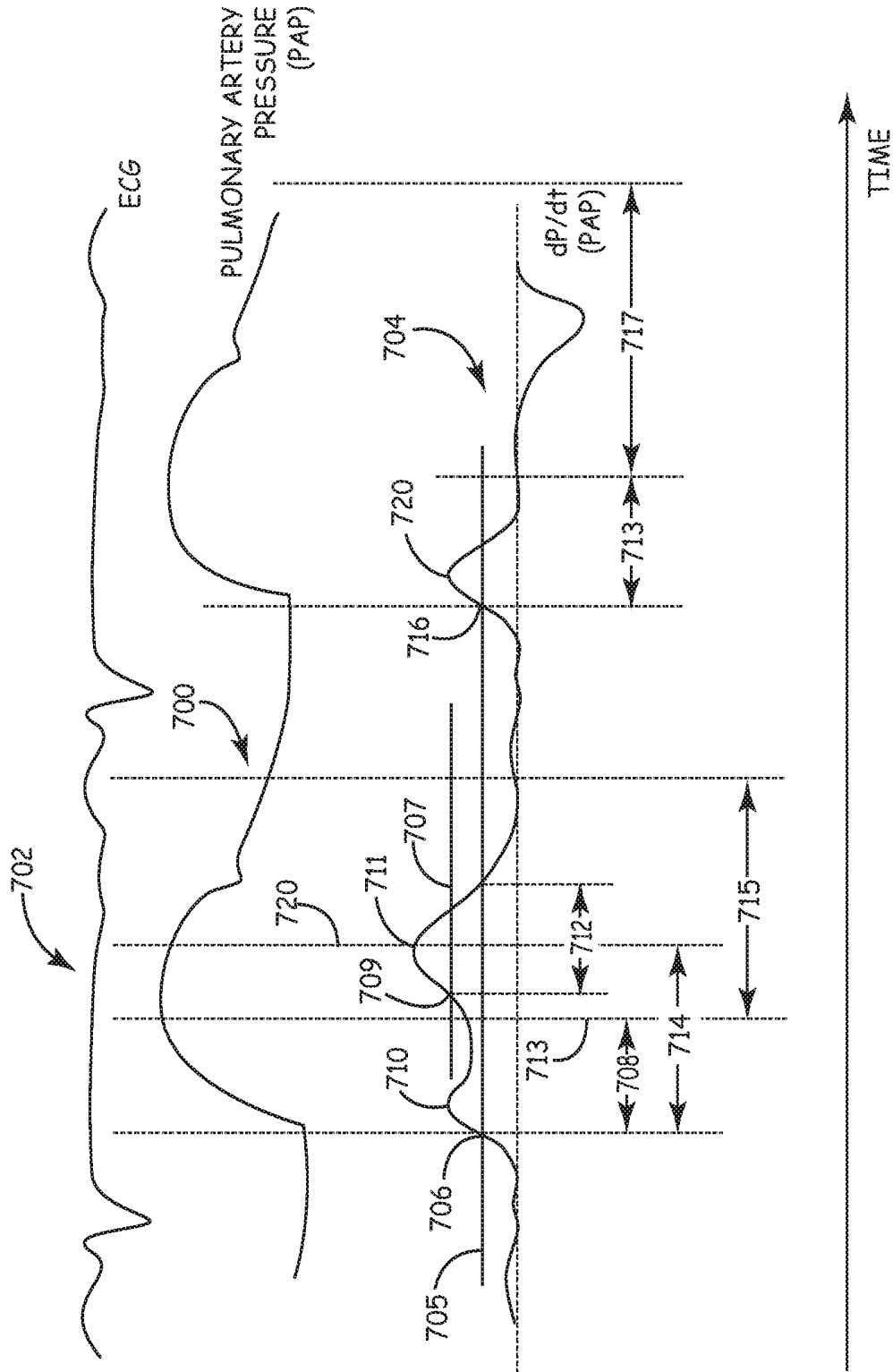


FIG. 14

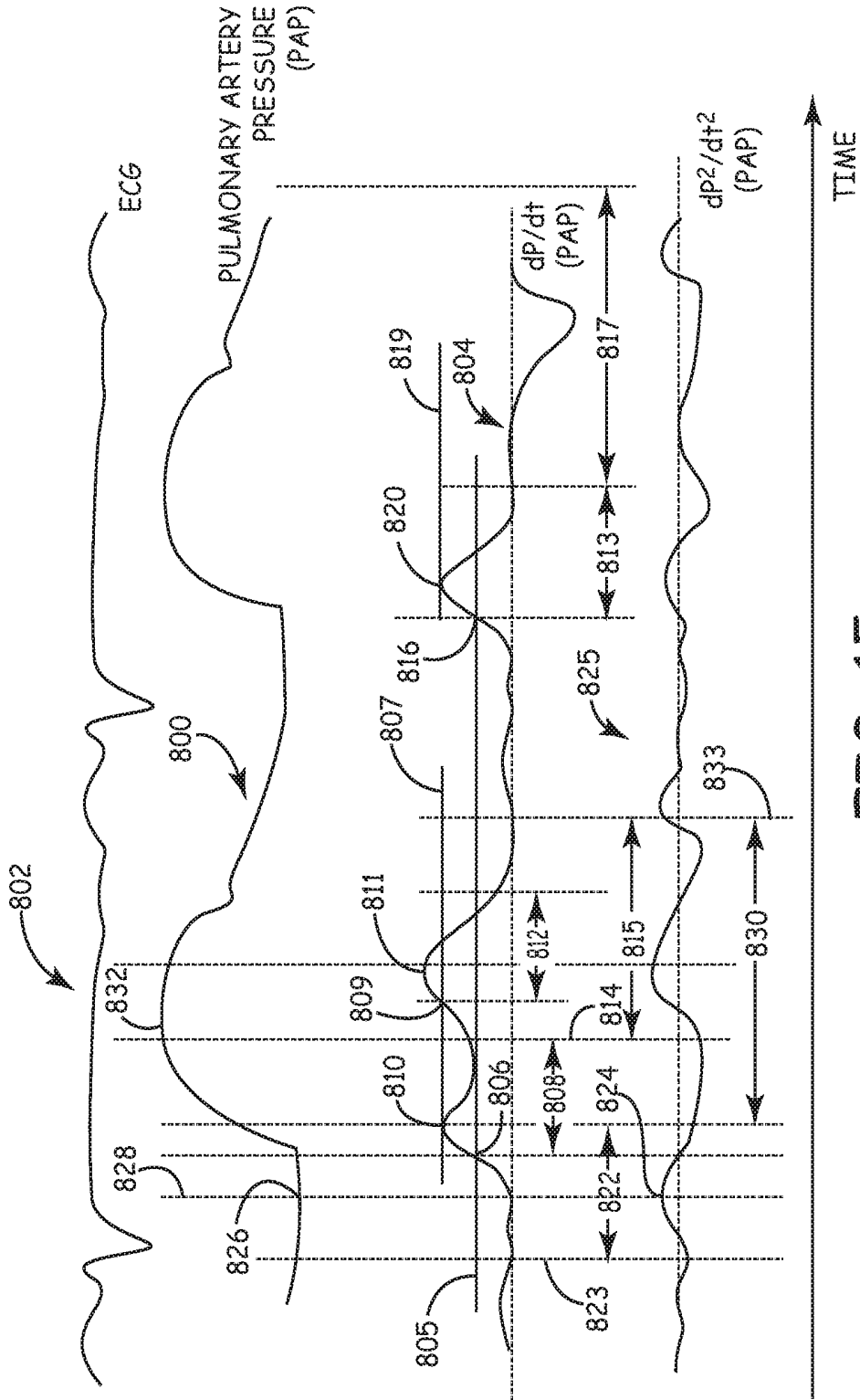


FIG. 15

MEASUREMENT OF CARDIAC CYCLE LENGTH AND PRESSURE METRICS FROM PULMONARY ARTERIAL PRESSURE

RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 13/096,012, filed on Apr. 28, 2011 and entitled “MEASUREMENT OF CARDIAC CYCLE LENGTH AND PRESSURE METRICS FROM PULMONARY ARTERIAL PRESSURE.” Cross-reference is hereby made to the commonly-assigned related U.S. patent application Ser. No. 13/096,004, filed on Apr. 28, 2011 and entitled “MEASUREMENT OF CARDIAC CYCLE LENGTH AND PRESSURE METRICS FROM PULMONARY ARTERIAL PRESSURE.” The contents of application Ser. Nos. 13/096,012 and 13/096,004 are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] The disclosure relates to medical devices and, more particularly, to implantable medical devices that monitor cardiac pressure.

BACKGROUND

[0003] A variety of implantable medical devices for delivering a therapy and/or monitoring a physiological condition have been clinically implanted or proposed for clinical implantation in patients. Implantable medical devices may deliver electrical stimulation or drug therapy to, and/or monitor conditions associated with, the heart, muscle, nerve, brain, stomach or other organs or tissue, as examples. Implantable medical devices may include or be coupled to one or more physiological sensors, which may be used in conjunction with the device to provide signals related to various physiological conditions from which a patient state or the need for a therapy can be assessed.

[0004] Some implantable medical devices may employ one or more elongated electrical leads carrying stimulation electrodes, sense electrodes, and/or other sensors. Implantable medical leads may be configured to allow electrodes or other sensors to be positioned at desired locations for delivery of stimulation or sensing. For example, electrodes or sensors may be carried at a distal portion of a lead. A proximal portion of the lead may be coupled to an implantable medical device housing, which may contain circuitry such as stimulation generation and/or sensing circuitry. Other implantable medical devices may employ one or more catheters through which the devices deliver a therapeutic fluid to a target site within a patient. Examples of such implantable medical devices include heart monitors, pacemakers, implantable cardioverter defibrillators (ICDs), myostimulators, neurostimulators, therapeutic fluid delivery devices, insulin pumps, and glucose monitors.

[0005] Pressure sensors may be employed in conjunction with implantable medical devices as physiological sensors configured to detect changes in blood pressure. Example pressure sensors that may be useful for measuring blood pressure may employ capacitive, piezoelectric, piezoresistive, electromagnetic, optical, resonant-frequency, or thermal methods of pressure transduction.

BRIEF DESCRIPTION OF DRAWINGS

[0006] Aspects and features of the present invention will be appreciated as the same becomes better understood by reference to the following detailed description of the embodiments of the invention when considered in connection with the accompanying drawings, wherein:

[0007] FIG. 1 is a conceptual diagram illustrating an example system that may be used to provide therapy to and/or monitor a heart of a patient;

[0008] FIG. 2 is a conceptual diagram illustrating the example implantable medical device (IMD) and the leads of the system shown in FIG. 1 in greater detail;

[0009] FIG. 3 is a functional block diagram illustrating an exemplary configuration of the IMD of FIG. 1;

[0010] FIG. 4 is a functional block diagram illustrating an exemplary configuration of a pressure sensor that may be used to implement certain techniques of this disclosure;

[0011] FIG. 5 is a diagram of a human heart, including a pressure sensor;

[0012] FIG. 6 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a systolic pressure, in accordance with certain techniques of this disclosure;

[0013] FIG. 7 is a flow diagram illustrating an exemplary method for determining systolic pressure, in accordance with various techniques of this disclosure;

[0014] FIG. 8 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first and second derivatives of the pulmonary arterial pressure signal, which may be used to determine a diastolic pressure, in accordance with certain techniques of this disclosure;

[0015] FIG. 9 is a flow diagram illustrating an exemplary method for determining a diastolic pressure, in accordance with various techniques of this disclosure;

[0016] FIG. 10 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a cardiac cycle length, in accordance with certain techniques of this disclosure;

[0017] FIG. 11 is a flow diagram illustrating an exemplary method for determining a cardiac cycle length, in accordance with various techniques of this disclosure;

[0018] FIG. 12 is a block diagram illustrating an exemplary system that includes a server and one or more computing devices that are coupled to the IMD and the programmer shown in FIG. 1 via a network;

[0019] FIG. 13 is block diagram of an embodiment of another example implantable medical device;

[0020] FIG. 14 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a cardiac cycle length and/or one or more pressure metrics, in accordance with certain techniques of this disclosure; and

[0021] FIG. 15 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first and second derivatives of the pulmonary arterial pressure signal, which may be used to determine a systolic pressure, a diastolic pressure, and/or a cycle length in accordance with certain techniques of this disclosure.

DETAILED DESCRIPTION

[0022] In general, this disclosure describes techniques for cardiovascular monitoring. The cardiovascular monitoring techniques may include determining a cardiac cycle length and/or cardiovascular pressure metrics such as systolic pressure and diastolic pressure from a pressure signal detected by a pressure sensor implanted within the pulmonary artery of a patient. In some cases, a derivative of the pressure signal may be used to determine the cardiac cycle length and/or the cardiac pressure metrics. Additionally, second or higher order derivatives may be taken in order to identify other morphological fiducial points on the pressure waveform that contribute to measurements with clinical diagnostic value. Averaging and cross correlation or mathematical transform techniques may also be used for this purpose. Using the techniques of this disclosure, an implantable medical device may deliver drug therapy or therapeutic electrical stimulation, or acquire diagnostic information, based on the determined cardiac cycle length and/or various pressure metrics.

[0023] In one example, the disclosure is directed to a method comprising identifying, by a medical device, a point within a derivative signal of a cardiovascular pressure signal without reference to electrical activity of a heart, initiating, by the medical device, a time window from the identified point in the derivative signal, identifying, with the medical device, a point within the cardiovascular signal within the time window, and determining, with the medical device, at least one of a systolic pressure or diastolic pressure based on the identified point.

[0024] In another example, the disclosure is directed to a system comprising at least one pressure sensor, and at least one pressure analysis module configured to identify a point within a derivative signal of a cardiovascular pressure signal without reference to electrical activity of a heart, initiate a time window from the identified point in the derivative signal, identify a point within the cardiovascular signal within the time window, and determine at least one of a systolic pressure or diastolic pressure based on the identified point.

[0025] In another example, the disclosure is directed to a computer-readable storage medium comprising instructions that, when executed, cause a pressure analysis module to identify a point within a derivative signal of a cardiovascular pressure signal without reference to electrical activity of a heart, initiate a time window from the identified point in the derivative signal, identify a point within the cardiovascular signal within the time window, and determine at least one of a systolic pressure or diastolic pressure based on the identified point.

[0026] In another example, the disclosure is directed to a method comprising identifying, by a medical device, a plurality of fiducial points within a derivative signal of a cardiovascular pressure signal, and identifying, by the medical device, a length of time between consecutive ones of the fiducial points as a cardiac cycle length, wherein identifying the plurality of fiducial points comprises comparing the derivative signal to a threshold, identifying a point within the derivative signal that satisfies the threshold, identifying the fiducial point within the derivative signal subsequent to the point within the derivative signal that satisfies the threshold, and initiating a blanking period that begins at the fiducial point, and wherein comparing the derivative signal to the threshold comprises not comparing the derivative

signal to the threshold for identification of a subsequent one of the fiducial points during the blanking period.

[0027] A system comprising at least one pressure sensor, and at least one pressure analysis module configured to identify a plurality of fiducial points within a derivative signal of a cardiovascular pressure signal, and identify a length of time between consecutive ones of the fiducial points as a cardiac cycle length, wherein the at least one pressure analysis module configured to identify the plurality of fiducial points is further configured to compare the derivative signal to a threshold, identify a point within the derivative signal that satisfies the threshold, identify the fiducial point within the derivative signal subsequent to the point within the derivative signal that satisfies the threshold, and initiate a blanking period that begins at the fiducial point, and wherein at least one pressure analysis module configured to compare the derivative signal to the threshold is configured to not compare the derivative signal to the threshold for identification of a subsequent one of the fiducial points during the blanking period.

[0028] A computer-readable storage medium comprising instructions that, when executed, cause a pressure analysis module to identify a plurality of fiducial points within a derivative signal of a cardiovascular pressure signal, and identify a length of time between consecutive ones of the fiducial points as a cardiac cycle length, wherein the instructions that, when executed, cause a pressure analysis module to identify the plurality of fiducial points comprise instructions that, when executed, cause the pressure analysis module to compare the derivative signal to a threshold, identify a point within the derivative signal that satisfies the threshold, identify the fiducial point within the derivative signal subsequent to the point within the derivative signal that satisfies the threshold, and initiate a blanking period that begins at the fiducial point, and wherein the instructions that, when executed, cause a pressure analysis module to compare the derivative signal to the threshold comprise instructions that, when executed, cause the pressure analysis module to not compare the derivative signal to the threshold for identification of a subsequent one of the fiducial points during the blanking period.

[0029] The details of one or more aspects of the disclosure are set forth in the accompanying drawings and the description below. Other features, objects, and advantages will be apparent from the description and drawings, and from the claims.

[0030] This disclosure describes various techniques for measuring cardiac cycle length and pressure metrics based on pulmonary artery pressures. Cardiac cycle length is often measured by sensing ventricular electrical depolarizations from an electrocardiogram (ECG) or intracardiac electrogram (EGM). However, because it may be desirable to limit the amount of hardware implanted within a patient and computing requirements, electrical measurements may not be available. Using the techniques of this disclosure, cardiac cycle length and pressure metrics such as systolic pressure and diastolic pressure may be derived from the pulmonary arterial pressure (PAP) from one or more pressure sensors in the pulmonary artery (PA), and without using a cardiac electrical signal. In this manner, cardiac cycle lengths, for example, may be determined without adding electrodes to a patient. It is understood that the techniques described in this disclosure may also be applied to measuring cardiac cycle

length and pressure metrics based on ventricular pressure with wired or wireless sensors located within the right ventricle (RV).

[0031] FIG. 1 is a schematic view of an implantable medical device. FIG. 1 is a conceptual diagram illustrating an example system 10 that may be used to monitor and/or provide therapy to heart 12 of patient 14. Patient 14 ordinarily, but not necessarily, will be a human. Therapy system 10 includes IMD 16, which is coupled to leads 18, 20, and 22, and programmer 24. IMD 16 may be, for example, an implantable pacemaker, cardioverter, and/or defibrillator that provides electrical signals to heart 12 via electrodes coupled to one or more of leads 18, 20, and 22. In accordance with certain techniques of this disclosure, IMD 16 may receive pressure information from a pressure sensor (not shown in FIG. 1) located within a pulmonary artery of patient 14 and, in some examples, provide electrical signals to heart 12 based on the received pressure information, as will be described in greater detail below. The pressure sensor may be coupled to IMD 16 via a lead, or wirelessly.

[0032] Leads 18, 20, 22 extend into the heart 12 of patient 14 to sense electrical activity of heart 12 and/or deliver electrical stimulation to heart 12. In the example shown in FIG. 1, right ventricular (RV) lead 18 extends through one or more veins (not shown), the superior vena cava (not shown), and right atrium 26, and into right ventricle 28. Left ventricular (LV) coronary sinus lead 20 extends through one or more veins, the vena cava, right atrium 26, and into the coronary sinus 30 to a region adjacent to the free wall of left ventricle 32 of heart 12. Right atrial (RA) lead 22 extends through one or more veins and the vena cava, and into the right atrium 26 of heart 12.

[0033] IMD 16 may sense electrical signals attendant to the depolarization and repolarization of heart 12 via electrodes (not shown in FIG. 1) coupled to at least one of the leads 18, 20, 22. In some examples, IMD 16 provides pacing pulses to heart 12 based on the electrical signals sensed within heart 12. The configurations of electrodes used by IMD 16 for sensing and pacing may be unipolar or bipolar. IMD 16 may also provide defibrillation therapy and/or cardioversion therapy via electrodes located on at least one of the leads 18, 20, 22. IMD 16 may detect arrhythmia of heart 12, such as fibrillation of ventricles 28 and 32, and deliver defibrillation therapy to heart 12 in the form of electrical pulses. In some examples, IMD 16 may be programmed to deliver a progression of therapies, e.g., pulses with increasing energy levels, until a fibrillation of heart 12 is stopped. IMD 16 detects fibrillation employing one or more fibrillation detection techniques known in the art.

[0034] In some examples, programmer 24 may be a handheld computing device or a computer workstation. A user, such as a physician, technician, or other clinician, may interact with programmer 24 to communicate with IMD 16. For example, the user may interact with programmer 24 to retrieve physiological or diagnostic information from IMD 16. A user may also interact with programmer 24 to program IMD 16, e.g., select values for operational parameters of the IMD.

[0035] For example, the user may use programmer 24 to retrieve information from IMD 16 regarding the rhythm of heart 12, trends therein over time, or arrhythmic episodes. As another example, the user may use programmer 24 to retrieve information from IMD 16 regarding other sensed physiological parameters of patient 14, such as intracardiac

or intravascular pressure, activity, posture, respiration, or thoracic impedance. As another example, the user may use programmer 24 to retrieve information from IMD 16 regarding the performance or integrity of IMD 16 or other components of system 10, such as leads 18, 20 and 22, or a power source of IMD 16. The user may use programmer 24 to program a therapy progression, select electrodes used to deliver defibrillation pulses, select waveforms for the defibrillation pulse, or select or configure a fibrillation detection algorithm for IMD 16. The user may also use programmer 24 to program aspects of other therapies provided by IMD 14, such as cardioversion or pacing therapies.

[0036] IMD 16 and programmer 24 may communicate via wireless communication using any techniques known in the art. Examples of communication techniques may include, for example, low frequency or radiofrequency (RF) telemetry, but other techniques are also contemplated. In some examples, programmer 24 may include a programming head that may be placed proximate to the patient's body near the IMD 16 implant site in order to improve the quality or security of communication between IMD 16 and programmer 24.

[0037] FIG. 2 is a conceptual diagram illustrating IMD 16 and leads 18, 20, and 22 of therapy system 10 in greater detail. Leads 18, 20, 22 may be electrically coupled to a signal generator and a sensing module of IMD 16 via connector block 34.

[0038] Each of the leads 18, 20, 22 includes an elongated insulative lead body carrying one or more conductors. Bipolar electrodes 40 and 42 are located adjacent to a distal end of lead 18. In addition, bipolar electrodes 44 and 46 are located adjacent to a distal end of lead 20 and bipolar electrodes 48 and 50 are located adjacent to a distal end of lead 22. Electrodes 40, 44 and 48 may take the form of ring electrodes, and electrodes 42, 46 and 50 may take the form of extendable helix tip electrodes mounted retractably within insulative electrode heads 52, 54 and 56, respectively.

[0039] Leads 18, 20, 22 also include elongated intracardiac electrodes 62, 64 and 66 respectively, which may take the form of a coil. In addition, one of leads 18, 20, 22, e.g., lead 22 as seen in FIG. 2, may include a superior vena cava (SVC) coil 67 for delivery of electrical stimulation, e.g., transvenous defibrillation. For example, lead 22 may be inserted through the superior vena cava and SVC coil 67 may be placed, for example, at the right atrial/SVC junction (low SVC) or in the left subclavian vein (high SVC). Each of the electrodes 40, 42, 44, 46, 48, 50, 62, 64, 66 and 67 may be electrically coupled to a respective one of the conductors within the lead body of its associated lead 18, 20, 22, and thereby individually coupled to the signal generator and sensing module of IMD 16. In some examples, as illustrated in FIG. 2, IMD 16 includes one or more housing electrodes, such as housing electrode 58, which may be formed integrally with an outer surface of hermetically-sealed housing 60 of IMD 16 or otherwise coupled to housing 60.

[0040] IMD 16 may sense electrical signals attendant to the depolarization and repolarization of heart 12 via electrodes 40, 42, 44, 46, 48, 50, 58, 62, 64, 66 and 67. The electrical signals are conducted to IMD 16 via the respective leads 18, 20, 22, or in the case of housing electrode 58, a conductor coupled to the housing electrode. IMD 16 may sense such electrical signals via any bipolar combination of electrodes 40, 42, 44, 46, 48, 50, 58, 62, 64, 66 and 67.

Furthermore, any of the electrodes **40**, **42**, **44**, **46**, **48**, **50**, **58**, **62**, **64**, **66** and **67** may be used for unipolar sensing in combination with housing electrode **58**.

[0041] In some examples, IMD **16** delivers pacing pulses via bipolar combinations of electrodes **40**, **42**, **44**, **46**, **48** and **50** to produce depolarization of cardiac tissue of heart **12**. In some examples, IMD **16** delivers pacing pulses via any of electrodes **40**, **42**, **44**, **46**, **48** and **50** in combination with housing electrode **58** in a unipolar configuration. For example, electrodes **40**, **42**, and/or **58** may be used to deliver RV pacing to heart **12**. Additionally or alternatively, electrodes **44**, **46**, and/or **58** may be used to deliver LV pacing to heart **12**, and electrodes **48**, **50** and/or **58** may be used to deliver RA pacing to heart **12**.

[0042] Furthermore, IMD **16** may deliver defibrillation pulses to heart **12** via any combination of elongated electrodes **62**, **64**, **66** and **67**, and housing electrode **58**. Electrodes **58**, **62**, **64**, **66** may also be used to deliver cardioversion pulses to heart **12**. Electrodes **62**, **64**, **66** and **67** may be fabricated from any suitable electrically conductive material, such as, but not limited to, platinum, platinum alloy or other materials known to be usable in implantable defibrillation electrodes.

[0043] The configuration of therapy system **10** illustrated in FIGS. **1** and **2** is merely one example. In other examples, a therapy system may include epicardial leads and/or patch electrodes instead of or in addition to the transvenous leads **18**, **20**, **22** illustrated in FIGS. **1** and **2**. Further, IMD **16** need not be implanted within patient **14**. In examples in which IMD **16** is not implanted in patient **14**, IMD **16** may deliver defibrillation pulses and other therapies to heart **12** via percutaneous leads that extend through the skin of patient **14** to a variety of positions within or outside of heart **12**.

[0044] In addition, in other examples, a therapy system may include any suitable number of leads coupled to IMD **16**, and each of the leads may extend to any location within or proximate to heart **12**. For example, other examples of therapy systems may include three transvenous leads located as illustrated in FIGS. **1** and **2**, and an additional lead located within or proximate to left atrium **36**. Other examples of therapy systems may include a single lead that extends from IMD **16** into right atrium **26** or right ventricle **28**, or two leads that extend into a respective one of the right ventricle **28** and right atrium **26** (not shown). The example of FIGS. **1** and **2** includes a single electrode per chamber of heart **12** engaged with the wall of heart **12**, e.g., free wall, for that chamber. Other examples may include multiple electrodes per chamber, at a variety of different locations on the wall of heart. The multiple electrodes may be carried by one lead or multiple leads per chamber.

[0045] In accordance with certain aspects of this disclosure, one or more pressure sensors located in a pulmonary artery of a patient may communicate with IMD **16** via wireless communication, or may be coupled to IMD **16** via one or more leads. For example, the pressure sensor(s) may communicate pressure information, e.g., data, that represents a pressure signal that is a function of a pressure in heart **12**, to IMD **16**. In response, IMD **16** and, in particular, a processor of IMD **16**, may determine a cardiac cycle length or various pressure metrics, as described in more detail below.

[0046] For conciseness, the disclosure generally refers to IMD **16** as performing any computations, but the disclosure is not so limited. In other examples, the pressure sensor(s)

may communicate the pressure information to programmer **24**. In response, programmer **24** may determine a cardiac cycle length or various pressure metrics, as described in more detail below. In other examples, the pressure sensor(s) may communicate the pressure information to another device, e.g., a computing device, server, network, or the like, for storage and/or analysis.

[0047] Furthermore, in other examples, the pressure sensor may itself analyze pressure information to determine, for example, a cardiac cycle length or various pressure metrics using the various techniques described herein. In such examples, the pressure sensor may store the cycle length and other metrics, and may communicate, e.g., wirelessly, the cycle length and other metrics to IMD **16**, programmer **24**, or another computing device.

[0048] FIG. **3** is a functional block diagram illustrating an exemplary configuration of IMD **16** that may be used to implement certain techniques of this disclosure. In the illustrated example, IMD **16** includes a processor **80**, memory **82**, signal generator **84**, sensing module **86**, telemetry module **88**, and pressure analysis module **90**. As seen in FIG. **3**, one or more pressure sensors **92** may be in communication with IMD **16** via telemetry module **88**. Pressure analysis module **90** analyzes the pressure data received from pressure sensor(s) **92**. Pressure analysis module **90** may be implemented as software, firmware, hardware or any combination thereof. In some example implementations, pressure analysis module **90** may be a software process implemented in or executed by processor **80**. Memory **82** is one example of a non-transitory, computer-readable storage medium that includes computer-readable instructions that, when executed by processor **80**, cause IMD **16** and processor **80** to perform various functions attributed to IMD **16** and processor **80** in this disclosure. Memory **82** may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital or analog media.

[0049] As indicated above, the techniques for measuring cardiac cycle length and pressure metrics based on pulmonary artery pressures described in this disclosure need not be used in conjunction with IMD **16**. However, in some example implementations, one or more pressure sensors **92** may communicate pressure information, e.g., data, that represents a pressure signal of a pressure in heart **12** to IMD **16**. In response, IMD **16** and, in particular, pressure analysis module **90**, may perform some or all of the calculations described below in order to determine a cardiac cycle length and/or various pressure metrics.

[0050] In some example implementations, implantable medical devices may deliver drug therapy based on the determined cardiac cycle length and/or various pressure metrics, as described in more detail below with respect to FIG. **13**. In other example implementations, processor **80** of IMD **16** may control signal generator **84** to deliver stimulation therapy to heart **12** based on the determined cardiac cycle length or various pressure metrics. For example, upon receiving pressure information representing a pressure signal from a pressure sensor, pressure analysis module **90** may determine that the systolic pressure in the pulmonary artery is below a predetermined threshold value. In response, processor **80** may, for example, control signal generator **84** to deliver pacing pulses to heart **12** to increase the amount

of blood flow. Processor **80** may also adjust pacing settings in response to the determination.

[0051] Processor **80** may include any one or more of a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), or equivalent discrete or analog logic circuitry. In some examples, processor **80** may include multiple components, such as any combination of one or more microprocessors, one or more controllers, one or more DSPs, one or more ASICs, or one or more FPGAs, as well as other discrete or integrated logic circuitry. The functions attributed to processor **80** in this disclosure may be embodied as software, firmware, hardware or any combination thereof.

[0052] In some examples, processor **80** controls signal generator **84** to deliver stimulation therapy to heart **12** according to a selected one or more of therapy programs, which may be stored in memory **82**. For example, processor **80** may control signal generator **84** to deliver electrical pulses with the amplitudes, pulse widths, frequency, or electrode polarities specified by the selected one or more therapy programs.

[0053] Signal generator **84** is electrically coupled to electrodes **40, 42, 44, 46, 48, 50, 58, 62, 64, 66, and 67** e.g., via conductors of the respective lead **18, 20, 22**, or, in the case of housing electrode **58**, via an electrical conductor disposed within housing **60** of IMD **16**. In some examples, signal generator **84** is configured to generate and deliver electrical stimulation therapy to heart **12**. For example, signal generator **84** may deliver defibrillation shocks as therapy to heart **12** via at least two electrodes **58, 62, 64, 66**. Signal generator **84** may deliver pacing pulses via ring electrodes **40, 44, 48** coupled to leads **18, 20, and 22**, respectively, and/or helical electrodes **42, 46, and 50** of leads **18, 20, and 22**, respectively. In some examples, signal generator **84** delivers pacing, cardioversion, or defibrillation stimulation in the form of electrical pulses. In other examples, signal generator **84** may deliver one or more of these types of stimulation in the form of other signals, such as sine waves, square waves, or other substantially continuous time signals.

[0054] Signal generator **84** may include a switch module, and processor **80** may use the switch module to select which of the available electrodes are used to deliver such stimulation. The switch module may include a switch array, switch matrix, multiplexer, or any other type of switching device suitable to selectively couple stimulation energy to selected electrodes.

[0055] In some examples, sensing module **86** monitors signals from at least one of electrodes **40, 42, 44, 46, 48, 50, 58, 62, 64, 66** or **67** in order to monitor electrical activity of heart **12**. Sensing module **86** may also include a switch module. In some examples, processor **80** may select the electrodes that function as sense electrodes via the switch module within sensing module **86**.

[0056] Sensing module **86** may include one or more detection channels (not shown), each of which may comprise an amplifier. The detection channels may be used to sense the cardiac signals. Some detection channels may detect cardiac events, such as R- or P-waves, and provide indications of the occurrences of such events to processor **80**. One or more other detection channels may provide the signals to an analog-to-digital converter, for processing or analysis by processor **80**. In some examples, processor **80** may store the digitized versions of signals from one or more

selected detection channels in memory **82** as EGM signals. In response to the signals from processor **80**, the switch module within sensing module **86** may couple selected electrodes to selected detection channels, e.g., for detecting events or acquiring an EGM in a particular chamber of heart **12**.

[0057] For some patients, it may be desirable to limit the amount of hardware implanted. As such, at least some of the electrical measurements that may be sensed by sensing module **86** may not be available to IMD **16**. Using various techniques of this disclosure, cardiac cycle length and/or pressure metrics such as peak-systolic pressure and end-diastolic pressure may be derived from the pulmonary arterial pressure (PAP) from one or more pressure sensors **92** in the pulmonary artery (PA). In this manner, cardiac cycle lengths, for example, may be determined without adding electrodes to a patient.

[0058] Processor **80** may maintain interval counters, such as A-A, V-V, A-V, RV-LV, A-RV, or A-LV interval counters. Processor **80** may reset such counters upon sensing of R-waves and P-waves with detection channels of sensing module **86**. Processor **80** may also control signal generator **84** to deliver pacing pulses when the interval counters reach a predetermined value without being reset, and then reset the escape interval counters upon the delivery of the pacing pulses by signal generator **84**. In this manner, processor **80** may control the basic timing of cardiac pacing functions, including anti-tachyarrhythmia pacing, based on pressure data.

[0059] The value of the count present in the interval counters when reset by sensed R-waves and P-waves may be used by processor **80** to measure the durations of R-R intervals, P-P intervals, PR intervals and R-P intervals, which are measurements that may be stored in memory **82**. Processor **80** may use the count in the interval counters to detect a suspected tachyarrhythmia event, such as ventricular fibrillation or ventricular tachycardia. In some examples, processor **80** may determine that tachyarrhythmia has occurred by identification of shortened R-R (or P-P) interval lengths. An interval length below a threshold may need to be detected for a certain number of consecutive cycles, or for a certain percentage of cycles within a running window, as examples. In some examples, processor **80** may additionally or alternatively employ digital signal analysis techniques to characterize one or more digitized signals from the detection channels of sensing module **86** to detect and classify tachyarrhythmias.

[0060] As illustrated in FIG. 3, in addition to program instructions, memory **82** may store pressure data **94** received from pressure sensor **92** via telemetry module **88**. Processor **80** may store pressure information received from pressure sensor **92** as pressure data **94**. Pressure data **94** may include raw, unprocessed pressure information that represents a pressure signal within a pulmonary artery of a patient. In other examples, processor **80** may store pressure information processed by pressure analysis module **90** in memory **82** as processed data **96**. Processed data **96** may represent the values determined based on pressure data **94**, such as cycle lengths, averages, trends over time. In particular, processed data **96** may include cycle length data, systolic pressure data, and diastolic pressure data as processed and/or determined by pressure analysis module **90**. In addition, in some example implementations, processor **80** may control pressure sensor **92** to measure a pressure within a pulmonary

artery of a patient. For example, based on predetermined timing data stored in memory 82, or timing data transmitted via a programmer, e.g., programmer 24, processor 80 may transmit, via telemetry module 88, instructions to pressure sensor 92 to take one or more pressure measurements.

[0061] FIG. 4 is a functional block diagram illustrating an exemplary configuration of a pressure sensor that may be used to implement certain techniques of this disclosure. In the illustrated example, pressure sensor 92 includes a processor 500, pressure analysis module 502, telemetry module 504, and memory 506. Processor 500 and telemetry module 504 may be similar to processor 80 and telemetry module 88 of FIG. 3. Processor 500 may store pressure information as pressure data 508 in memory 506. Pressure data 508 may include raw, unprocessed pressure information that represents a pressure signal within a pulmonary artery of a patient. In some examples, telemetry module 504 may transmit pressure data 508 to IMD 16 for processing. In other examples, telemetry module 504 may transmit pressure data 508 to programmer 24, or to another external device, e.g., for further analysis.

[0062] In some examples, pressure analysis module 502 may process pressure information sensed by pressure sensor 92 and store the processed information in memory 506 as processor data 510. Pressure analysis module 502 may be implemented as software, firmware, hardware or any combination thereof. In some example implementations, pressure analysis module 502 may be a software process implemented in or executed by processor 500. Processed data 510 may represent the values determined based on pressure data 508, such as cycle lengths, averages, trends over time. In particular, processed data 510 may include cycle length data, systolic pressure data, and diastolic pressure data as processed and/or determined by pressure analysis module 502. Then, telemetry module 504 may transmit processed data 510 to IMD 16, programmer 24, or another external device, e.g., for further analysis.

[0063] FIG. 5 is a diagram of a human heart, including a leadless pressure sensor. Heart 12 of FIG. 5 depicts pulmonary artery 100, right atrium 150, right ventricle 152, left atrium 154, left ventricle 156, right pulmonary artery 158, left pulmonary artery 160, aorta 162, atrioventricular valve 164, pulmonary valve 166, aortic valve 168, and superior vena cava 176. Pressure sensor 92 may, as shown in FIG. 5, be placed inside pulmonary artery 100 of heart 12. In some example implementations, sensor 92 may be placed within main pulmonary artery 100, the right pulmonary artery 158 or any of its branches, and/or within left pulmonary artery 160 or any of its branches, or within the right ventricle. In other example implementations, multiple pressure sensors 92 may be placed at various locations within pulmonary artery 100, right pulmonary artery 158 or any of its branches, and/or left pulmonary artery 160 or any of its branches.

[0064] As shown in FIG. 5, pressure sensor 92 may be a leadless assembly, e.g., need not be coupled to an IMD or other device via a lead, and need not otherwise be coupled to any leads. Although not depicted, pressure sensor 92 may include wireless communication capabilities such as low frequency or radiofrequency (RF) telemetry, as well other wireless communication techniques that allow sensor 92 to communicate with IMD 16, programmer 24, or another device. Pressure sensor 92 may be affixed to the wall of the pulmonary artery or the wall of the right ventricle using any number of well-known techniques. For example, pressure

sensor 92 may include fixation elements, e.g., helical tines, hooked tines, barbs, or the like, that allow sensor 92 to be secured to pulmonary artery 100. In other examples, pressure sensor 92 may be attached to a stent having any variety of conformations, for example, and the stent/sensor combination may be implanted within pulmonary artery 100.

[0065] Pressure sensor 92 may be implanted within pulmonary artery 100, for example, using a delivery catheter. For example, a physician may deliver pressure sensor(s) 92 via a delivery catheter, transvenously through either the internal jugular or femoral veins. The delivery catheter then extends through superior vena cava 176, right atrioventricular valve 164, right ventricle 152, and pulmonary valve 166 into pulmonary artery 100. In other examples, pressure sensor 92 may be implanted after a physician has opened the patient's chest by cutting through the sternum.

[0066] Pressure sensor 92 generates pressure information representing a pressure signal as a function of the fluid pressure in pulmonary artery 100, for example. IMD 16, programmer 24, and/or another device, e.g., external monitoring equipment, may receive, monitor, and analyze the pressure information, as will be described in more detail below, in order to determine a cardiac cycle length and/or other pressure metrics. In other examples, pressure sensor 92 may itself analyze the pressure information in order to determine a cardiac cycle length and/or other pressure metrics according to the techniques described herein.

[0067] FIG. 6 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a systolic pressure, in accordance with certain techniques of this disclosure. Pulmonary artery pressure signal 200 from pressure sensor 92 in pulmonary artery 100 is shown in reference to electrocardiogram (ECG) signal 202. ECG signal 202 shows pacing spikes 204A and 204B. ECG signal 202 may be sensed by electrodes, as described above in detail with respect to FIG. 2. R-wave 206 in ECG signal 202 of FIG. 6 represents ventricular depolarization of heart 12. ECG signal 202 is shown for reference purposes only. The techniques of this disclosure need not use or rely upon ECG signal 202 in order to determine cardiac cycle lengths.

[0068] Using certain techniques of this disclosure, various pressures measured during systole, e.g., peak-systolic pressure, may be determined from pulmonary artery pressure signal 200 and derivatives, e.g., dP/dt signal 208, derived therefrom. Briefly, in order to determine peak-systolic pressure, for example, a point of maximum value, e.g., peak, in the first derivative of a pressure signal is identified, the pressure signal being a function of a pressure in heart 12. After identifying the point in the first derivative of the pressure signal, a time window is initiated that begins at the point of maximum value and that extends forward in time. Peak-systolic pressure is determined by identifying a maximum value of pulmonary artery pressure signal 200 within the time window. Using the techniques of this disclosure, a peak-systolic pressure may be determined without reference to electrical activity of the heart.

[0069] This technique for determining peak-systolic pressure is described with reference to FIG. 6 as follows. The slope in pulmonary artery pressure signal 200 is shown graphically as dP/dt signal 208, i.e., the first order derivative of pressure with respect to time. A maximum value in the first derivative of the pressure signal, i.e., peak dP/dt, is

identified, as shown at **210** in dP/dt signal **208**. The peak dP/dt may be determined via a threshold crossing algorithm, e.g., the threshold crossing algorithm used to sense PAP waveforms. A window may be initiated once dP/dt exceeds a threshold value and either d^2P/dt^2 is greater than zero or a number “*n*” samples, e.g., 1-3, are below the threshold value prior to becoming suprathreshold. The window may be approximately 100 milliseconds to about 200 milliseconds in length. A maximum value in the first derivative of the pressure signal, i.e., peak dP/dt , is identified within this window.

[0070] A time window that extends forward in time, e.g., time window **212**, is initiated at the peak in the first derivative of the pressure signal, e.g., point **210** of dP/dt signal **208**. The time window may be predetermined, or its duration may be modulated adaptively, based on one or more other physiologic variables, e.g., heart rate. Peak-systolic pressure is determined by identifying a maximum value of pulmonary artery pressure signal **200** within time window **212**, as indicated at **214**. In this manner, peak-systolic pressure may be determined without the use of invasive electrodes or other hardware. Delivery of a therapeutic substance or therapeutic electrical stimulation, e.g., via IMD **16**, may be controlled based on the identified maximum value of the pressure signal, i.e., the peak-systolic pressure. In some example implementations, pressure information may be determined and stored, without adjusting therapy based on the information.

[0071] FIG. 7 is a flow diagram illustrating an exemplary method for determining systolic pressure, in accordance with various techniques of this disclosure. As indicated above, pressure analysis module **90** of IMD **16** (FIG. 3) or pressure analysis module **502** of pressure sensor **92** (FIG. 4) may be used to perform some or all of the calculations described above in order to calculate systolic pressure. For example, pressure sensor **92** (FIG. 3) may transmit pressure information, or data, representing pulmonary artery pressure signal **200** to a processor, e.g., processor **80** (FIG. 3), via telemetry module **88** (FIG. 3) (**250**). In response, processor **80** stores the received pressure information in memory **82** (FIG. 3) as pressure data **94** and then pressure analysis module **90** (FIG. 3) processes pressure data **94** (FIG. 3) by applying a high pass filter, e.g., a derivative filter, to pressure data **94** to determine a derivative, e.g., first, second, or other higher derivative, of pulmonary artery signal **200** (**252**). In other words, pressure analysis module **90** generates a plurality of points of slope in the pressure signal. Filtering the pressure information may reduce or eliminate noise caused by respiration. By applying a first order derivative filter to pulmonary artery signal **200**, pressure analysis module **90** determines the slope of pulmonary artery signal **200** e.g., dP/dt signal **208**, and helps identify sections of the signal with the greatest rate of change. It should be noted that, in some examples, pressure analysis module **90** processes the pressure information received from pressure sensor **92** without first storing the information in memory **82**.

[0072] After applying a first order derivative filter to pulmonary artery signal **200** to determine a slope of pulmonary artery signal **200**, pressure analysis module **90** identifies a point within a derivative signal of a cardiovascular pressure signal without reference to electrical activity of a heart (**254**). In particular, pressure analysis module **90** identifies a maximum value of the first derivative signal. Pressure analysis module **90** then initiates a time window,

e.g., time window **212** of FIG. 6, which extends forward in time from the maximum value (**256**). The length of the time window may be stored as a parameter within memory **82** of IMD **16**, for example. The time window may have a fixed length, e.g., about 50 milliseconds (ms) to about 500 ms, that may be user configurable or otherwise preprogrammed.

[0073] In other examples, the time window may have a variable length which may adapt to physiological conditions. For example, the time window may decrease in length if the heart rate increases or increase in length if the heart rate decreases. To provide an adaptive time window, pressure analysis module **90** may, for example, determine the mean, median, mode, or the like (referred to collectively as an “average”) of several cardiac cycle length measurements, which may be determined as described below, compare the determined average cycle length to one or more predetermined threshold values, or a function, lookup table, or the like, and then adjust the time window accordingly to account for any increase or decrease in heart rate.

[0074] The cardiac cycle length may be determined from the pulmonary artery pressure signal as the length of time between any two corresponding points, e.g., maximum values, in pulmonary artery pressure signal **200**. For example, the time between points **214** and **216** in pulmonary artery pressure signal **200** represents a cardiac cycle, and thus a cardiac cycle length. Similarly, cardiac cycle length may be determined from derivative signal **208** as the length of time between any two corresponding points, e.g., peaks, of the derivative signal. For example, the time between points **210** and **218** in first derivative signal **208** represents a cardiac cycle length. Regardless of whether time window **212** of FIG. 6 is fixed or adaptive, pressure analysis module **90** identifies a point within the cardiovascular pressure signal within the time window (**258**). Then, pressure analysis module **90** determines a systolic pressure based on the identified point (**260**). In particular, pressure analysis module **90** determines, within the time window, a maximum value of pulmonary artery pressure signal **200**, which corresponds to the peak-systolic pressure. If there is a group of adjacent points of the pressure waveform within time window **212** that all have the maximal value (i.e., the PA pressure peak has a small flattened area), then an algorithm may be used to choose one of those identically-valued points. Examples include choosing the first point in the group, choosing the last point, or choosing a middle point. If the points that all had the maximal value were not adjacent, a similar rule may be used to choose the point to be deemed the correct peak-systolic pressure and its time of occurrence.

[0075] Although the determination of peak-systolic pressure was described above with respect to pressure analysis module **90**, as mentioned above, pressure analysis module **502** of pressure sensor **92**, a pressure analysis module of programmer **24**, or a pressure analysis module of another device, may be used to determine peak-systolic pressure using the techniques of this disclosure. In some examples, a pressure analysis module may be implemented in one or more devices identified herein, such as one or more processors of the devices such as pressure sensor **92**, IMD **16**, and programmer **24** to determine peak-systolic pressure using the techniques of this disclosure.

[0076] In addition to determining peak-systolic pressure within a pulmonary artery, e.g., pulmonary artery **100**, various techniques of this disclosure may be used to deter-

mine a diastolic pressure, e.g., an end-diastolic pressure, within the pulmonary artery, as described below with respect to FIG. 8.

[0077] FIG. 8 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first and second derivatives of the pulmonary arterial pressure signal, which may be used to determine a diastolic pressure, in accordance with certain techniques of this disclosure.

[0078] Similar to FIG. 6, FIG. 8 depicts pulmonary artery pressure signal 300 from pressure sensor 92 (FIG. 3) in pulmonary artery 100 in reference to electrocardiogram (ECG) signal 302. ECG signal 302 is shown for reference purposes only. The techniques of this disclosure do not use or rely upon ECG signal 302. Using certain techniques of this disclosure, various pressures measured during diastole, e.g., end-diastolic pressure, may be determined from pulmonary artery pressure signal 300 and derivatives, e.g., dP/dt signal 304 and d^2P/dt^2 signal 306, derived therefrom. In order to determine end-diastolic pressure, for example, a point of maximum value, e.g., peak, in the first derivative of a pressure signal is identified, the pressure signal being a function of a pressure in heart 12. After identifying the point in the first derivative of the pressure signal, a time window is initiated that begins at the point of maximum value and that extends backward in time. Then, a point of maximum second derivative within the time window is identified. An end-diastolic pressure is determined by identifying the point on the pulmonary artery pressure signal 300 within the time window that corresponds in time to the point of maximum second derivative. If there is a group of adjacent points of the second derivative that all have the maximal value (i.e., the second derivative peak has a small flattened area), then an algorithm may be used to choose one of those identically-valued points. Examples include choosing the first point in the group, choosing the last point, or choosing a middle point. If the points that all had the maximal value were not adjacent, a similar rule may be used to choose the point to be deemed the correct end-diastolic pressure and its time of occurrence. Using certain techniques of this disclosure, an end-diastolic pressure may be determined without reference to electrical activity of the heart.

[0079] This technique for determining end-diastolic pressure is described with reference to FIG. 8 as follows. The slope in pulmonary artery pressure signal 300 is shown graphically as dP/dt signal 304, i.e., the first order derivative of pulmonary artery pressure with respect to time. A point of maximum value in the first derivative of the pulmonary artery pressure, i.e., peak dP/dt , is shown at 308 in dP/dt signal 304. The peak dP/dt may be determined via a threshold crossing algorithm, e.g., the threshold crossing algorithm used to sense PAP waveforms. A window may be initiated once dP/dt exceeds a threshold value and either d^2P/dt^2 is greater than zero or a number "n" samples, e.g., 1-3, are below the threshold value prior to becoming suprathreshold. The window may be about 100 milliseconds to about 200 milliseconds in length. The maximum value in the first derivative of the pulmonary artery pressure, i.e., peak dP/dt , is identified within this window.

[0080] A time window, e.g., time window 310, which extends backward in time is initiated at the point of maximum value in the first derivative of the pressure signal, e.g., point 308 of dP/dt signal 304. Then, a point of maximum second derivative (an inflection point) within time window 310 is identified, as shown at 312 in d^2P/dt^2 signal 306. An

end-diastolic pressure is then determined by identifying the value of pulmonary artery pressure signal 300 within time window 310 that corresponds in time to the point of maximum second derivative, as shown at 314 by the intersection of dashed line 316 and pulmonary artery pressure signal 300. In this manner, an end-diastolic pressure may be determined without the use of invasive electrodes or other hardware. Delivery of a therapeutic substance or therapeutic electrical stimulation, e.g., via IMD 16, may be controlled based on the identified maximum value of the second derivative of the pressure signal, i.e., the end-diastolic pressure. In some example implementations, pressure information may be determined and stored, without adjusting therapy based on the information.

[0081] FIG. 9 is a flow diagram illustrating an exemplary method for determining an end-diastolic pressure, in accordance with various techniques of this disclosure. As mentioned above, a pressure analysis module, e.g., pressure analysis module 90 of IMD 16 (FIG. 3), may be used to perform some or all of the calculations described above in order to calculate an end-diastolic pressure. For example, pressure sensor 92 (FIG. 3) may transmit pressure information representing pulmonary artery pressure signal 200 to processor 80 (FIG. 3) via telemetry module 88 (FIG. 3) (350). In response, processor 80 stores the received pressure information in memory 82 (FIG. 3) as pressure data 94 (FIG. 3) and then pressure analysis module 90 (FIG. 3) processes pressure data 94 by applying high pass filters, e.g., derivative filters, to pressure data 94 to determine first and second order derivatives of pulmonary artery signal 300 (352). By applying a first order derivative filter to pulmonary artery signal 300, pressure analysis module 90 determines the slope of pulmonary artery signal 300, e.g., dP/dt signal 304. By applying a second order derivative filter to pulmonary artery signal 300, pressure analysis module 90 determines the second derivative of pulmonary artery signal 300, e.g., d^2P/dt^2 signal 306. It should be noted that, in some examples, pressure analysis module 90 processes the pressure information received from pressure sensor 92 without first storing the information in memory 82.

[0082] After applying derivative filters to pulmonary artery signal 300, pressure analysis module 90 identifies a point within a derivative signal of a cardiovascular pressure signal without reference to electrical activity of a heart (354). In particular, pressure analysis module 90 identifies a point of maximum value from the determined slope, e.g., point 308. Pressure analysis module 90 then initiates a time window, e.g., time window 310 of FIG. 8, from the identified point which extends backward in time from the point of maximum value (356). The length of the time window may be stored as a parameter within memory 82 of IMD 16, for example. The time window may have a fixed length that may be user configurable or otherwise preprogrammed. In one example of a time window having a fixed length, the time window may be set such that the end-diastolic pressure is identified within 200 ms, for example, prior to the identified maximum dP/dt value. In some examples, the time window may have variable length which may adapt to physiological conditions, such as cardiac cycle length, as described above with respect to determination of systolic pressure and FIG. 6.

[0083] Within the time window, e.g., time window 310 of FIG. 8, pressure analysis module 90 identifies a point of maximum second derivative within time window 310, e.g.,

point **312** in d^2P/dt^2 signal **306**. Pressure analysis module **90** then identifies a point within the cardiovascular signal within the time window (**358**). Then pressure analysis module **90** determines an end-diastolic pressure based on the identified point (**360**). In particular, pressure analysis module **90** determines an end-diastolic pressure by identifying the value of the pulmonary artery pressure signal **300** within time window **310** that corresponds in time to the point of maximum second derivative, e.g., point **314**. In this manner, an end-diastolic pressure may be determined without the use of invasive electrodes or other hardware.

[**0084**] Although the determination of end-diastolic pressure was described above with respect to pressure analysis module **90**, as mentioned above, pressure analysis module **502** of pressure sensor **92**, a pressure analysis module of programmer **24**, or a pressure analysis module of another device, may be used to determine end-diastolic pressure using the techniques of this disclosure. In some examples, a pressure analysis module may be implemented in one or more devices identified herein, such as one or more processors of the devices such as pressure sensor **92**, IMD **16**, and programmer **24** to determine end-diastolic pressure using the techniques of this disclosure.

[**0085**] In addition to pressure metrics such as end-diastolic and systolic pressures, various techniques of this disclosure may be used to determine a cardiac cycle length, as described in detail below with respect to FIG. **10**. A cardiac cycle is the complete cycle of events in the heart, and a cardiac cycle length is the amount of time between a first event of a first heart beat and a corresponding second event of a second heart beat that immediately follows the first heart beat.

[**0086**] FIG. **10** is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a cardiac cycle length, in accordance with certain techniques of this disclosure. FIG. **10** depicts pulmonary artery pressure signal **400** from pressure sensor **92** in pulmonary artery **100** in reference to electrocardiogram (ECG) signal **402**. ECG signal **402** is shown for reference purposes only. The techniques of this disclosure do not use or rely upon ECG signal **402**.

[**0087**] An exemplary technique for determining a length of a cardiac cycle is described with reference to FIG. **10** as follows. The slope in pulmonary artery pressure signal **400** is shown graphically as dP/dt signal **404**, i.e., the first order derivative of pulmonary artery pressure with respect to time. First order derivative signal **404** comprises a plurality of points of slope. A first one of the plurality of points of slope of signal **404** that is greater than a threshold value, indicated by line **405**, is identified, as shown at **406**. Useful thresholds in humans span the approximate range of about 40 mmHg/s to about 600 mmHg/s. The thresholds are specified to the algorithm in mmHg/W, where “W” is the window duration over which the derivative is estimated. For example, if the derivative was estimated over 4 samples at a sampling frequency of 128 Hz, then W, the window length, would be $4/128 \text{ Hz} = 0.0313$ seconds. Then, if the optimal threshold with this derivative estimator was found to be 16 mmHg/W, the corresponding derivative threshold in mmHg/s would be $16/0.0313 = 512$ mmHg/s. Higher values may be useful in non-human subjects. This identified point may also be referred to as a “sense,” i.e., a suprathreshold value of the first order derivative of the pulmonary artery pressure signal.

In some example implementations, the threshold value may be a fixed value. In other example implementations, the threshold value may be adaptive and adapt to changing physiological conditions. For example, the threshold may vary with the value of the last dP/dt maximum. The threshold could also decrease with time from some function of the previous dP/dt maximum.

[**0088**] In addition to dP/dt being suprathreshold, i.e., satisfying the threshold, there may be additional conditions before identifying the “sense.” One example condition is that d^2P/dt^2 be greater than zero when dP/dt becomes suprathreshold. This condition may help ensure that the signal is rising when the sense is identified. Another example condition is to make sure that a number “n” samples of dP/dt , e.g., 1-3 samples, are below the threshold prior to becoming suprathreshold. This may help ensure that there was a “-” to “+” threshold cross. These conditions may be useful when the signal first exits the blanking period.

[**0089**] After a sense, i.e., after a point of slope of signal **404** that is greater than a threshold value is identified, e.g., point **406** in FIG. **10**, a first time window is initiated that extends forward in time, e.g., time window **408**. During first time window **408**, a first point of maximum value of dP/dt signal **404** is identified, depicted in FIG. **10** at **410**. Time window **408** may have a length of about 200 ms to about 400 ms, for example.

[**0090**] First time window **408** is searched until the first point of maximum value of dP/dt signal **404** is identified, e.g., maximum value **410**. Then, a second one of the plurality of points of slope in the pressure signal within the time window **408** is identified, e.g., first point of maximum value of dP/dt **410**. This second one of the plurality of points of slope serves as a first reference point for determining the length of the cardiac cycle. As described below, a corresponding second reference point is identified and the cardiac cycle length is the time between the first and second reference points. For example, a corresponding second reference point may be a second point of maximum value of dP/dt , shown at **420**. In such an example, the cardiac cycle length is the time between point **410** and point **420**. In other examples, the first reference point may be first sense **406**, the second reference point may be second sense **416**, and the cardiac cycle length is the time between point **406** and **416**. In another example, the cardiac cycle length may be determined instead between two peak-systolic pressures, or between two end-diastolic pressures. It should be noted that any pre-defined point derived from pressure or dP/dt may be used as a cardiac cycle delimiter.

[**0091**] A second time window, e.g., time window **414**, that extends forward in time to second time **415** may be initiated at the first sense. The second time window **414** is greater than the first time window **408** and therefore extends beyond the first time window **408**, i.e., later in time than the first time window **408**. The second time window **414** represents a blanking period, e.g., an idle period, during which the determination of a sense, i.e., identification of a point of slope signal **404** being greater than the threshold value **405**, is no longer made in order to prevent extraneous measurements caused by respiration, cardiac variations, and the like from being sensed by pressure sensor **92**. The effective blanking period is actually the time from the first sense, e.g., point **406**, to second time **415**, i.e., second time window **414**. Second time **415**, i.e., the end of the effective blanking period, is determined by finding the time at which the

peak-systolic pressure occurs and adding a blanking period, e.g., about 100 milliseconds to about 300 milliseconds. This blanking technique may prevent double senses in the event that pressure increases because of respiration, e.g., at the beginning of expiration, or because of normal cardiac-caused waveform variations, e.g., the dicrotic notch. By determining the end of the blanking period from the time of peak-systolic pressure, i.e., terminating the blanking period based on a time since peak-systolic pressure, this technique also results in a rate adaptive blanking period. Because the time from the sense to the maximum pressure decreases as heart rate increases, the effective blanking period also decreases as rate increases. Using various techniques of this disclosure may help to prevent missed senses at higher heart rates, while providing adequate blanking at lower heart rates. The minimum detected cycle length is equal to the effective blanking period, i.e., second time window 414 and the maximum heart rate equals 60,000 divided by the minimum detected cycle length.

[0092] The effective blanking period described above, i.e., second time window 414, may be rate adaptive and adapt to physiological conditions in additional ways to that described above. For example, the blanking period may be timed from the sense and made rate adaptive with respect to measured heart rate, e.g., decrease in duration if the heart rate increases or increase in duration if the heart rate decreases. To provide an adaptive blanking period, a processor may, for example, determine the mean, median, mode, or the like (referred to collectively as an “average”) of several cycle lengths of the pulmonary artery pressure signal, of a first derivative signal, or of a higher order derivative signal, compare the determined average cycle length to a predetermined threshold value, and then adjust the blanking window accordingly to account for any increase or decrease in heart rate. In other examples, the blanking period may be fixed. For example, a fixed blanking period may be initiated at the first sense, e.g., point 406.

[0093] After the blanking period represented by second time window 414 has expired, a third one of the plurality of points of slope of signal 404 that is greater than the threshold value, indicated by line 405, is identified, as shown at 416. In other words, a third one of the plurality of points of slope of signal 404 that is greater than the threshold value is identified outside the second time window, e.g., time window 414. This identified point may also be referred to as a second “sense,” i.e., a suprathreshold value of the first order derivative of the pulmonary artery pressure signal. In addition to dP/dt being suprathreshold, there may be additional conditions before identifying the “sense,” as described above.

[0094] After identifying the third one of the plurality of points of slope of signal 404, i.e., the second sense, shown at 416, a fourth one of the plurality of points of slope in the pressure signal that corresponds in dP/dt signal 404, i.e., the slope in the pressure signal, to the previously identified second one of the plurality of points of slope in the pressure signal within the first time window. This fourth one of the plurality of points of slope serves as a second reference point for determining the length of the cardiac cycle. For example, if first point of maximum value of dP/dt 410 was selected as a first reference point, then second point of maximum value of dP/dt 420 should be selected as the corresponding second reference point. Or, if first sense 406 was selected as the first reference point, then second sense 416 should be selected as

the corresponding second reference point. Although described above with respect to a first maximum value of dP/dt and a second maximum value of dP/dt and a first sense and a second sense, a cardiac cycle length may be measured also be measured between a first end-diastolic pressure and a second end-diastolic pressure and a first peak-systolic pressure and a second peak-systolic pressure.

[0095] Finally, a difference in time is determined between the identified fourth one of the plurality of points of slope in the pressure signal, e.g., the second reference point shown at 420 in FIG. 10, and the identified second one of the plurality of points of slope in the pressure signal within the first time window, e.g., the first reference point shown at 410 in FIG. 10. This difference in time represents the length of the cardiac cycle. Delivery of a therapeutic substance or therapeutic electrical stimulation, e.g., via IMD 16, may be controlled based on the determined difference in time, i.e., the cardiac cycle length. In some example implementations, pressure information may be determined and stored, without adjusting therapy based on the information.

[0096] FIG. 11 is a flow diagram illustrating an exemplary method for determining a cardiac cycle length, in accordance with various techniques of this disclosure. A pressure analysis module, e.g., pressure analysis module 90 of IMD 16, may be used to perform some or all of the calculations described above in order to calculate a cardiac cycle length. For example, pressure sensor 92 may transmit pressure information representing pulmonary artery pressure signal 200 to processor 80 via telemetry module 88. In response, processor 80 stores the received pressure information in memory 82 as pressure data 94 and then pressure analysis module 90 processes pressure data 94 by applying a derivative filter to pressure data 94 to determine a derivative, e.g., first, second, or other higher derivative, of pulmonary artery signal 400. By applying a first order derivative filter to pulmonary artery signal 400, pressure analysis module 90 generates a derivative signal of the cardiovascular pressure signal. Pressure analysis module 90 identifies a plurality of fiducial points, i.e., time reference points, within the derivative signal of the cardiovascular pressure signal. It should be noted that, in some examples, pressure analysis module 90 processes the pressure information received from pressure sensor 92 without first storing the information in memory 82.

[0097] After identifying a plurality of fiducial points within the derivative signal of the cardiovascular pressure signal, pressure analysis module 90 identifies a length of time between consecutive ones of the fiducial points as a cardiac cycle length. For example, as indicated above, a cardiac cycle length may be measured between a first sense and a second sense, a first end-diastolic pressure and a second end-diastolic pressure, a first peak-systolic pressure and a second peak-systolic pressure, or a first maximum dP/dt and a second maximum dP/dt. In particular, pressure analysis module 90 compares the derivative signal to a threshold (450). For example, pressure analysis module 90 compares pressure signal 404 to threshold 405. Then, pressure analysis module 90 identifies a point within the derivative signal that satisfies the threshold (452). For example, pressure analysis module 90 identifies that point 406 of FIG. 10 is greater than then threshold value indicated by line 405. Pressure analysis module 90 identifies a fiducial point within the derivative signal subsequent to the identified point within the derivative signal that satisfied the threshold (454).

For example, as described above, pressure analysis module 90 may identify first point of maximum value of dp/dt 410 within window 408 of FIG. 10 as a fiducial point. In another example, pressure analysis module 90 may identify first sense 406 as a fiducial point. Then, pressure analysis module 90 initiates a blanking period, e.g., blanking period 414, that begins at the first sense, e.g., point 406 (456). Finally, pressure analysis module 90 identifies a length of time between consecutive ones of the fiducial points as a cardiac cycle length (458). For example, pressure analysis module 90 identifies a length of time between points 410 and 420, or between point 406 and point 416 in FIG. 10 as a cardiac cycle length. It should be noted that the derivative signal is not compared to the threshold for identification of a subsequent one of the fiducial points during the blanking period.

[0098] Although the determination of a cardiac cycle length was described above with respect to pressure analysis module 90, as mentioned above, pressure analysis module 502 of pressure sensor 92, a pressure analysis module of programmer 24, or a pressure analysis module of another device, may be used to determine a cardiac cycle length using the techniques of this disclosure. In some examples, a pressure analysis module may be implemented in one or more devices identified herein, such as one or more processors of the devices such as pressure sensor 92, IMD 16, and programmer 24 to determine a cardiac cycle length using the techniques of this disclosure.

[0099] FIG. 12 is a block diagram illustrating an exemplary system 600 that includes an external device, such as a server 602, and one or more computing devices 604A-604N, that are coupled to the IMD 16 and programmer 24 shown in FIG. 1 via a network 606. In this example, IMD 16 may use its telemetry module 88 to communicate with programmer 24 via a first wireless connection, and to communication with an access point 608 via a second wireless connection. In the example of FIG. 12, access point 608, programmer 24, server 602, and computing devices 604A-604N are interconnected, and able to communicate with each other, through network 606. In some cases, one or more of access point 608, programmer 24, server 602, and computing devices 604A-604N may be coupled to network 606 through one or more wireless connections. IMD 16, programmer 24, server 602, and computing devices 604A-604N may each comprise one or more processors, such as one or more microprocessors, DSPs, ASICs, FPGAs, programmable logic circuitry, or the like, that may perform various functions and operations, such as those described herein.

[0100] Access point 608 may comprise a device that connects to network 606 via any of a variety of connections, such as telephone dial-up, digital subscriber line (DSL), or cable modem connections. In other examples, access point 608 may be coupled to network 606 through different forms of connections, including wired or wireless connections. In some examples, access point 608 may be co-located with patient 14 and may comprise one or more programming units and/or computing devices (e.g., one or more monitoring units) that may perform various functions and operations described herein. For example, access point 608 may include a home-monitoring unit that is co-located with patient 14 and that may monitor the activity of IMD 16.

[0101] In some cases, server 602 may be configured to provide a secure storage site for data that has been collected from IMD 16 and/or programmer 24. Network 606 may comprise a local area network, wide area network, or global

network, such as the Internet. In some cases, programmer 24 or server 602 may assemble data in web pages or other documents for viewing by trained professionals, such as clinicians, via viewing terminals associated with computing devices 604A-604N. The illustrated system of FIG. 12 may be implemented, in some aspects, with general network technology and functionality similar to that provided by the Medtronic CareLink® Network developed by Medtronic, Inc., of Minneapolis, Minn.

[0102] In some examples, processor 610 of server 602 may be configured to receive pressure information from pressure sensor(s) 92 for processing by pressure analysis module 612 in the manner described throughout this disclosure. In other examples, processor 610 may received data processed by a pressure analysis module, e.g., processed data 96 processed by pressure analysis module 90 of IMD 16. Pressure analysis module 612 may determine cardiac cycle lengths, systolic pressures, and/or diastolic pressures based on the received pressure information using any of the techniques described in this disclosure. Processor 610 may provide alerts to users, e.g., to the patient via access point 608 or to a clinician via one of computing devices 604, identifying change, e.g., worsening, in patient condition based on cardiac cycle length and/or pressure metrics measured from pulmonary arterial pressures. Processor 610 may suggest to a clinician, e.g., via programmer 24 or a computing device 604, a change in a therapy, such as CRT, based on cardiac cycle length and/or pressure metrics measured from pulmonary arterial pressures. Processor 610 may also adjust or control the delivery of therapy by IMD 16, e.g., electrical stimulation therapy and/or a therapeutic substance, via network 606.

[0103] FIG. 13 is block diagram of an embodiment of another example implantable medical device that may be used to delivery drug therapy based on the determined cycle lengths and/or various pressure metrics. IMD 712 includes fill port 726, reservoir 730, processor 770, memory 772, telemetry module 774, power source 776, and drug pump 778. Processor 770 may include a microprocessor, a controller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), discrete logic circuitry, or the like. Drug pump 778 may be a mechanism that delivers a therapeutic agent in some metered or other desired flow dosage to the therapy site within patient 14 from reservoir 730 via the catheter 718 based on the determined cycle lengths and/or various pressure metrics measured using the techniques of this disclosure.

[0104] Processor 770 controls the operation of drug pump 778 with the aid of instructions that are stored in memory 772. For example, the instructions may define therapy programs that specify the bolus size of a therapeutic agent that is delivered to a target tissue site within patient 14 from reservoir 730 via catheter 718. The therapy programs may also include other therapy parameters, such as the frequency of bolus delivery, the concentration of the therapeutic agent delivered in each bolus, the type of therapeutic agent delivered (if IMD 712 is configured to deliver more than one type of therapeutic agent), and so forth.

[0105] Memory 772 may include any volatile or non-volatile media, such as a random access memory (RAM), read only memory (ROM), non-volatile RAM (NVRAM), electrically erasable programmable ROM (EEPROM), flash memory, and the like. Memory 772 may store instructions

for execution by processor 770, such as therapy programs and any other information regarding therapy of patient 14. Memory 772 may include separate memories for storing instructions, patient information, therapy parameters (e.g., grouped into sets referred to as “therapy programs”), and other categories of information. In some embodiments, memory 772 stores program instructions that, when executed by processor 770, cause IMD 712 and processor 770 to perform the functions attributed to them herein.

[0106] Telemetry module 774 in IMD 712, as well as telemetry modules in other devices, e.g., a patient or clinician programmer, may accomplish communication by RF communication techniques. One or more pressure sensors 92 may be in communication with IMD 712 via telemetry module 774. Pressure analysis module 790 analyzes the pressure data received from pressure sensor(s) 92. Pressure analysis module 790 may be implemented as software, firmware, hardware or any combination thereof. In some example implementations, pressure analysis module 790 may be a software process implemented in or executed by processor 770. Memory 772 is one example of a non-transitory, computer-readable storage medium that includes computer-readable instructions that, when executed by processor 770, cause IMD 712 and processor 770 to titrate deliver of a therapeutic agent based on the determined cycle lengths and/or various pressure metrics. Memory 772 may include any volatile, non-volatile, magnetic, optical, or electrical media, such as a random access memory (RAM), read-only memory (ROM), non-volatile RAM (NVRAM), electrically-erasable programmable ROM (EEPROM), flash memory, or any other digital or analog media.

[0107] FIG. 14 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first derivative of the pulmonary arterial pressure signal, which may be used to determine a cardiac cycle length and/or one or more pressure metrics, in accordance with certain techniques of this disclosure. FIG. 14 depicts pulmonary artery pressure signal 700 from pressure sensor 92 in pulmonary artery 100 in reference to electrocardiogram (ECG) signal 802. ECG signal 702 is shown for reference purposes only. The techniques of this disclosure do not use or rely upon ECG signal 702.

[0108] An exemplary technique for determining a length of a cardiac cycle is described with reference to FIG. 14 as follows. The slope in pulmonary artery pressure signal 700 is shown graphically as dP/dt signal 704, i.e., the first order derivative of pulmonary artery pressure with respect to time. First order derivative signal 704 comprises a plurality of points of slope. A first one of the plurality of points of slope of signal 704 that is greater than a threshold value, such as described below and indicated by line 705, is identified, as shown at 706. This identified point may also be referred to as a “sense”. As described above, in some exemplary implementations, the threshold value may be a fixed value. In other exemplary implementations, the threshold value may be adaptive and adapt to changing physiological conditions. For example, the threshold may vary with the value of the last dP/dt maximum. The threshold could also decrease with time from some function of the previous dP/dt maximum.

[0109] In addition to dP/dt being determined to be greater than the threshold 705, there may be additional conditions before identifying the “sense.” One example condition is that d^2P/dt^2 also be greater than zero when dP/dt is greater

than threshold 705. This condition may help ensure that the signal is rising when the sense is identified. Another example condition is to make sure that a number “n” samples of dP/dt , e.g., 1-3 samples, are below the threshold prior to dP/dt being greater than threshold 705. This may help ensure that there was a “-” to “+” threshold cross. These conditions may be useful when the signal first exits the blanking period.

[0110] According to an embodiment of the disclosure, in order to improve the accuracy of pressure waveform sensing and pressure measurements on waveforms that may be corrupted as a result of oversensing or being sensed too early, for example, a false sense thresholding process may be included. Utilization of a false sense threshold effectively allows the sensing threshold for determining when the slope of the pressure signal corresponds to a sense to be set lower to sense low dP/dt waveforms, while at the same time appropriately delaying sensing, and therefore pressure measurement, if the sense threshold is crossed too early for the coming pressure waveform as a result of the initial low setting of the sense threshold. As a result, pressure waveform sensing and pressure measurement may be improved.

[0111] For example, according to an embodiment for determining of cycle length, once a point of slope of signal 704 is determined to be greater than the sense threshold 705 and therefore a sense 705 has occurred, a time window 708 is initiated that extends forward in time from the determined sense 706, and a maximum value 710 of the first derivative pressure dP/dt signal 704 is determined during the time window 708. According to an embodiment that includes the false sense threshold feature, time window 708 may have a length of approximately 150 ms, for example.

[0112] As described above, a second time window, e.g., time window 714, that extends forward in time to second time 720 from sense 706 is also initiated at sense 706. The second time window 714 is greater than the first time window 708 and therefore extends beyond the first time window 708, i.e., later in time than the first time window 708. The second time window 714 represents a blanking period, e.g., an idle period, during which the determination of a sense, i.e., identification of a point of slope signal 704 being greater than the threshold value 705, is no longer made in order to prevent extraneous measurements caused by respiration, cardiac variations, and the like from being sensed by pressure sensor 92.

[0113] According to one embodiment that includes the use of the false sense threshold, once time window 708 during which determination of the maximum value of dP/dt signal 710 is made has expired, the slope signal 704 is compared to a second sense threshold 707 greater than the initial sense threshold 705. For example, according to one embodiment, the second sense threshold 707 is set equal to the previously determined maximum value 710 of the slope signal 704. In the alternative, the second sense threshold may be set equal to a predetermined increased value of the initial sense threshold 705.

[0114] The slope signal 704 is then compared to the second sense threshold 707 for a predetermined time period 715. According to one embodiment, the time period 715 extends forward in time from the end 713 of time window 708, for example. The time window 715 for the sense threshold 705 being set equal to the maximum slope value 710 may have a fixed length, e.g., approximately 50 to 500

ms, that may be user configurable or otherwise preprogrammed, or may have an adaptive or variable length, as described above.

[0115] If a sense 709 occurs, i.e., the slope signal 704 becomes greater than the second sense threshold 707 during the time window 715, a time window 712, similar to time window 708, for example, is initiated that extends forward in time from the sense 709. A maximum value 711 of the slope signal 704 is determined during time window 712. The previous sense 706 and corresponding maximum slope 710 are then discarded, and the pressure measurement analysis is resumed based on the most recent sense 709 and the corresponding updated maximum slope 711. In particular, once the time window 712 has expired, a next sense 716 is identified by comparing the slope signal 704 to the initial sense threshold 705, a time window 713 is initiated that extends forward in time from the determined sense 716, and a maximum slope signal 720 occurring during the time window 713 is determined. The cycle length is then determined based on the interval between sense 709 and sense 716, or between maximum slope signal 711 and maximum slope signal 720, as described above in reference to FIG. 10.

[0116] According to an embodiment of the disclosure, the false sense threshold process may be repeated after the subsequent sense 716 occurs, using the maximum slope signal 720 as the second sense threshold 707, for example, and if the slope signal 704 is determined to be greater than the second threshold 707 during a predetermined time period 717, similar to time window 713, the immediately prior sense 709 is discarded, and the pressure measurement analysis is repeated based on the most recent sense 716.

[0117] If a sense does not occur during time window 715 initiated after the initial sense 706, i.e., the slope signal 704 does not become greater than the second sense threshold 707 during the time window 715, the pressure measurement analysis continues based upon the most recent sense 706 and corresponding determined maximum 710 of the slope signal 704. In particular, once the second time window 715 has expired and no sense has occurred during time window 715, the next sense 716 is identified by comparing the slope signal 704 to the initial sense threshold 705, the time window 713 is initiated that extends forward in time from the determined sense 716, and the maximum slope signal 720 occurring during the time window 713 is determined. The cycle length is then determined based on the interval between sense 706 and sense 716, or between maximum slope signal 710 and maximum slope signal 720, as described above in reference to FIG. 10. According to an embodiment of the disclosure, application of the false sense threshold may also be repeated subsequent to the determined sense 716, which, if a sense occurs during the time window 717 using an updated sense threshold, such as the maximum sense 720 for example, could result in the process being initiated again using the sense determined during time window 717, and so forth.

[0118] In either event, once two consecutive maximum slope values have been determined without a false sense threshold being exceeded, resulting in a cycle length being determined, delivery of a therapeutic substance or therapeutic electrical stimulation, e.g., via IMD 16, may be controlled based on the determined difference in time, i.e., the cardiac cycle length. In some example implementations, pressure information may be determined and stored, without adjusting therapy based on the information.

[0119] It is understood that while utilization of the false sense threshold has been described as being implemented during the determination of cycle length, the false sense threshold may also be utilized during other pressure measurement processes, such as determination of one or both of systolic pressure and diastolic pressure, for example.

[0120] FIG. 15 is a timing diagram showing a signal indicative of pulmonary arterial pressure, and the first and second derivatives of the pulmonary arterial pressure signal, which may be used to determine a systolic pressure, a diastolic pressure, and/or a cycle length in accordance with certain techniques of this disclosure. Similar to FIG. 8 described above, FIG. 15 depicts pulmonary artery pressure signal 800 from pressure sensor 92 in pulmonary artery 100 in reference to electrocardiogram (ECG) signal 802, along with a first derivative signal dP/dt 804 and a second derivative signal d^2P/dt^2 806, derived therefrom. ECG signal 802 is shown for reference purposes only. The techniques of this disclosure do not use or rely upon ECG signal 802.

[0121] FIG. 15 illustrates an exemplary technique of analyzing a pressure signal for determining one or both of systolic pressure and diastolic pressure in a medical device, according to an embodiment of the disclosure. As illustrated in FIG. 15, following first derivative filtering of a pressure signal 800, a determination is made as to whether the resulting first order derivative dP/dt signal 804 is greater than a predetermined sense threshold 805. According to one embodiment, for example, the sense threshold 805 is set as 27 mmHg/sec. This identified point when the first order derivative signal 804 is determined to be greater than the predetermined sense threshold 805 may also be referred to as a “sense”. As described above, in some exemplary implementations, the sense threshold 805 may be a fixed value. In other exemplary implementations, the sense threshold 805 may be adaptive and adapt to changing physiological conditions. For example, the sense threshold 805 may vary with the value of the last dP/dt maximum. The sense threshold 805 could also decrease with time from some function of the previous dP/dt maximum.

[0122] In addition to dP/dt being determined to be greater than the threshold 805, there may be additional conditions before identifying the “sense.” One exemplary condition is that a second order derivative d^2P/dt^2 signal also be greater than zero when dP/dt is greater than threshold 805. This condition may help ensure that the signal is rising when the sense is determined. Another exemplary condition is to make sure that a number “n” samples of dP/dt , e.g., 1-3 samples, are below the threshold prior to dP/dt being greater than threshold 805. This may help ensure that there was a “-” to “+” threshold cross. These conditions may be useful when the signal first exits the blanking period.

[0123] Once the first order derivative signal 804 is determined to be greater than the sense threshold 805, and therefore a sense 806 has been determined to occur, a time window 808 is initiated during which a maximum value 810 of the derivative signal 804 is determined. Time window 808 extends a predetermined time period from the occurrence of the sense 806 to an end time 814. In one embodiment, for example, time window 808 extends 150 ms from the occurrence of sense 806.

[0124] Once the maximum value 810 of the derivative signal 804 is determined, the maximum value 810 then serves as a fiducial marker for determining end diastolic and peak systolic pressures. For example, similar to the deter-

mination of an end diastolic pressure described above, a diastolic window **822** may be initiated during which a maximum value **824** or inflection point of a second derivative signal **825** is determined. Diastolic time window **822** extends beginning from a point in time **823** prior to the sense **806** and ending at the maximum value **810** of the derivative signal **804**, for example. An end-diastolic pressure is then determined by identifying the value of the pulmonary artery pressure signal **800** that corresponds in time to the point of the determined maximum second derivative **824**, as shown at **826** of FIG. 15 by the intersection of dashed line **828** corresponding in time to the maximum value **824** of the second derivative pressure signal **825** and pulmonary artery pressure signal **800**.

[0125] In addition, once the maximum value **810** of the derivative signal **804** is determined, a systolic time window **830** may be initiated during which a maximum value **832** of the pulmonary artery pressure signal **800** is determined in order to determine a peak systolic pressure similar to the determination of the peak systolic pressure described above. Time window **830** extends forward a predetermined time period from the occurrence of the sense **806** to an end time **833**. In one embodiment, for example, time window **830** extends 200 ms from the occurrence of sense **806**.

[0126] In this manner, as described above, one or both of end diastolic and peak-systolic pressure, either individually or in combination, may be determined without the use of invasive electrodes or other hardware. Delivery of a therapeutic substance or therapeutic electrical stimulation, e.g., via IMD **16**, may be controlled based on one or a combination of the identified maximum value of the pressure signal **832**, i.e., the peak-systolic pressure, and the identified value of pulmonary artery pressure signal **800** within time window **822** that corresponds in time to the point of maximum second derivative **824**, i.e., the end-diastolic pressure. In some example implementations, pressure information may be determined and stored, without adjusting therapy based on the information.

[0127] As described above in reference to FIG. 14, in order to improve pressure waveform sensing and pressure measurements on waveforms that may result from oversensing or being sensed too early as a result of baseline fluctuations during diastole, for example, a false sense threshold may be included. The false sense threshold effectively allows the sensing threshold, for determining when the slope of the pressure signal corresponds to a sense, to be set lower to sense low dp/dt waveforms, while at the same time appropriately delays sensing, and therefore pressure measurement, if the sense threshold **505** is crossed too early for the coming pressure waveform as a result of the low setting of the sense threshold. As a result, pressure waveform sensing and pressure measurement may be improved on waveforms that had previously been oversensed or sensed early because of baseline fluctuations during diastole.

[0128] For example, the determination of one or the combination of both the end diastolic and the peak systolic pressure, described above, may include the use of a false sense threshold to improve the pressure waveform sensing. In particular, once time window **808** during which determination of the maximum value of dp/dt signal **810** is made has expired, the slope signal **804** may be compared to a second sense threshold **807** greater than the initial sense threshold **805** that was utilized previously. For example, in one embodiment the second sense threshold **807** is set equal to

the previously determined maximum value **810** of the slope signal **804**. In the alternative, the second sense threshold **807** may be set equal to a predetermined increased value of the initial sense threshold **805**.

[0129] The slope signal **804** is compared to the second sense threshold **807** for a predetermined time period **815**. According to one embodiment, the time period **815** extends forward in time from the end **814** of time window **808**, for example. The time window **815** for the sense threshold being set equal to the determined maximum slope value **810** may have a fixed length that may be user configurable or otherwise preprogrammed, and may have an adaptive or variable length, as described above. According to one embodiment, illustrated in FIG. 15, time window **815** extends from the end **814** of time window **808** to the end **833** of time window **830** used for determining the maximum value **832** of the pulmonary artery pressure signal **800** during determination of the peak systolic pressure.

[0130] If a sense **809** occurs during utilization of the false sense threshold, i.e., the slope signal **804** becomes greater than the second sense threshold **807** during the time window **815**, a time window **812**, similar to time window **808**, for example, is initiated that extends forward in time from sense **809**. A maximum value **811** of the slope signal **804** is determined during time window **812**, and the previous sense **806** and corresponding maximum slope **810** are then discarded, and the pressure measurement analysis is repeated based on the most recent sense **809** and the corresponding updated maximum slope **811**. In particular, once the time window **812** has expired, a next sense **816** is identified by comparing the slope signal **804** to the initial sense threshold **805**, a time window **813** is initiated that extends from forward in time from the determined sense **816**, and a maximum slope signal **820** occurring during the time window **813** is determined. One or both of the peak systolic pressure and the end diastolic pressure may then be determined as described above using sense **816** and corresponding maximum slope **820** rather than sense **806** and corresponding maximum sense **810**.

[0131] According to an embodiment of the disclosure, the false sense threshold process may be repeated after the subsequent sense **816** occurs, using the maximum slope signal **820** as the second sense threshold **819**, for example, and if the slope signal **804** is determined to be greater than the second threshold **819** during a predetermined time period **817**, similar to time window **813** for example, sense **816** is discarded, and the pressure measurement analysis is repeated based on a next sense determined after time window **817**, which may or may not also include the false sense threshold process, and so forth.

[0132] If a sense does not occur during time window **515** initiated after the initial sense **806**, i.e., the slope signal **804** does not become greater than the second sense threshold **807** during the time window **815**, the pressure measurement analysis continues based upon the most recent sense **806** and corresponding determined maximum **810** of the slope signal **804**. In particular, once the second time window **815** has expired and no sense has occurred during time window **815**, one or both of the peak systolic pressure and the end diastolic pressure may then be determined as described above using sense **806** and corresponding maximum slope **810**.

[0133] Using the various techniques described above, cardiac cycle length and/or pressure metrics such as systolic

pressure and diastolic pressure may be derived from the pulmonary arterial pressure (PAP) from one or more pressure sensors in the pulmonary artery (PA) without adding electrodes to a patient.

[0134] Various example implementations of the disclosure have been described. These and other example implementations are within the scope of the following claims.

What is claimed is:

1. A method of monitoring a cardiovascular pressure signal, the method comprising:

sensing, by a medical device, the cardiovascular pressure signal;

determining, by the medical device, a first derivative of the sensed cardiovascular pressure signal;

determining, by the medical device, whether the first derivative of the sensed cardiovascular pressure signal is greater than a first threshold;

determining, by the medical device, a first maximum of the first derivative of the cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold;

determining, by the medical device, whether the first derivative of the sensed cardiovascular pressure signal is greater than a second threshold not equal to the first threshold;

determining, by the medical device, a second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second pressure threshold; and

determining, by the medical device, at least one of a systolic pressure or a diastolic pressure, wherein the at least one of the systolic pressure or the diastolic pressure is determined based on the first maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal not being greater than the second threshold, and based on the second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold.

2. The method of claim 1, further comprising controlling, based on the determined at least one of the systolic pressure or the diastolic pressure, delivery of at least one of electrical stimulation or a therapeutic agent.

3. The method of claim 1, further comprising delivering, based on the determined at least one of the systolic pressure or the diastolic pressure, delivery of at least one of electrical stimulation or a therapeutic agent.

4. The method of claim 1, wherein the second threshold is equal to the determined first maximum of the first derivative of the sensed cardiovascular pressure signal.

5. The method of claim 1, wherein determining the at least one of the systolic pressure or the diastolic pressure comprises:

setting a time window extending from a point prior to one of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold to a corresponding one of the first maximum of the first derivative of the sensed cardiovascular pressure signal

and the second maximum of the first derivative of the sensed cardiovascular pressure signal;

determining a second derivative of the sensed cardiovascular pressure signal;

determining a third maximum of the second derivative of the sensed cardiovascular pressure signal occurring during the time window; and

determining a value of the sensed cardiovascular pressure signal corresponding to the third maximum of the second derivative of the sensed cardiovascular pressure signal as the diastolic pressure.

6. The method of claim 1, wherein determining at least one of the systolic pressure or the diastolic pressure comprises:

setting a time window extending from one of the first maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the second maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold;

determining a second derivative of the sensed cardiovascular pressure signal;

determining a third maximum of the second derivative of the sensed cardiovascular pressure signal occurring during the time window; and

determining a value of the sensed cardiovascular pressure signal corresponding to the determined third maximum of the second derivative of the sensed cardiovascular pressure signal as the systolic pressure.

7. The method of claim 1, wherein determining the at least one of the systolic pressure or the diastolic pressure comprises:

setting a first time window extending from a point prior to one of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold to a corresponding one of the first maximum of the first derivative of the sensed cardiovascular pressure signal or the second maximum of the first derivative of the sensed cardiovascular pressure signal;

determining a second derivative of the sensed cardiovascular pressure signal;

determining a first maximum of the second derivative the sensed cardiovascular pressure signal occurring during the first time window;

determining a value of the sensed cardiovascular pressure signal corresponding to the first maximum of the second derivative of the sensed cardiovascular pressure signal as the diastolic pressure;

setting a second time window extending from one of the first maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the second maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold;

determining a second maximum of the second derivative of the sensed cardiovascular pressure signal occurring during the second time window; and

determining a value of the sensed cardiovascular pressure signal corresponding to the determined second maximum of the second derivative of the sensed cardiovascular pressure signal as the systolic pressure.

8. The method of claim 7, wherein the second threshold is equal to the determined first maximum of the first derivative of the sensed cardiovascular pressure signal.

9. The method of claim 1, wherein the medical device is an implantable medical device.

10. The method of claim 9, wherein sensing the cardiovascular pressure signal comprises, sensing, by the implantable medical device implanted within a pulmonary artery, a pulmonary artery pressure signal as the cardiovascular pressure signal.

11. The method of claim 1, wherein the cardiovascular pressure signal comprises a pulmonary artery pressure signal.

12. A medical device system for monitoring a cardiovascular pressure signal, the system comprising:

a sensor configured to sense the cardiovascular pressure signal; and

processing circuitry configured to:

determine a first derivative of the sensed cardiovascular pressure signal;

determine whether the first derivative of the sensed cardiovascular pressure signal is greater than a first threshold;

determine a first maximum of the first derivative of the cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold;

determine whether the first derivative of the sensed cardiovascular pressure signal is greater than a second threshold not equal to the first threshold;

determine a second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second pressure threshold; and

determine at least one of a systolic pressure or a diastolic pressure, wherein the at least one of the systolic pressure or the diastolic pressure is determined based on the first maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal not being greater than the second threshold, and based on the second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold.

13. The system of claim 12, wherein the processing circuitry is configured to control, based on the determined at least one of the systolic pressure or the diastolic pressure, delivery of at least one of electrical stimulation or a therapeutic agent.

14. The system of claim 12, wherein the second threshold is equal to the determined first maximum of the first derivative of the sensed cardiovascular pressure signal.

15. The system of claim 12, wherein the processing circuitry is configured to determine the at least one of the systolic pressure or the diastolic pressure by:

setting a time window extending from a point prior to one of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold to a corresponding one of the first maximum of the first

derivative of the sensed cardiovascular pressure signal and the second maximum of the first derivative of the sensed cardiovascular pressure signal;

determining a second derivative of the sensed cardiovascular pressure signal;

determining a third maximum of the second derivative of the sensed cardiovascular pressure signal occurring during the time window; and

determining a value of the sensed cardiovascular pressure signal corresponding to the third maximum of the second derivative of the sensed cardiovascular pressure signal as the diastolic pressure.

16. The system of claim 12, wherein the processing circuitry is configured to determine at least one of the systolic pressure or the diastolic pressure by:

setting a time window extending from one of the first maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold or the second maximum of the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold;

determining a second derivative of the sensed cardiovascular pressure signal;

determining a third maximum of the second derivative of the sensed cardiovascular pressure signal occurring during the time window; and

determining a value of the sensed cardiovascular pressure signal corresponding to the determined third maximum of the second derivative of the sensed cardiovascular pressure signal as the systolic pressure.

17. The system of claim 12, wherein the medical device system comprises an implantable medical device comprising the sensor and the processing circuitry.

18. The system of claim 12, wherein the sensor is configured to be implanted within a pulmonary artery and sense a pulmonary artery pressure signal as the cardiovascular pressure signal.

19. The system of claim 12, wherein the cardiovascular pressure signal comprises a pulmonary artery pressure signal.

20. A computer readable medium comprising computer executable instructions that, when executed, cause a processor of an implantable medical device to:

control sensing of the cardiovascular pressure signal;

determine a first derivative of the sensed cardiovascular pressure signal;

determine whether the first derivative of the sensed cardiovascular pressure signal is greater than a first threshold;

determine a first maximum of the first derivative of the cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the first threshold;

determine whether the first derivative of the sensed cardiovascular pressure signal is greater than a second threshold not equal to the first threshold;

determine a second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second pressure threshold; and

determine at least one of a systolic pressure or a diastolic pressure, wherein the at least one of the systolic pressure or the diastolic pressure is determined based on the

first maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal not being greater than the second threshold, and based on the second maximum of the first derivative of the sensed cardiovascular pressure signal in response to the first derivative of the sensed cardiovascular pressure signal being greater than the second threshold.

21. An implantable pressure sensor for monitoring a pulmonary artery pressure signal, the system comprising:

a sensor configured to sense the pulmonary artery pressure signal;

processing circuitry configured to:

determine a first derivative of the sensed pulmonary artery pressure signal;

determine whether the first derivative of the sensed pulmonary artery pressure signal is greater than a first threshold;

determine a first maximum of the first derivative of the pulmonary artery pressure signal in response to the first derivative of the sensed pulmonary artery pressure signal being greater than the first threshold;

determine whether the first derivative of the sensed pulmonary artery pressure signal is greater than a second threshold not equal to the first threshold;

determine a second maximum of the first derivative of the sensed pulmonary artery pressure signal in response to the first derivative of the sensed pulmonary artery pressure signal being greater than the second pressure threshold; and

determine at least one of a systolic pressure or a diastolic pressure, wherein the at least one of the systolic pressure or the diastolic pressure is determined based on the first maximum of the first derivative of the sensed pulmonary artery pressure signal in response to the first derivative of the sensed pulmonary artery pressure signal not being greater than the second threshold, and based on the second maximum of the first derivative of the sensed pulmonary artery pressure signal in response to the first derivative of the sensed pulmonary artery pressure signal being greater than the second threshold; and telemetry circuitry configured to transmit the at least one of the systolic pressure or the diastolic pressure to another device.

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专利名称(译)	肺动脉压测量心动周期长度和压力指标		
公开(公告)号	US20190350467A1	公开(公告)日	2019-11-21
申请号	US16/524360	申请日	2019-07-29
[标]申请(专利权)人(译)	美敦力公司		
申请(专利权)人(译)	美敦力公司, INC.		
当前申请(专利权)人(译)	美敦力公司, INC.		
[标]发明人	GREENHUT SAUL E		
发明人	GREENHUT, SAUL E.		
IPC分类号	A61B5/0215 A61N1/365 A61M5/172 A61N1/08 A61B5/021 A61B5/00		
CPC分类号	A61B5/4839 A61N1/08 A61B5/7246 A61M5/1723 A61B5/6869 A61N1/36564 A61B5/02108 A61B5/7239 A61B5/0215		
外部链接	Espacenet USPTO		

摘要(译)

一种用于监视医疗设备中的心血管压力信号的方法和装置，包括确定感测到的压力信号是否大于第一压力阈值，响应于感测到的压力信号大于第一压力阈值来确定压力信号的第一度量。压力阈值，确定感测到的压力信号是否大于不等于第一压力阈值的第二压力阈值，响应于感测到的压力信号大于第一压力阈值，确定压力信号的第二度量，并确定为收缩压或舒张压中的至少一个，其中响应于压力信号不大于第二阈值，基于第一度量确定收缩压或舒张压中的至少一个，并且基于第二响应于压力信号大于第二阈值而确定“最大”。

