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**Greenhut**

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

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(65) **Prior Publication Data**

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(51) **Int. Cl.**

| | |
|---|---|
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| ***A61B 5/00*** | (2006.01) |
| ***A61B 5/021*** | (2006.01) |
| ***A61B 5/0215*** | (2006.01) |

(52) **U.S. Cl.**

CPC ..... ***A61B 5/4839*** (2013.01); ***A61B 5/0215*** (2013.01); ***A61B 5/02108*** (2013.01); ***A61B 5/6869*** (2013.01); ***A61B 5/7239*** (2013.01)

(58) **Field of Classification Search**

CPC ..... A61B 5/02108; A61B 5/0215; A61B 5/7239; A61B 5/6869; A61B 5/4839; A61B 5/021; A61M 5/168; A61N 1/36

USPC ..... 600/481, 483–486, 488, 500–503, 513

See application file for complete search history.

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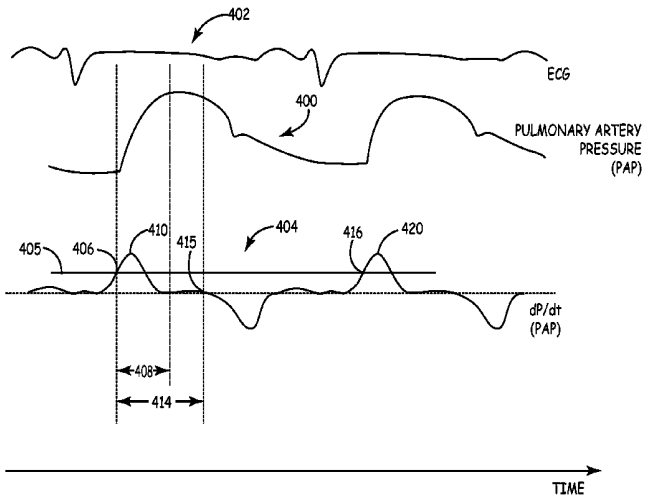
(57) **ABSTRACT**

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.

**15 Claims, 15 Drawing Sheets**



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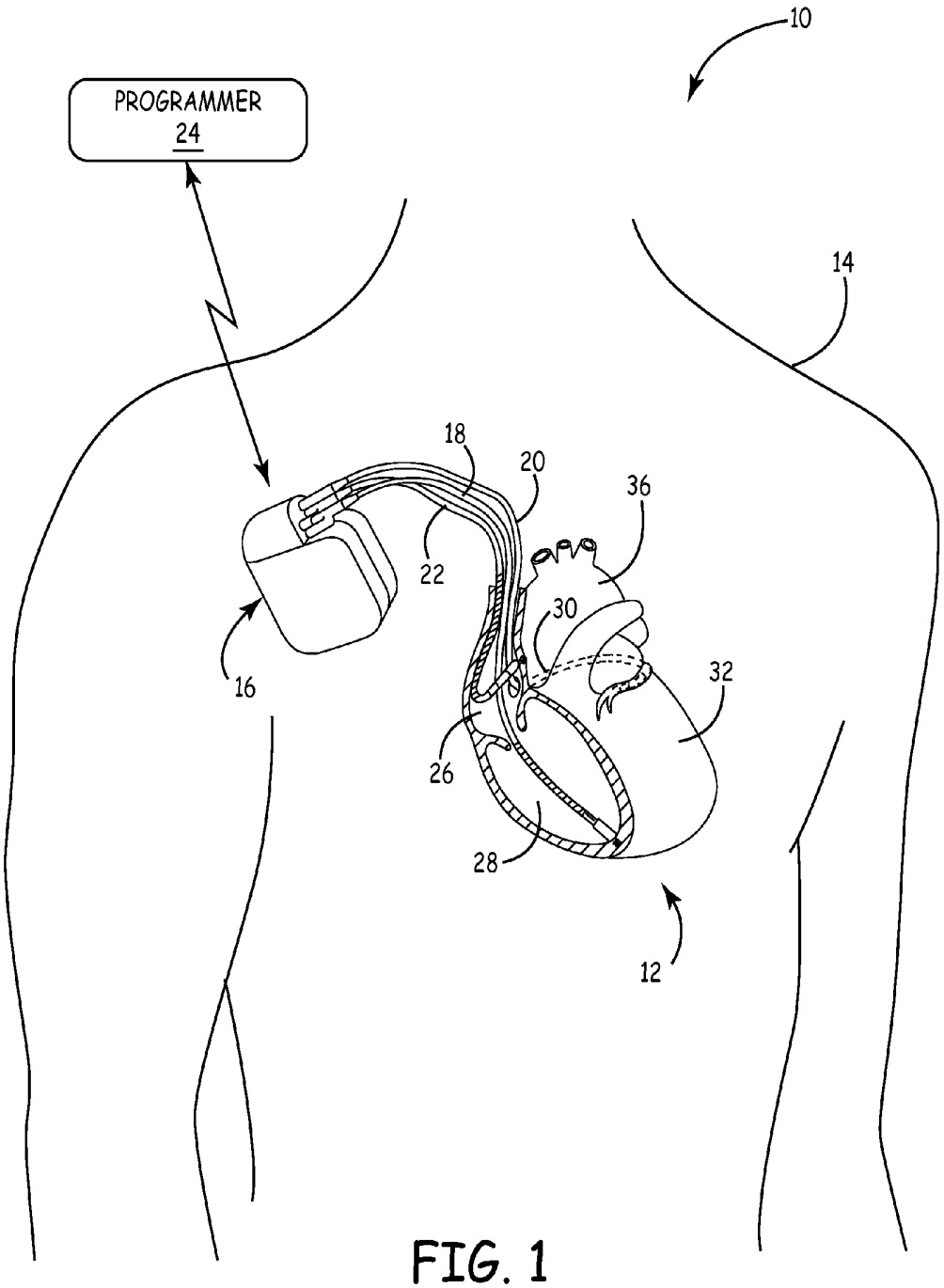
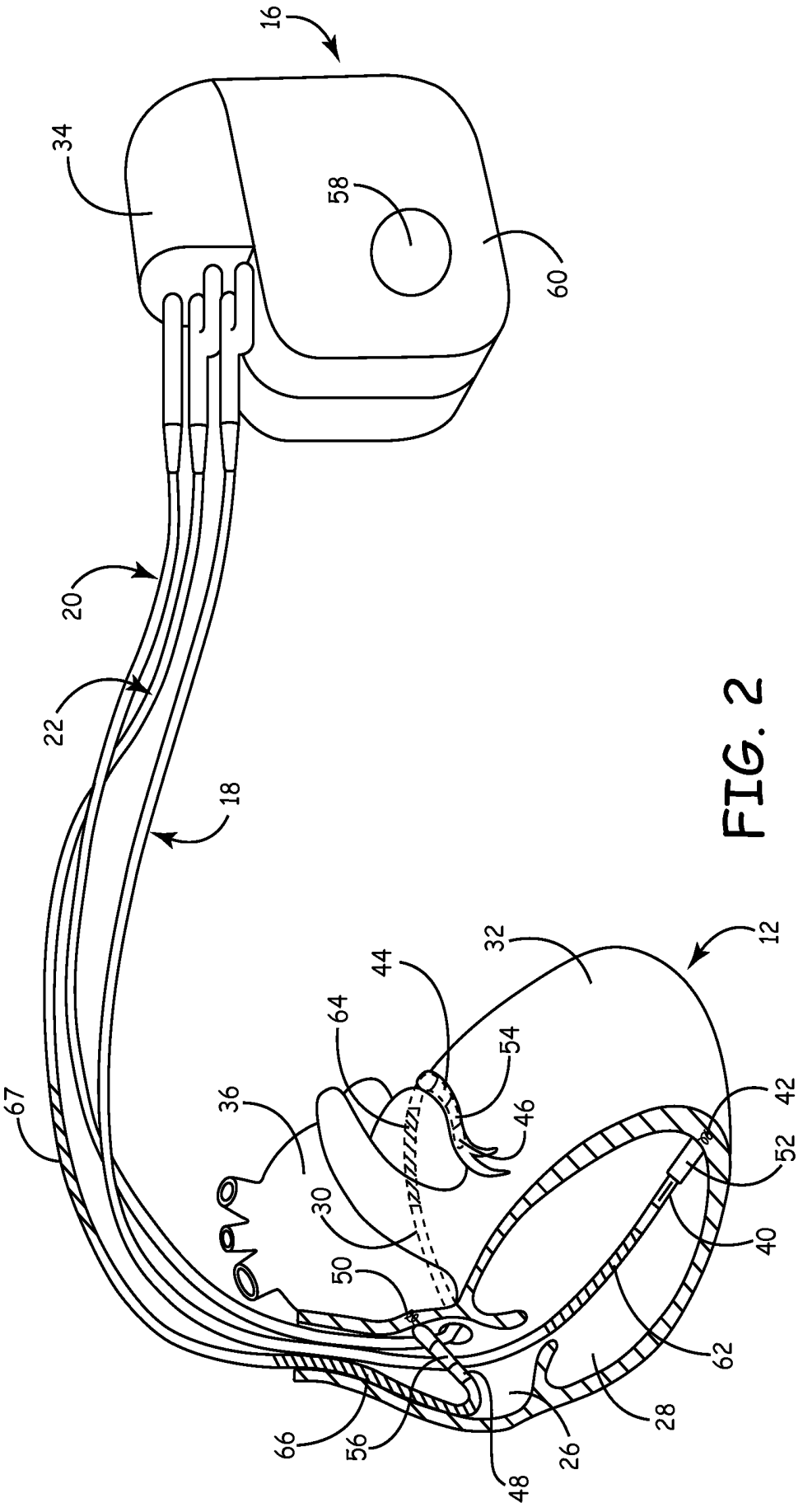



FIG. 1


16
34
58
60
20
22
18
67
36
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66
56
48
26
28
62
40
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42
12
32
44
64
54
46

FIG. 2

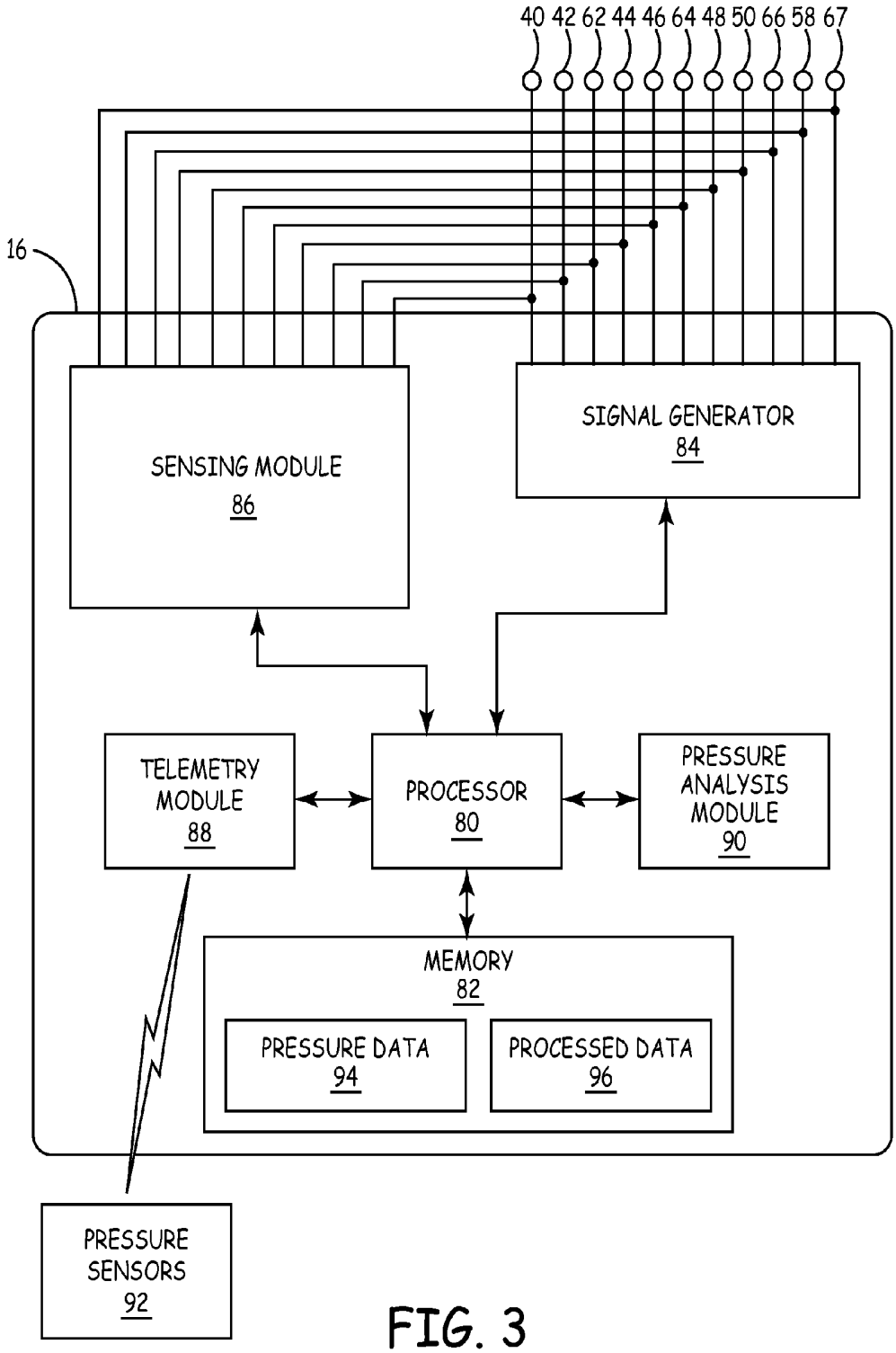
40 42 62 44 46 64 48 50 66 58 67
16
SENSING MODULE
86
SIGNAL GENERATOR
84
TELEMETRY MODULE
88
PROCESSOR
80
PRESSURE ANALYSIS MODULE
90
MEMORY
82
PRESSURE DATA
94
PROCESSED DATA
96
PRESSURE SENSORS
92

FIG. 3

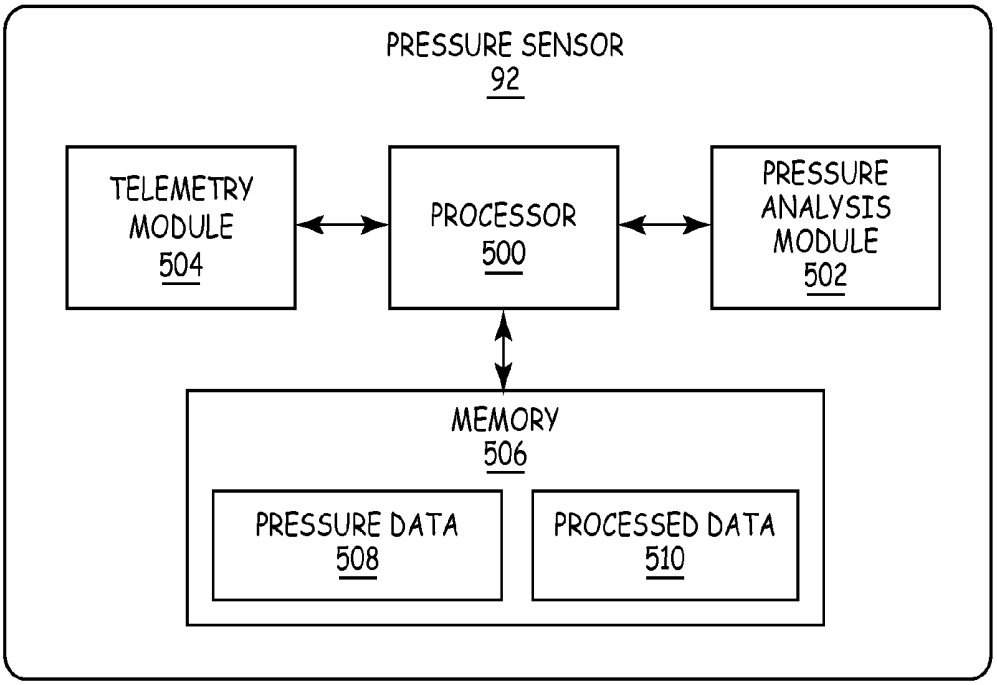
PRESSURE SENSOR
92
TELEMETRY MODULE
504
PROCESSOR
500
PRESSURE ANALYSIS MODULE
502
MEMORY
506
PRESSURE DATA
508
PROCESSED DATA
510

FIG. 4

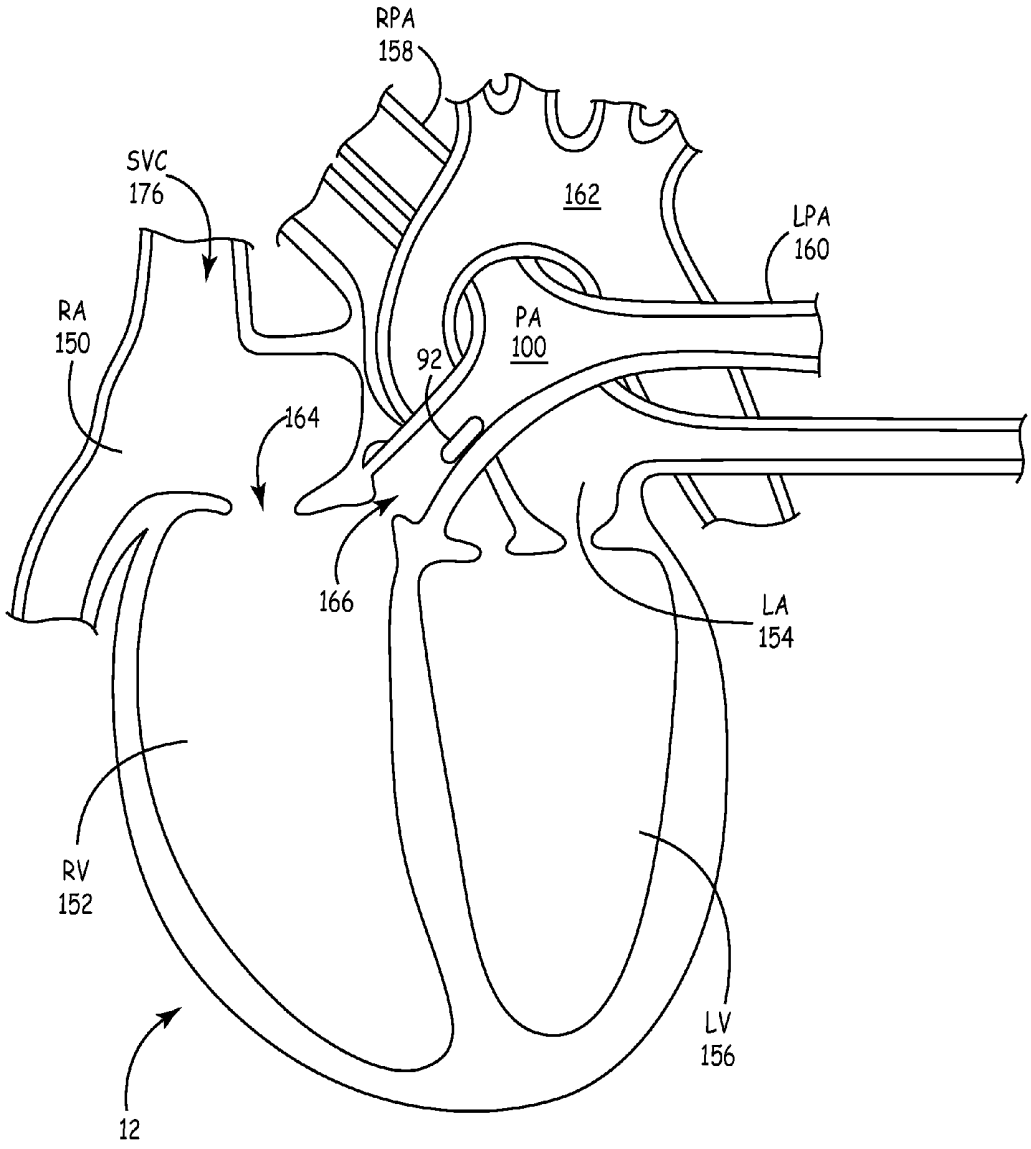
RPA
158
SVC
176
162
LPA
160
RA
150
PA
100
92
164
166
LA
154
RV
152
LV
156
12

FIG. 5

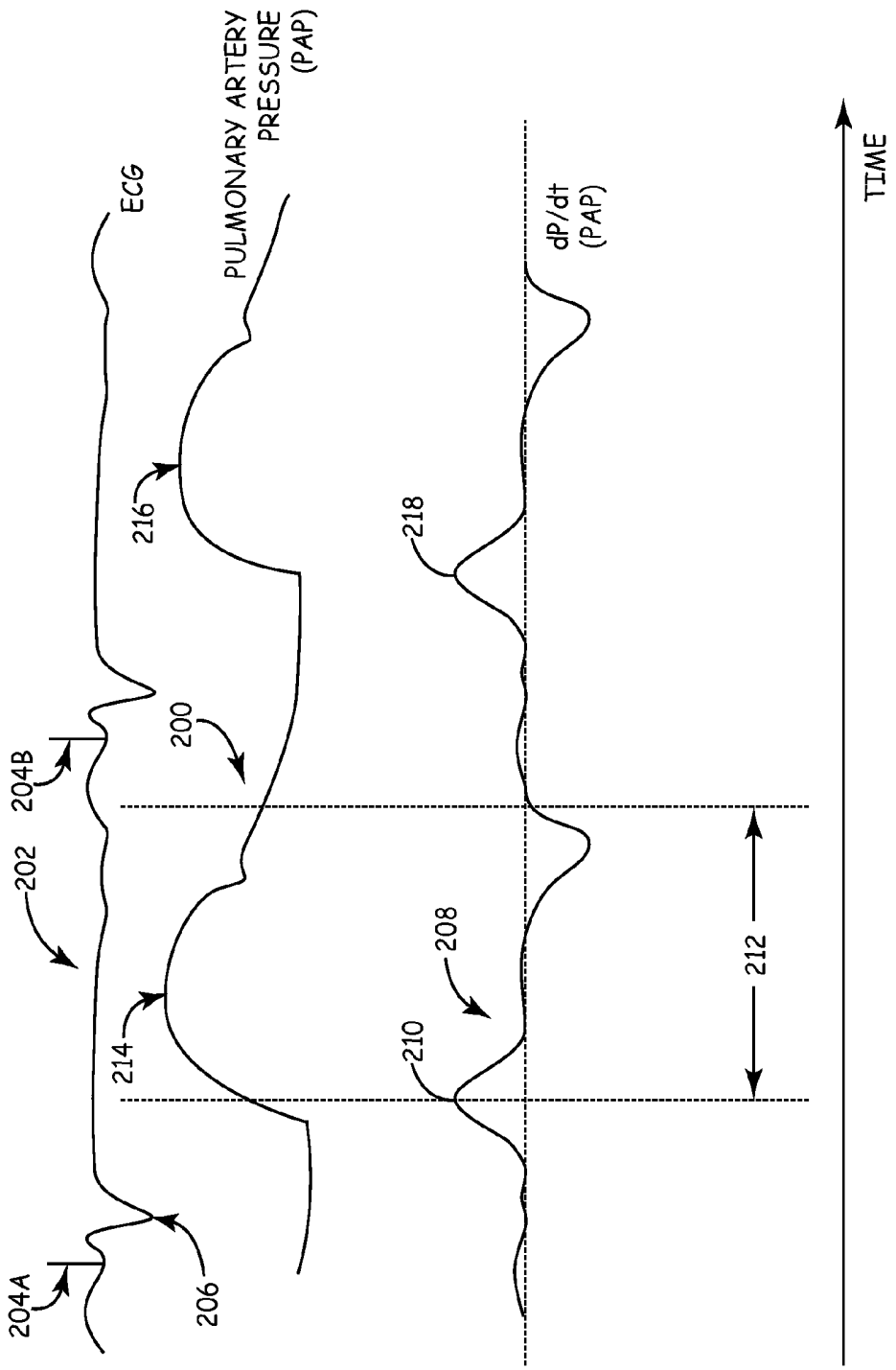
ECG
PULMONARY ARTERY PRESSURE (PAP)
dP/dt (PAP)
TIME
204A
206
214
202
204B
200
216
218
208
210
212

FIG. 6

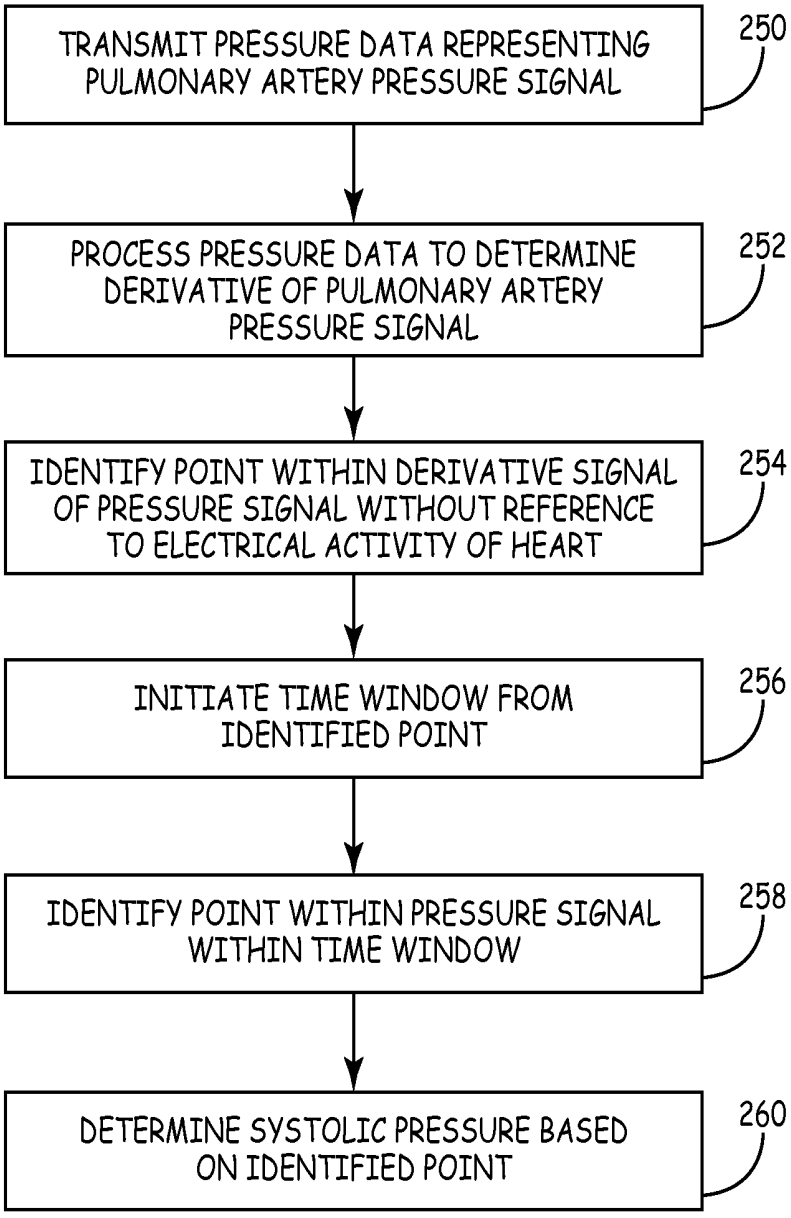
TRANSMIT PRESSURE DATA REPRESENTING PULMONARY ARTERY PRESSURE SIGNAL
250
PROCESS PRESSURE DATA TO DETERMINE DERIVATIVE OF PULMONARY ARTERY PRESSURE SIGNAL
252
IDENTIFY POINT WITHIN DERIVATIVE SIGNAL OF PRESSURE SIGNAL WITHOUT REFERENCE TO ELECTRICAL ACTIVITY OF HEART
254
INITIATE TIME WINDOW FROM IDENTIFIED POINT
256
IDENTIFY POINT WITHIN PRESSURE SIGNAL WITHIN TIME WINDOW
258
DETERMINE SYSTOLIC PRESSURE BASED ON IDENTIFIED POINT
260

FIG. 7

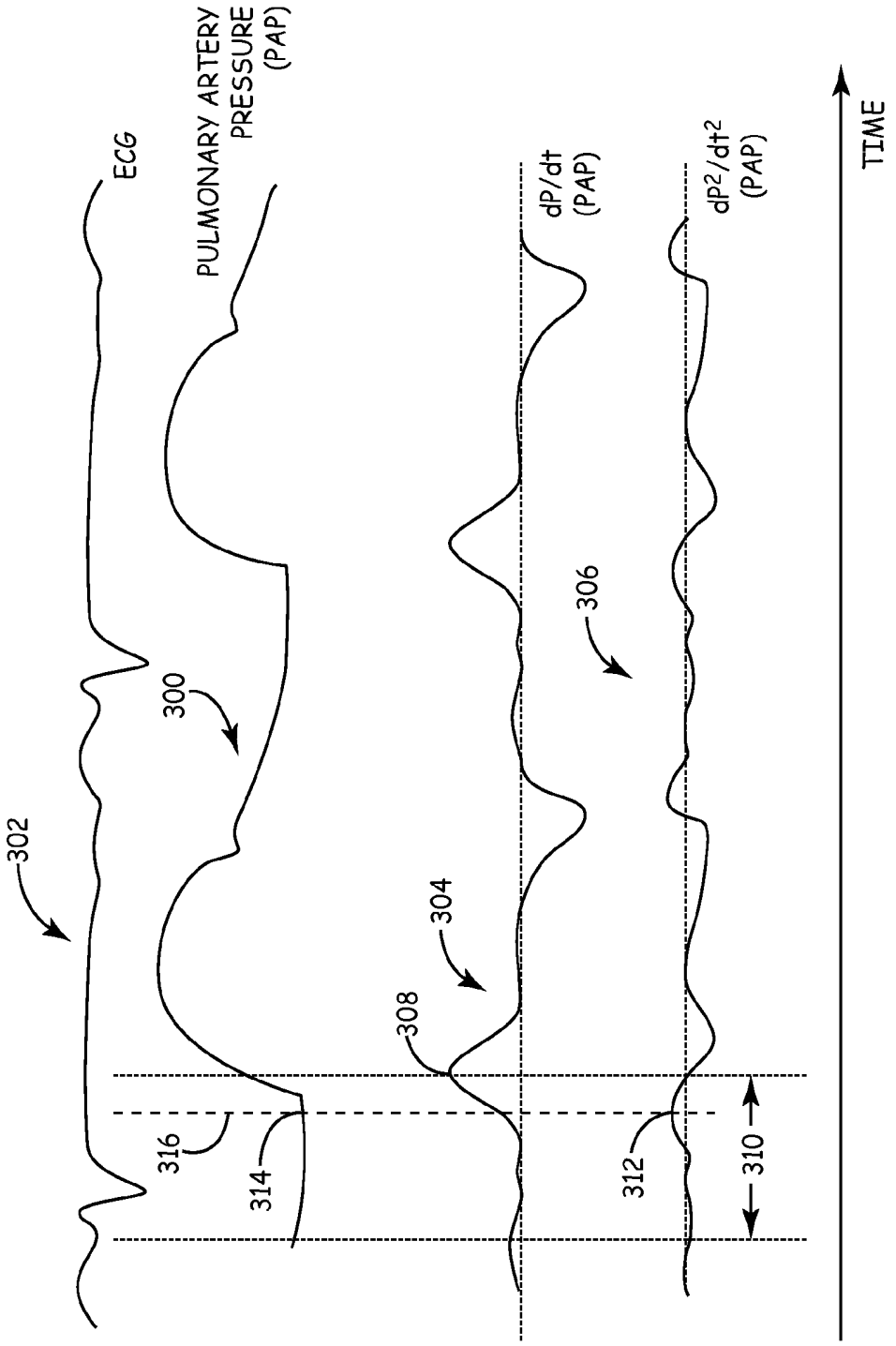
ECG
PULMONARY ARTERY PRESSURE (PAP)
dP/dt (PAP)
dP²/dt² (PAP)
TIME
300
302
304
306
308
310
312
314
316

FIG. 8

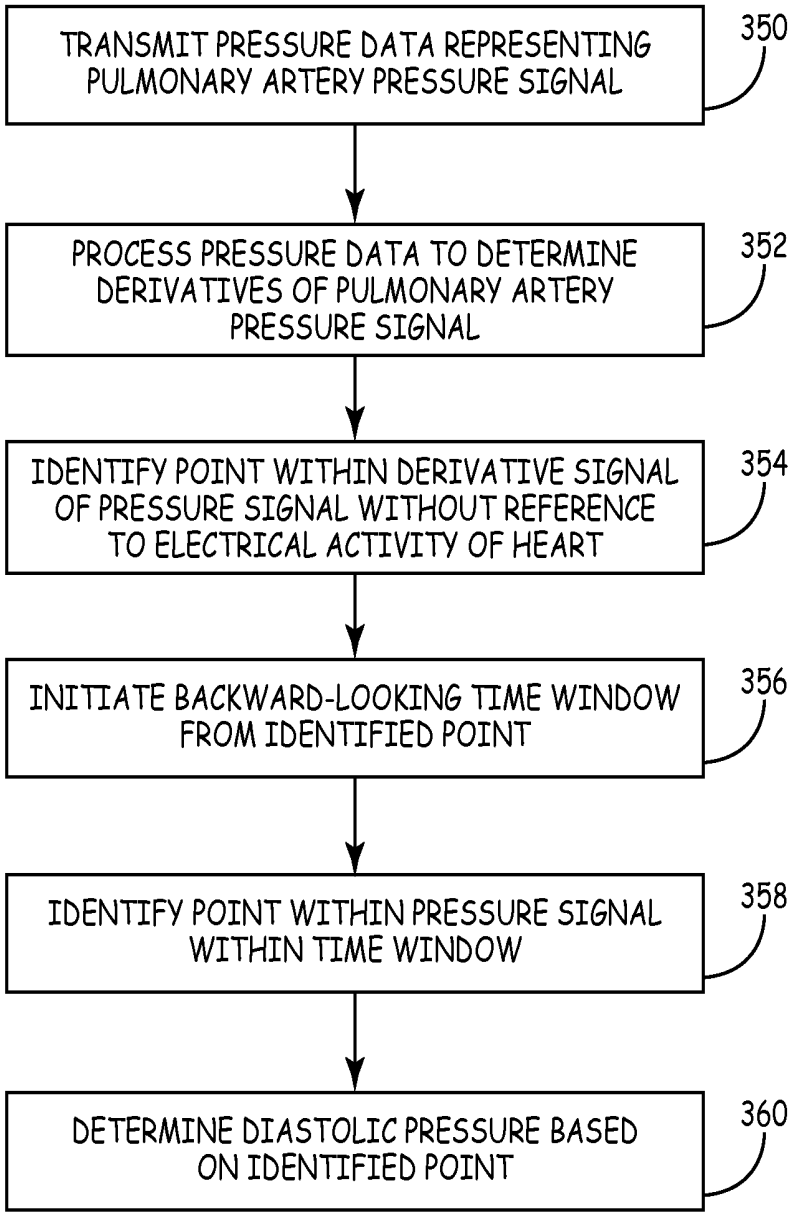
TRANSMIT PRESSURE DATA REPRESENTING PULMONARY ARTERY PRESSURE SIGNAL
350
PROCESS PRESSURE DATA TO DETERMINE DERIVATIVES OF PULMONARY ARTERY PRESSURE SIGNAL
352
IDENTIFY POINT WITHIN DERIVATIVE SIGNAL OF PRESSURE SIGNAL WITHOUT REFERENCE TO ELECTRICAL ACTIVITY OF HEART
354
INITIATE BACKWARD-LOOKING TIME WINDOW FROM IDENTIFIED POINT
356
IDENTIFY POINT WITHIN PRESSURE SIGNAL WITHIN TIME WINDOW
358
DETERMINE DIASTOLIC PRESSURE BASED ON IDENTIFIED POINT
360

FIG. 9

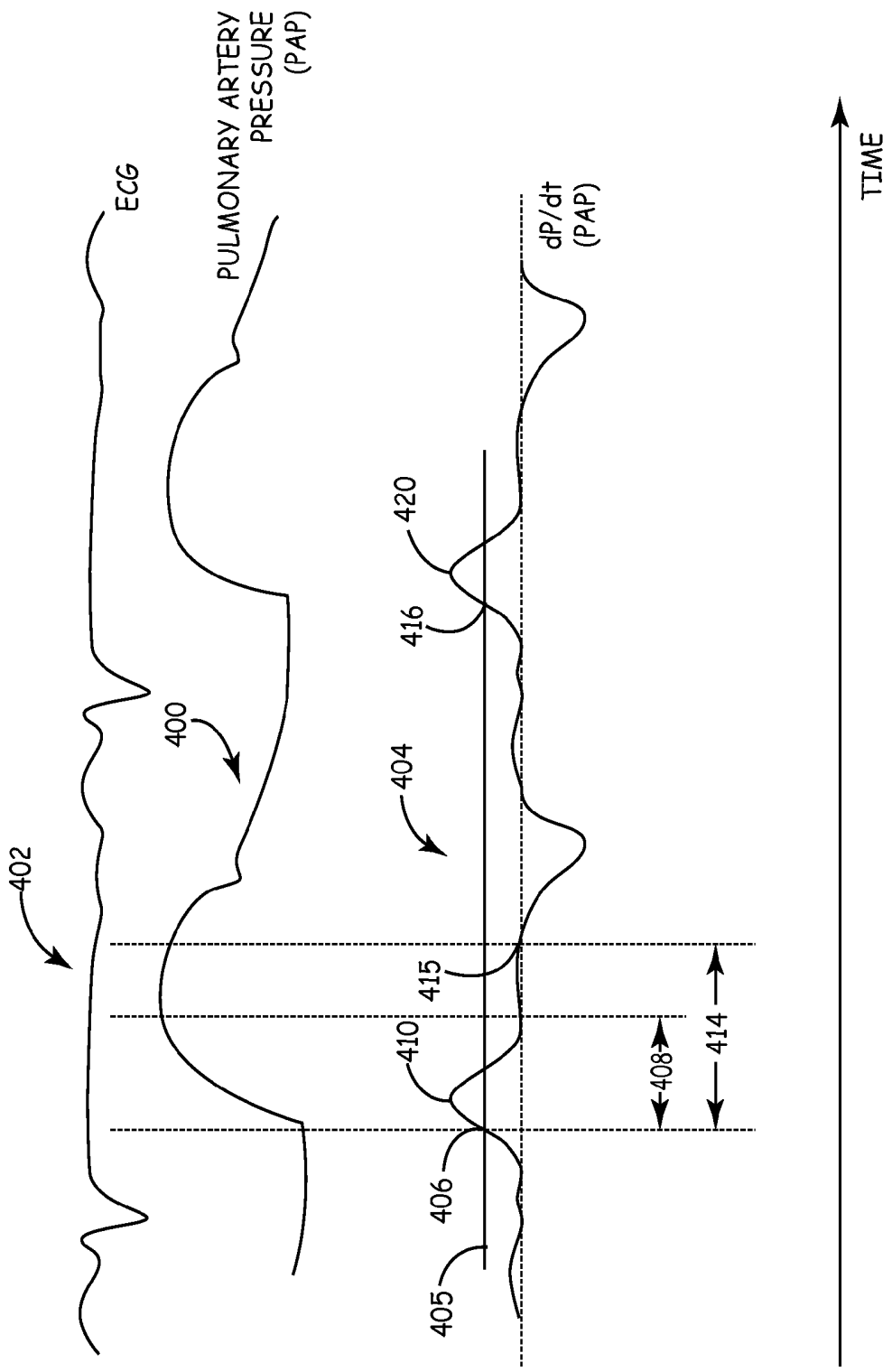
ECG
PULMONARY ARTERY PRESSURE (PAP)
dP/dt (PAP)
TIME
400
402
404
405
406
408
410
414
415
416
420

FIG. 10

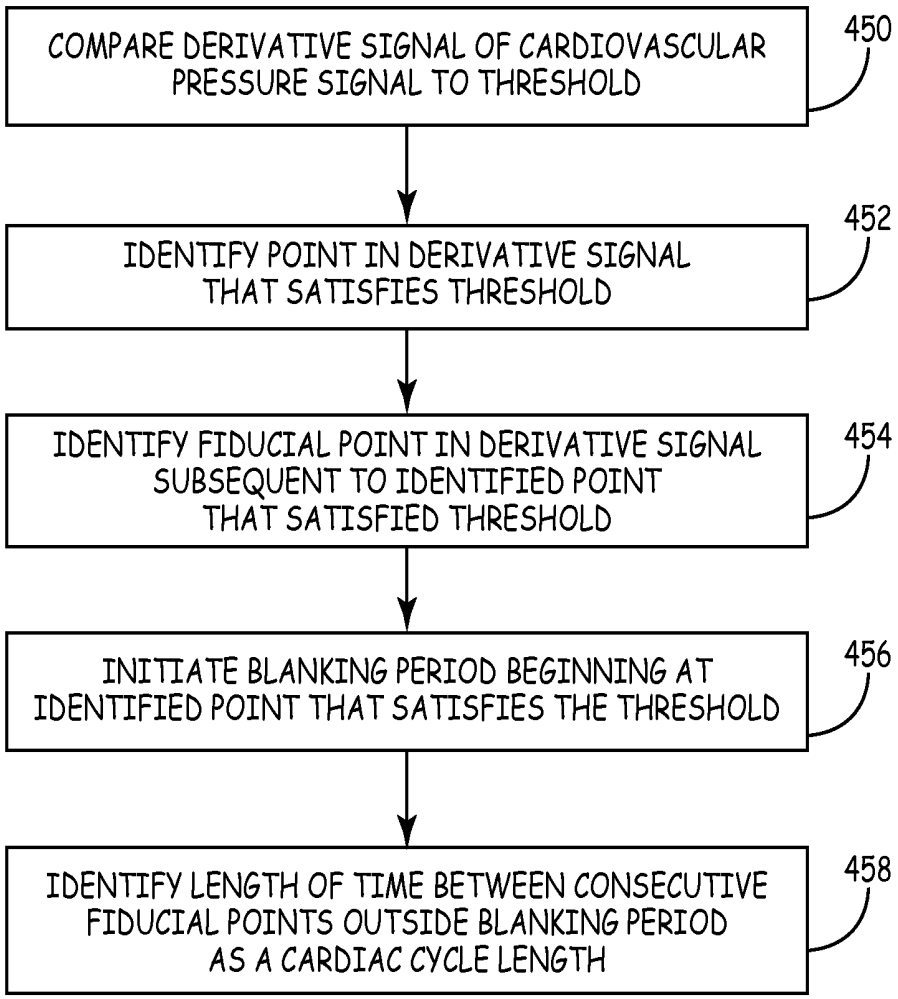
COMPARE DERIVATIVE SIGNAL OF CARDIOVASCULAR PRESSURE SIGNAL TO THRESHOLD
450
IDENTIFY POINT IN DERIVATIVE SIGNAL THAT SATISFIES THRESHOLD
452
IDENTIFY FIDUCIAL POINT IN DERIVATIVE SIGNAL SUBSEQUENT TO IDENTIFIED POINT THAT SATISFIED THRESHOLD
454
INITIATE BLANKING PERIOD BEGINNING AT IDENTIFIED POINT THAT SATISFIES THE THRESHOLD
456
IDENTIFY LENGTH OF TIME BETWEEN CONSECUTIVE FIDUCIAL POINTS OUTSIDE BLANKING PERIOD AS A CARDIAC CYCLE LENGTH
458

FIG. 11

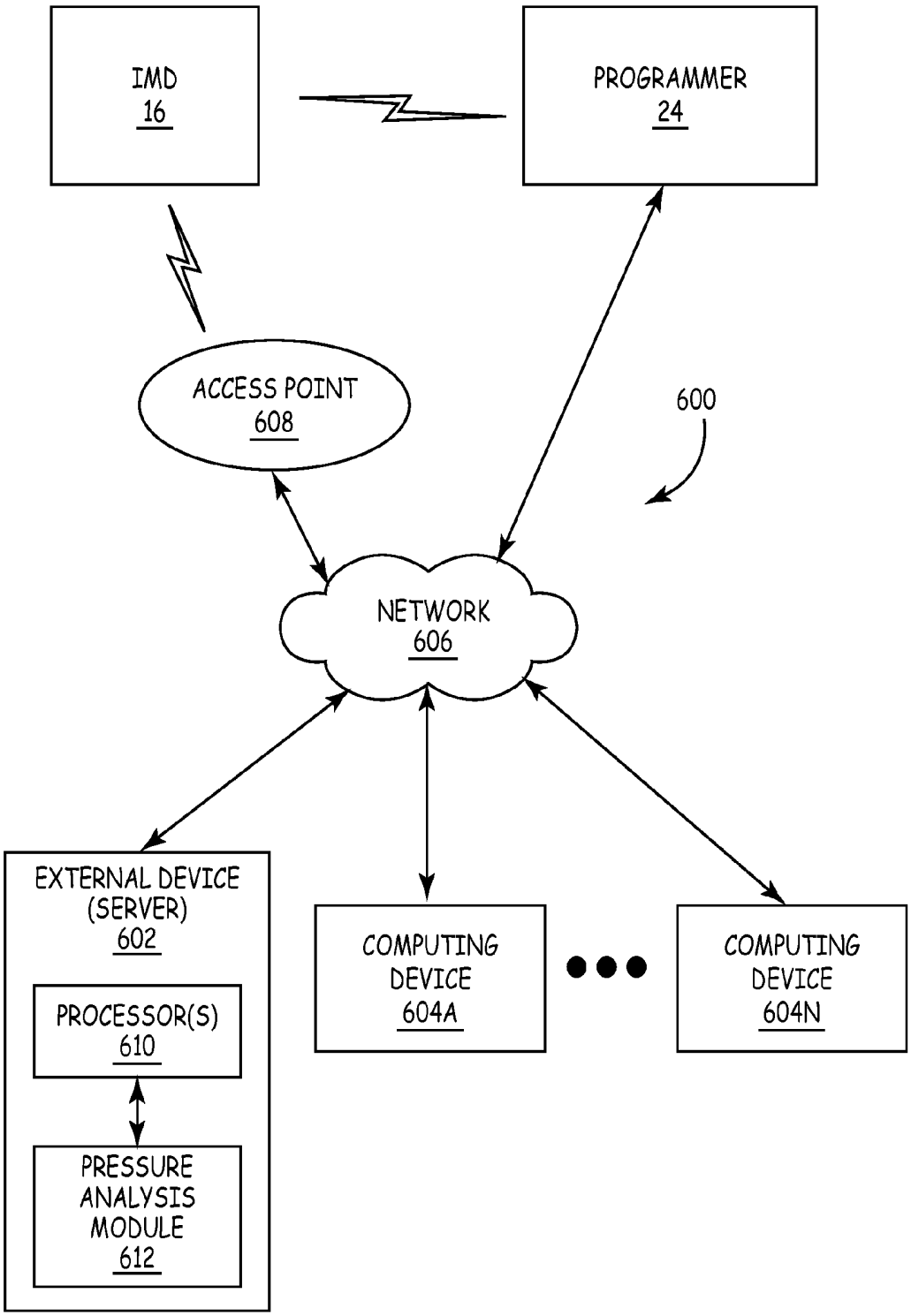
IMD
16
PROGRAMMER
24
ACCESS POINT
608
600
NETWORK
606
EXTERNAL DEVICE
(SERVER)
602
PROCESSOR(S)
610
PRESSURE
ANALYSIS
MODULE
612
COMPUTING
DEVICE
604A
COMPUTING
DEVICE
604N

FIG. 12

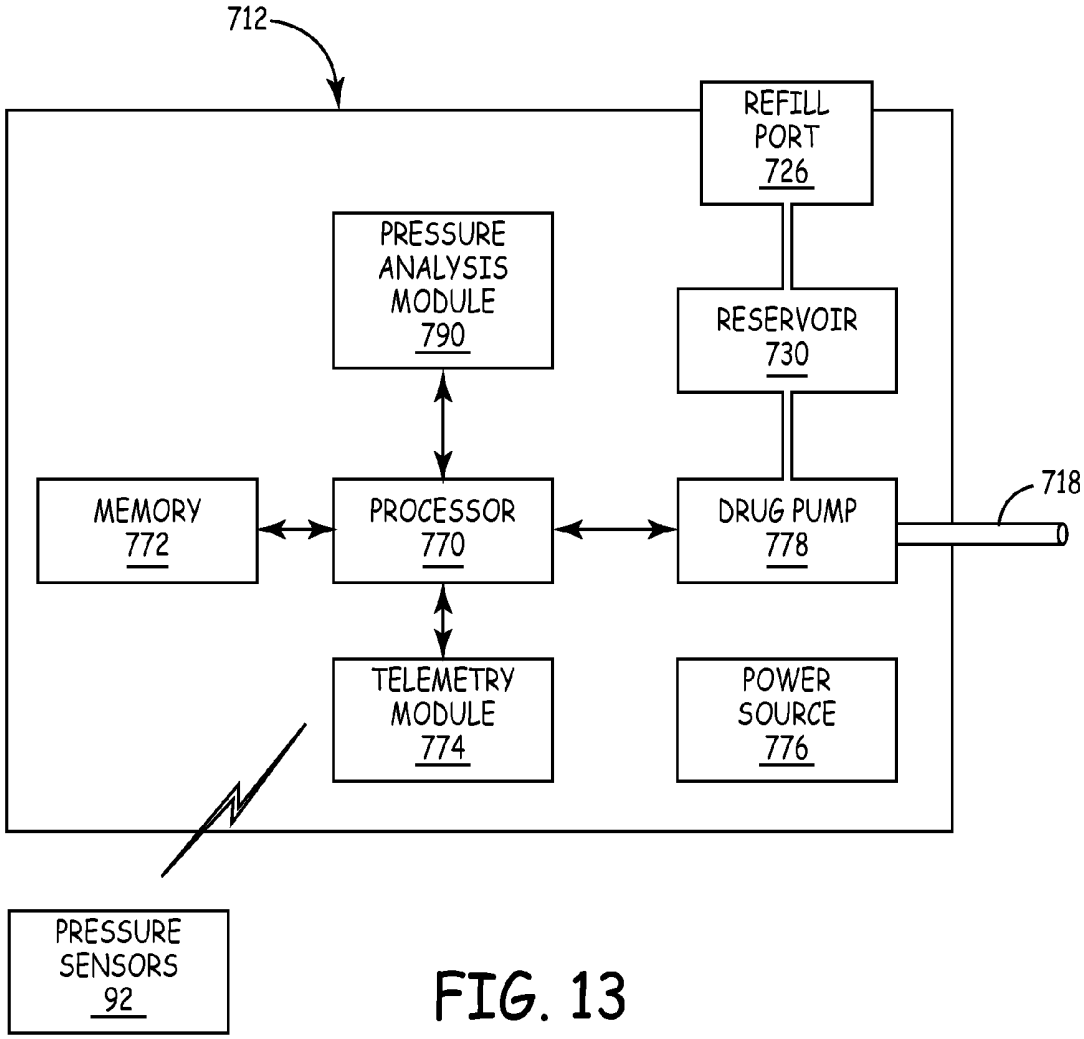
712
REFILL PORT 726
PRESSURE ANALYSIS MODULE 790
RESERVOIR 730
MEMORY 772
PROCESSOR 770
DRUG PUMP 778
718
TELEMETRY MODULE 774
POWER SOURCE 776
PRESSURE SENSORS 92

FIG. 13

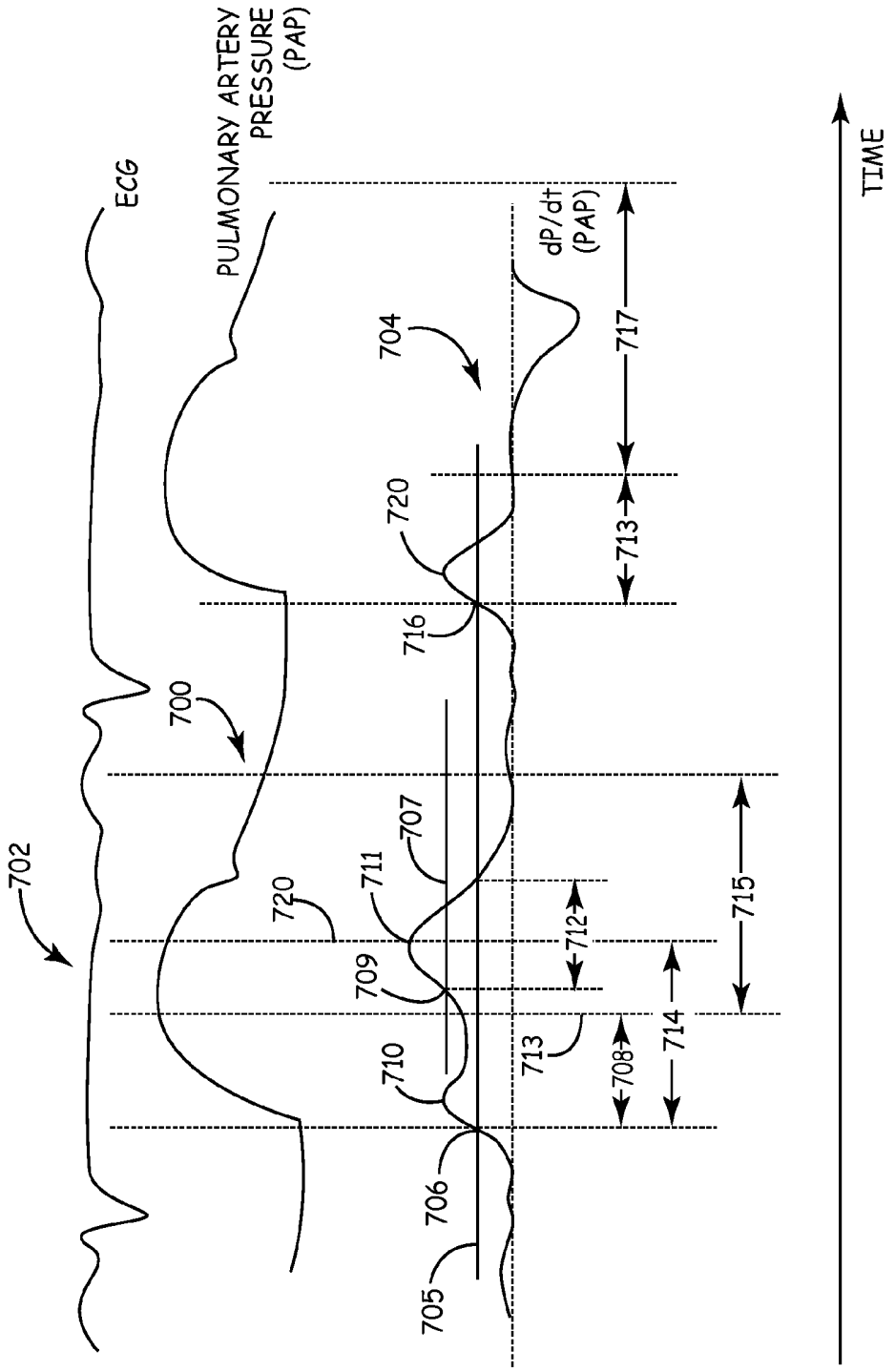
ECG
PULMONARY ARTERY PRESSURE (PAP)
dP/dt (PAP)
TIME
700
702
704
705
706
707
708
709
710
711
712
713
714
715
716
717
720

FIG. 14

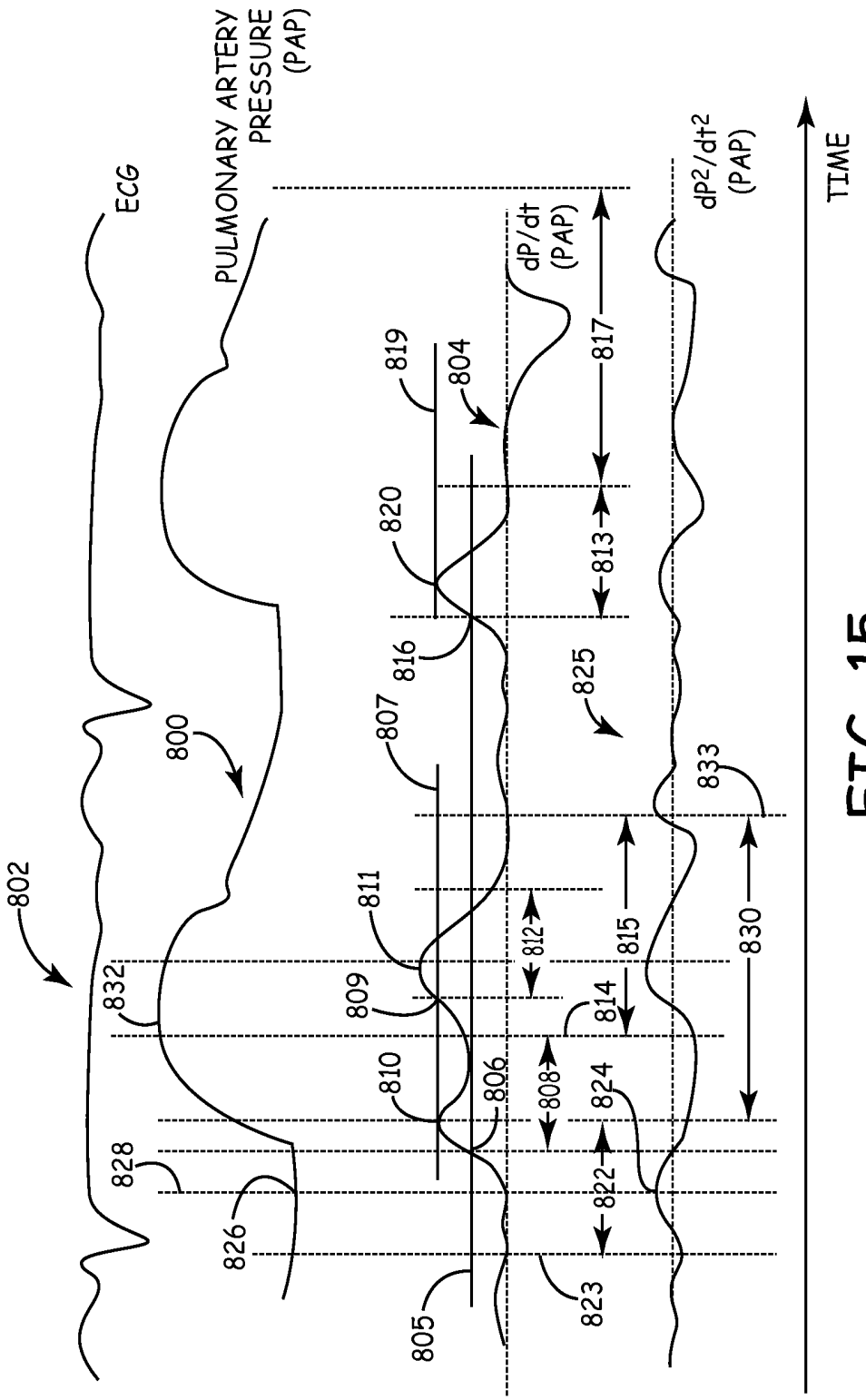
ECG
PULMONARY ARTERY PRESSURE (PAP)
dP/dt (PAP)
dP²/dt² (PAP)
TIME
800
802
804
805
806
807
808
809
810
811
812
813
814
815
816
817
819
820
822
823
824
825
826
828
830
832
833

FIG. 15

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

## CROSS-REFERENCE TO RELATED APPLICATION

Cross-reference is hereby made to the commonly-assigned related U.S. application Ser. No. 13/096,004, entitled "MEASUREMENT OF CARDIAC CYCLE LENGTH AND PRESSURE METRICS FROM PULMONARY ARTERIAL PRESSURE", filed concurrently herewith and incorporated herein by reference in it's entirety.

## TECHNICAL FIELD

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

## BACKGROUND

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.

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.

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

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:



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;

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;

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

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;

FIG. **5** is a diagram of a human heart, including a pressure sensor;

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;

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

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;

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

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

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;

FIG. **13** is block diagram of an embodiment of another example implantable medical device;

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

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

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.

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.

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.

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.

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.

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.

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.

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.

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).

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.

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**.

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.

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.

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.

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**.

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**.

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.

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**.

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**.

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**. 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.

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**.

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.

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.

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.

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.

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-transistory, 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.

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.

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.

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.

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.

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.

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.

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**.

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**.

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.

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.

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.

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.

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.

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.

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.

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**.

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.

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.

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 **204**A and **204**B. 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.

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.

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.

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.

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**.

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.

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.

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.

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.

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

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.

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.

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.

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.

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**.

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**.

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.

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.

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.

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**.

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 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.

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.

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.

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.

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.

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**.

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.

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.

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.

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**.

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.

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.

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 **604**A-**604**N, 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 **604**A-**604**N 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 **604**A-**604**N may be coupled to network **606** through one or more wireless connections. IMD **16**, programmer **24**, server **602**, and computing devices **604**A-**604**N 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.

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**.

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 **604**A-**604**N. 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.

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**.

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.

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.

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. 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-transistory, 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.

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**.

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.

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.

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.

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.

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**.

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**.

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.

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**.

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**.

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 from 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.

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.

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.

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**.

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.

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.

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**.

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 determination 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**.

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**.

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.

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.

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**.

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.

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**.

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.

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**.

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.

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

The invention claimed is:

1. A method of monitoring a cardiovascular pressure signal in a medical device, comprising:

sensing and high pass filtering the cardiovascular pressure signal, by the medical device, to generate a resulting sensed pressure signal;

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

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

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

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

determining, by the medical device, 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 maximum of the first derivative signal in response to the pressure signal not being greater than the second threshold, and based on the second maximum of the first derivative signal in response to the pressure signal being greater than the second threshold; and

controlling delivery of at least one of electrical stimulation and a therapeutic agent in response to the determined at least one of a systolic pressure or a diastolic pressure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

determining a second maximum of the second derivative signal of the sensed pressure signal; and

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

7. The method of claim 6, wherein the second pressure threshold is equal to the determined first maximum of the first derivative of the pressure signal.

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

a sensor sensing a cardiovascular pressure signal and generating a corresponding sensor signal;

a high pass filter high pass filtering the sensor signal to generate a sensed pressure signal; and

a pressure analysis module configured to:

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

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

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

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

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

controlling delivery of at least one of electrical stimulation and a therapeutic agent in response to the determined at least one of a systolic pressure or a diastolic pressure.

9. The system of claim 8, further comprising a controller configured to control delivery of at least one of electrical stimulation and a therapeutic agent in response to the determined at least one of a systolic pressure or a diastolic pressure.

10. The system of claim 8, wherein the second pressure threshold is equal to the determined first maximum of the first derivative signal of the pressure signal.

11. The system of claim 8, wherein determining at least one of a systolic pressure or a diastolic pressure comprises:

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

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

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

12. The system of claim 8, wherein determining at least one of a systolic pressure or a diastolic pressure comprises:

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

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

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

13. The system of claim 8, wherein determining at least one of a systolic pressure or a diastolic pressure comprises:

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

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

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

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

determining a a second maximum of the second derivative signal of the sensed pressure signal; and

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

14. The system of claim 13, wherein the second pressure threshold is equal to the determined first maximum of the first derivative of the pressure signal.

15. A non-transitory computer readable medium having computer executable instructions for performing a method in an implantable medical device, the method comprising:

sensing and high pass filtering the cardiovascular pressure signal to generate a resulting sensed pressure signal;

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

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

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

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

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

controlling delivery of at least one of electrical stimulation and a therapeutic agent in response to the determined at least one of a systolic pressure or a diastolic pressure.

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摘要(译)

一种用于监测医疗装置中的心血管压力信号的方法和装置，包括确定所感测的压力信号是否大于第一压力阈值，响应于所感测的压力信号大于第一压力信号，确定压力信号的第一度量。压力阈值，确定所感测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，响应于所感测的压力信号大于第一压力阈值确定压力信号的第二度量，并确定在收缩压或舒张压中的至少一个，其中收缩压或舒张压中的至少一个是基于响应于压力信号不大于第二阈值的第一度量确定的，并且基于第二阈值响应于压力信号的度量大于第二阈值。