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(54) **MULTI-DEVICE CARDIAC
RESYNCHRONIZATION THERAPY WITH
TIMING ENHANCEMENTS**

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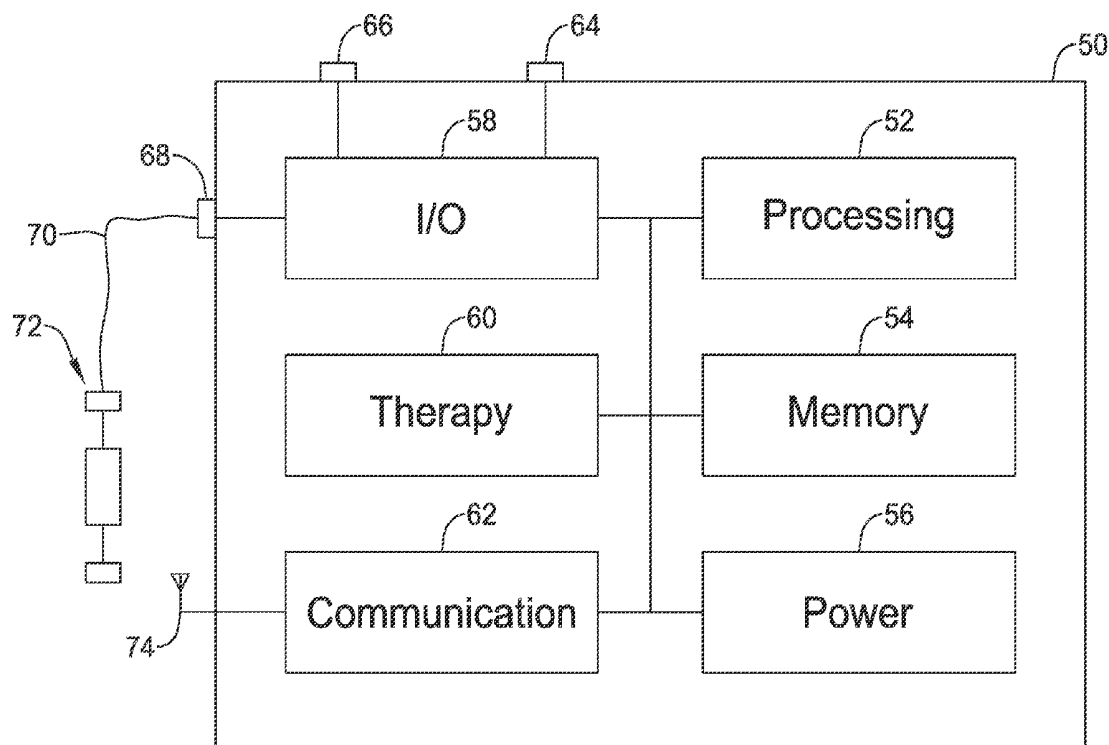
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(57)

ABSTRACT

Methods, systems and devices for providing cardiac resynchronization therapy (CRT) to a patient using a leadless cardiac pacemaker (LCP) and an extracardiac device (ED). The system is configured to identify atrial events to use as timing markers for the LCP to deliver CRT, and further to determine whether the timing markers are incorrectly sensed and to make adjustment or call for re-initialization as needed.



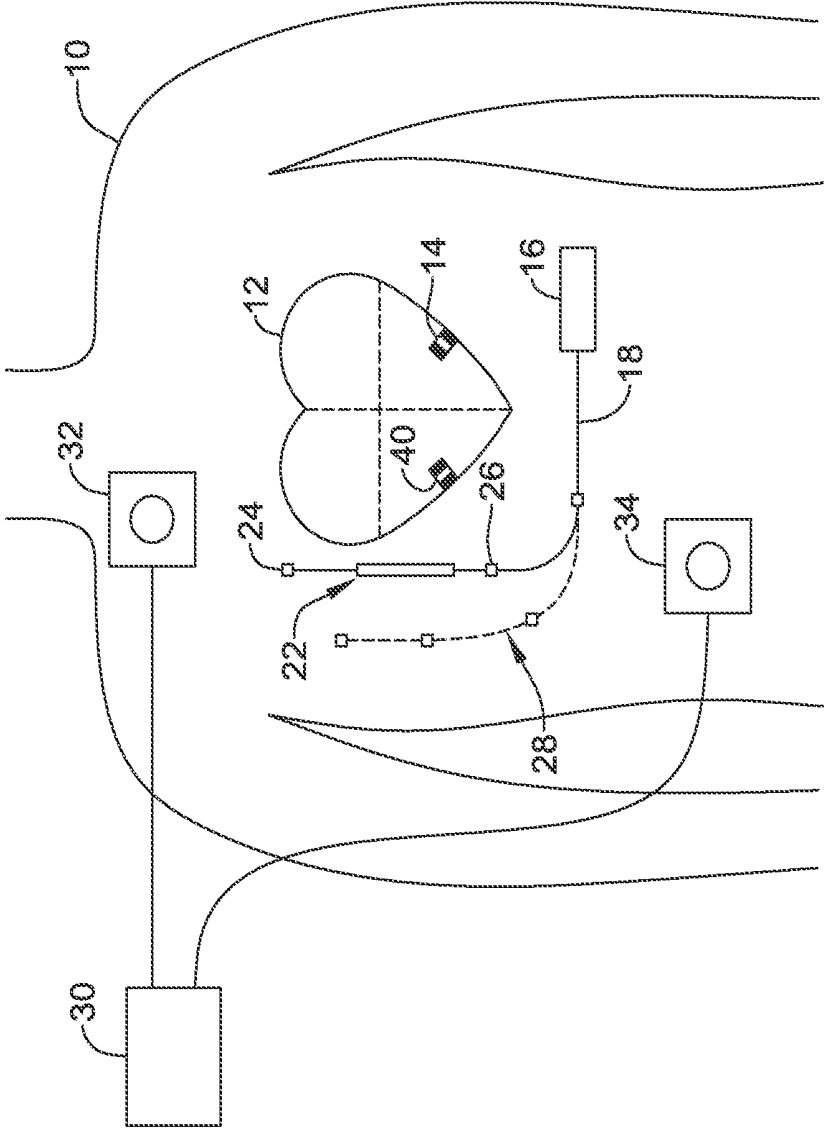


Figure 1

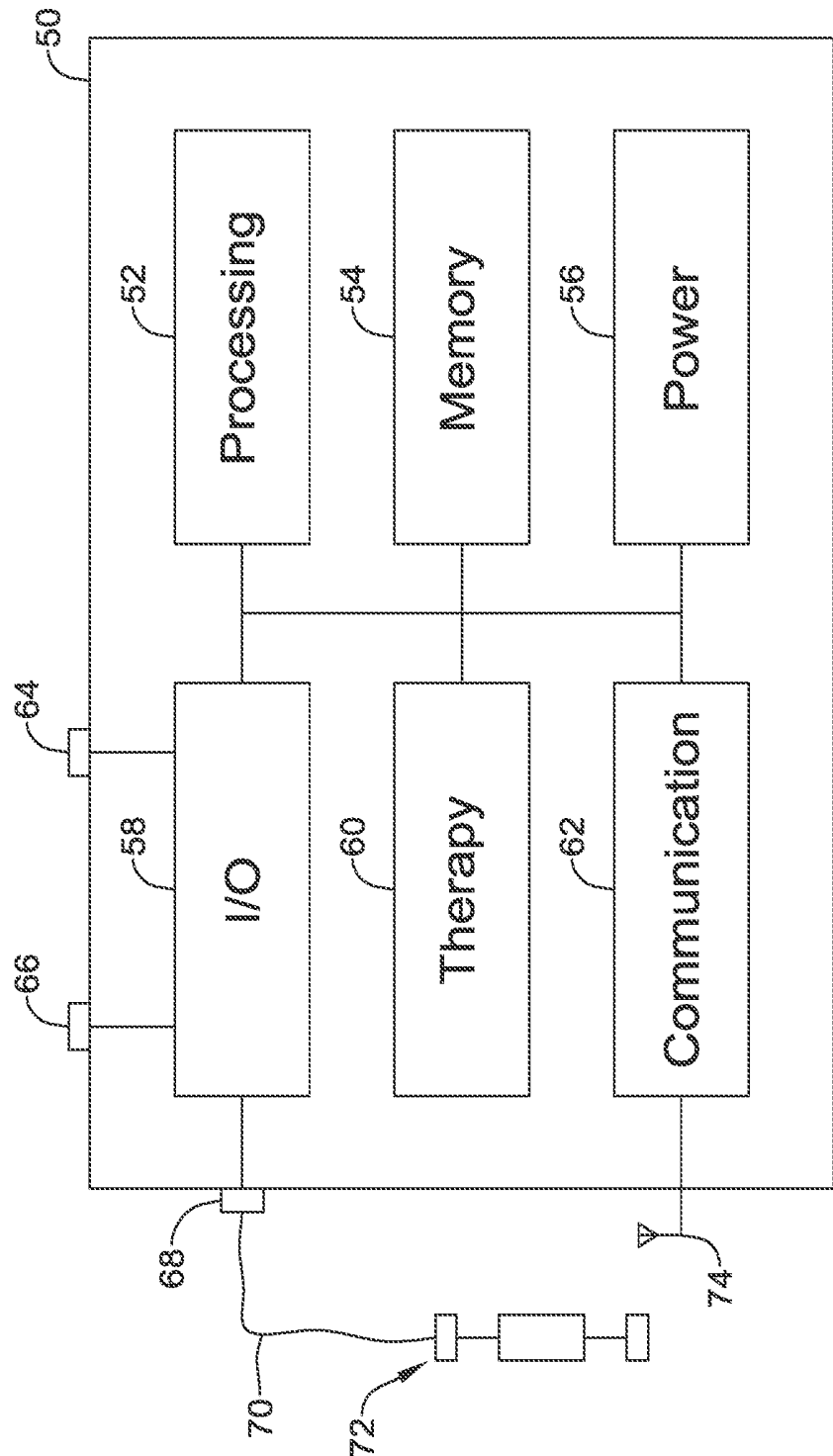


Figure 2

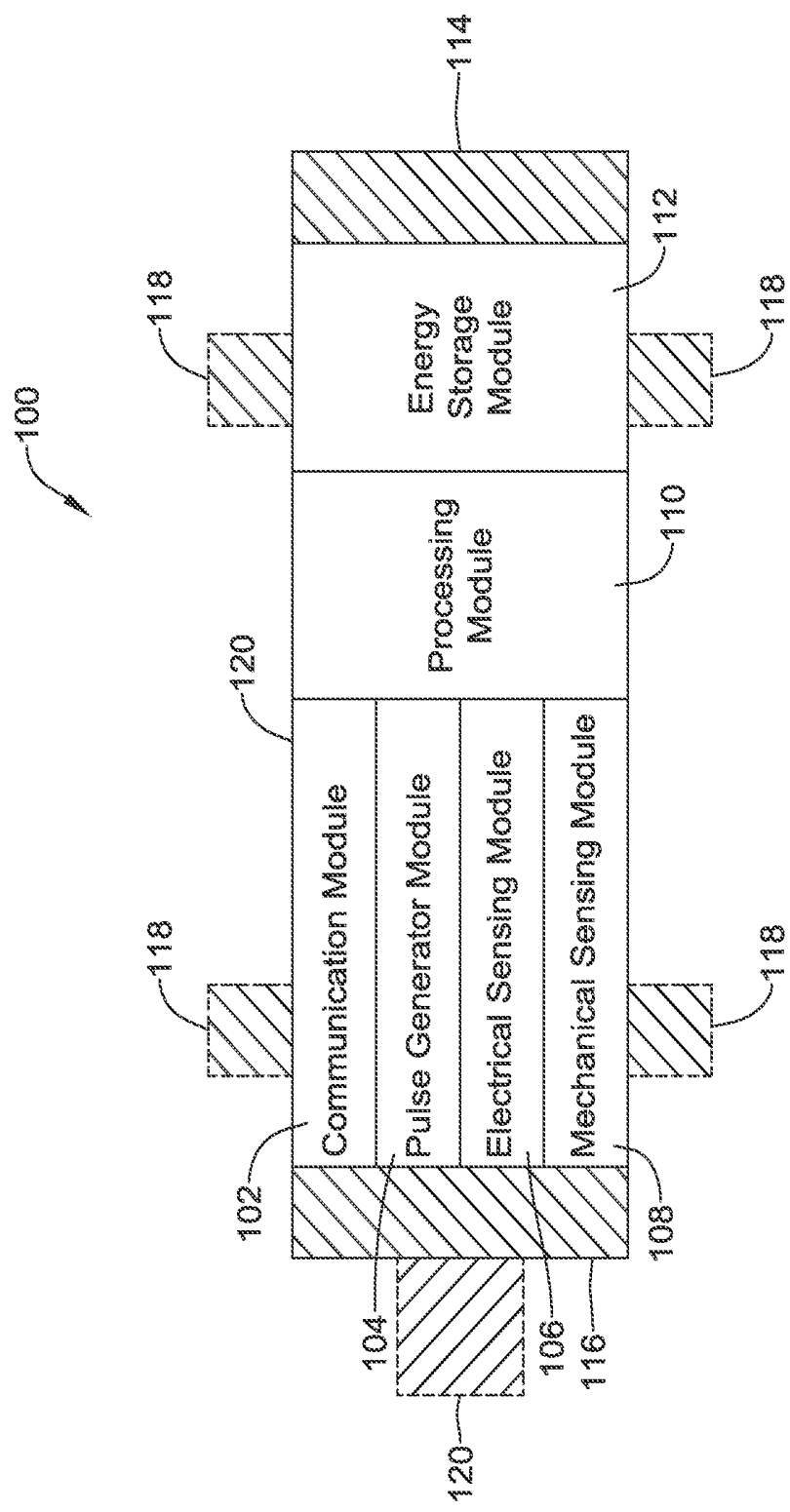


Figure 3

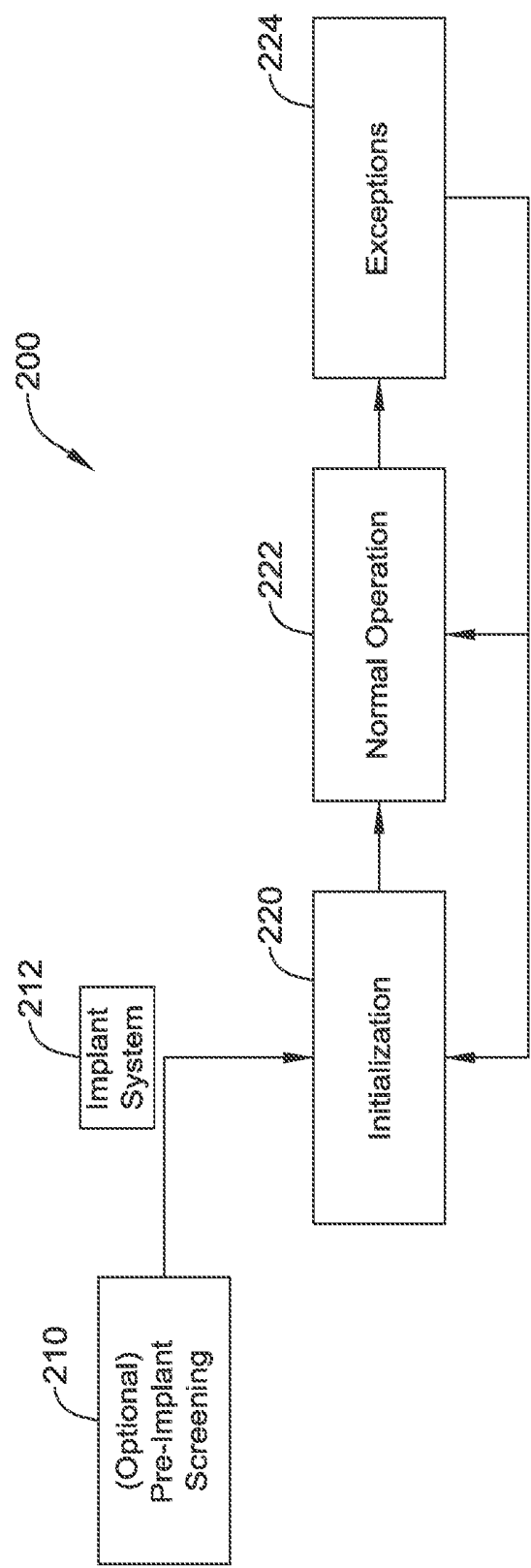


Figure 4

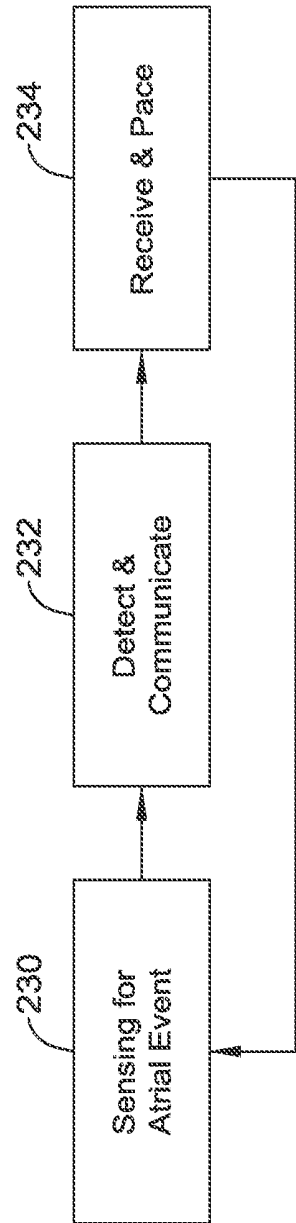


Figure 5

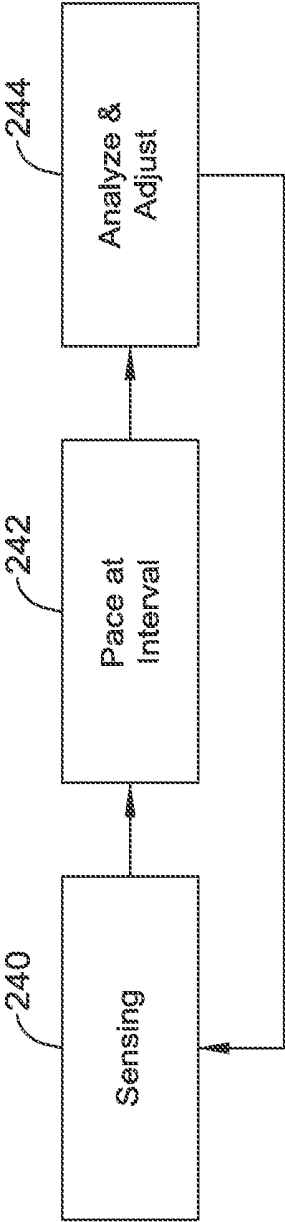


Figure 6

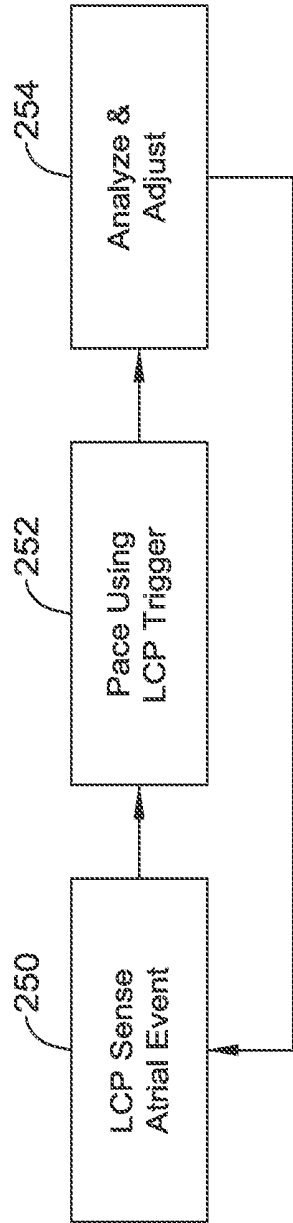


Figure 7

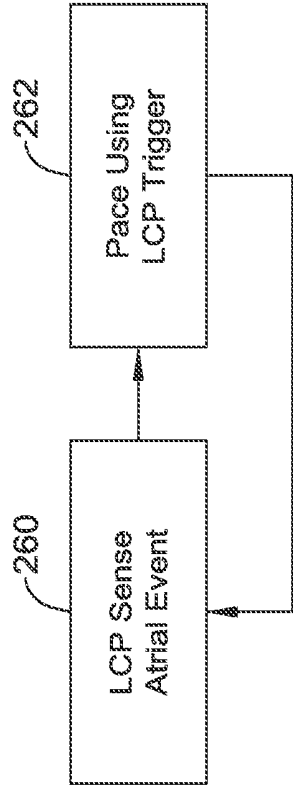


Figure 8

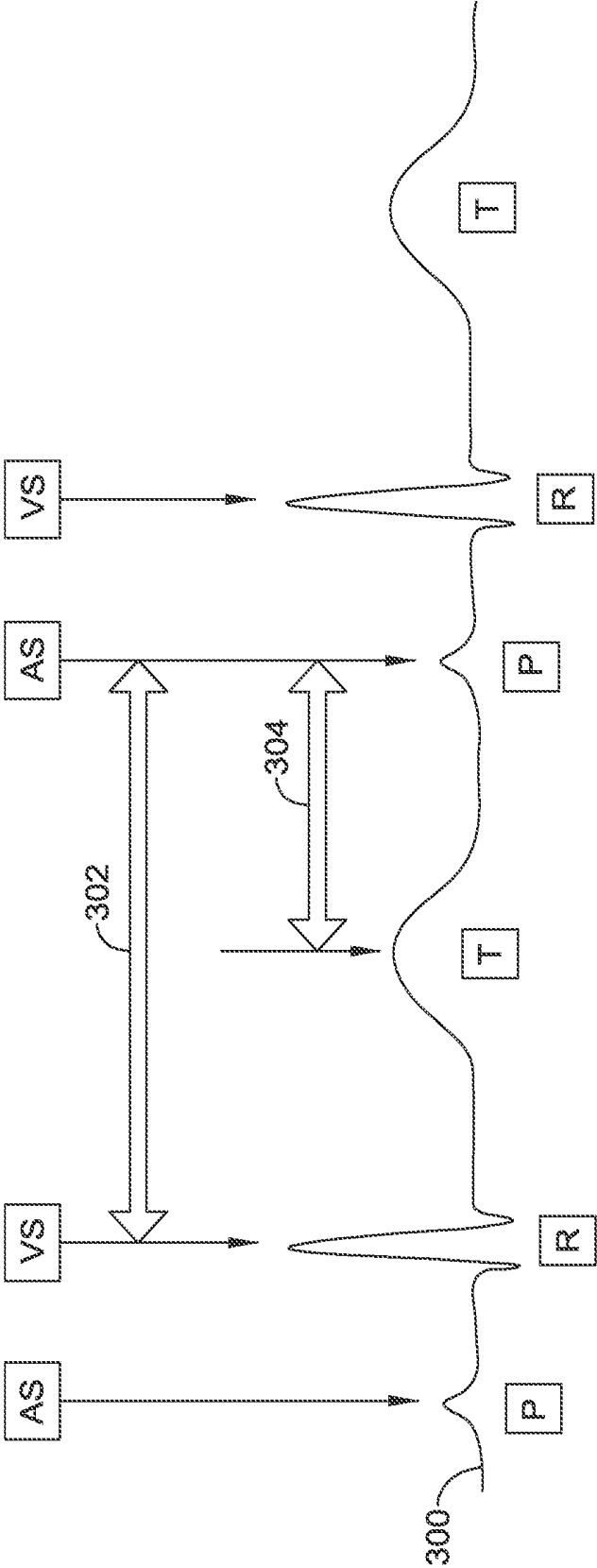


Figure 9

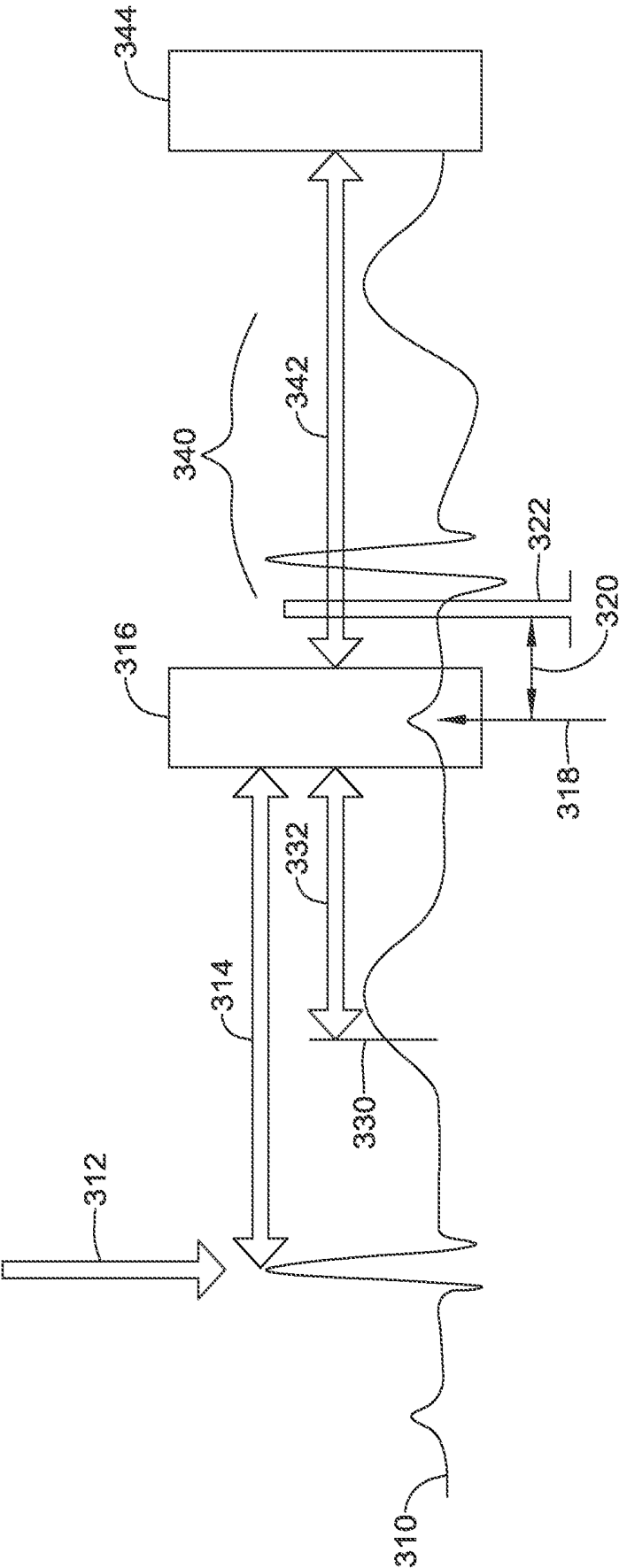


Figure 10

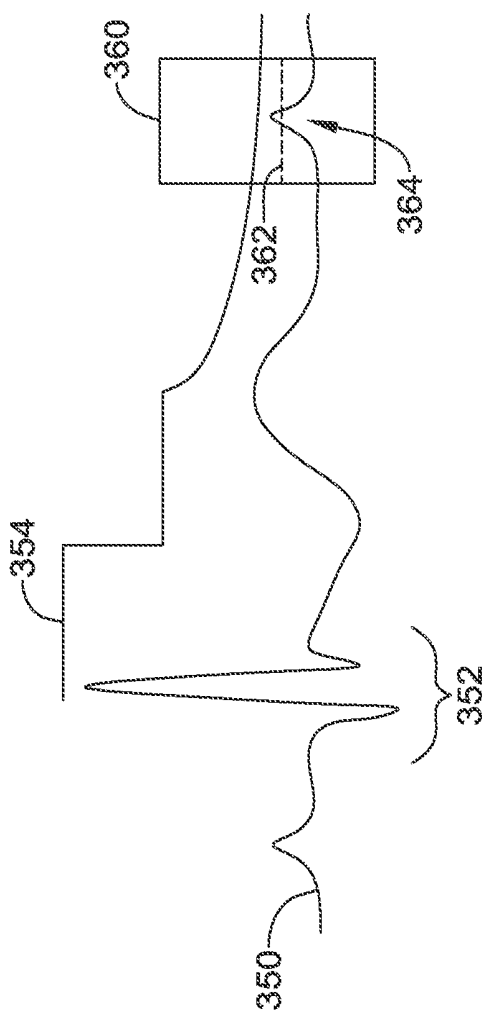


Figure 11

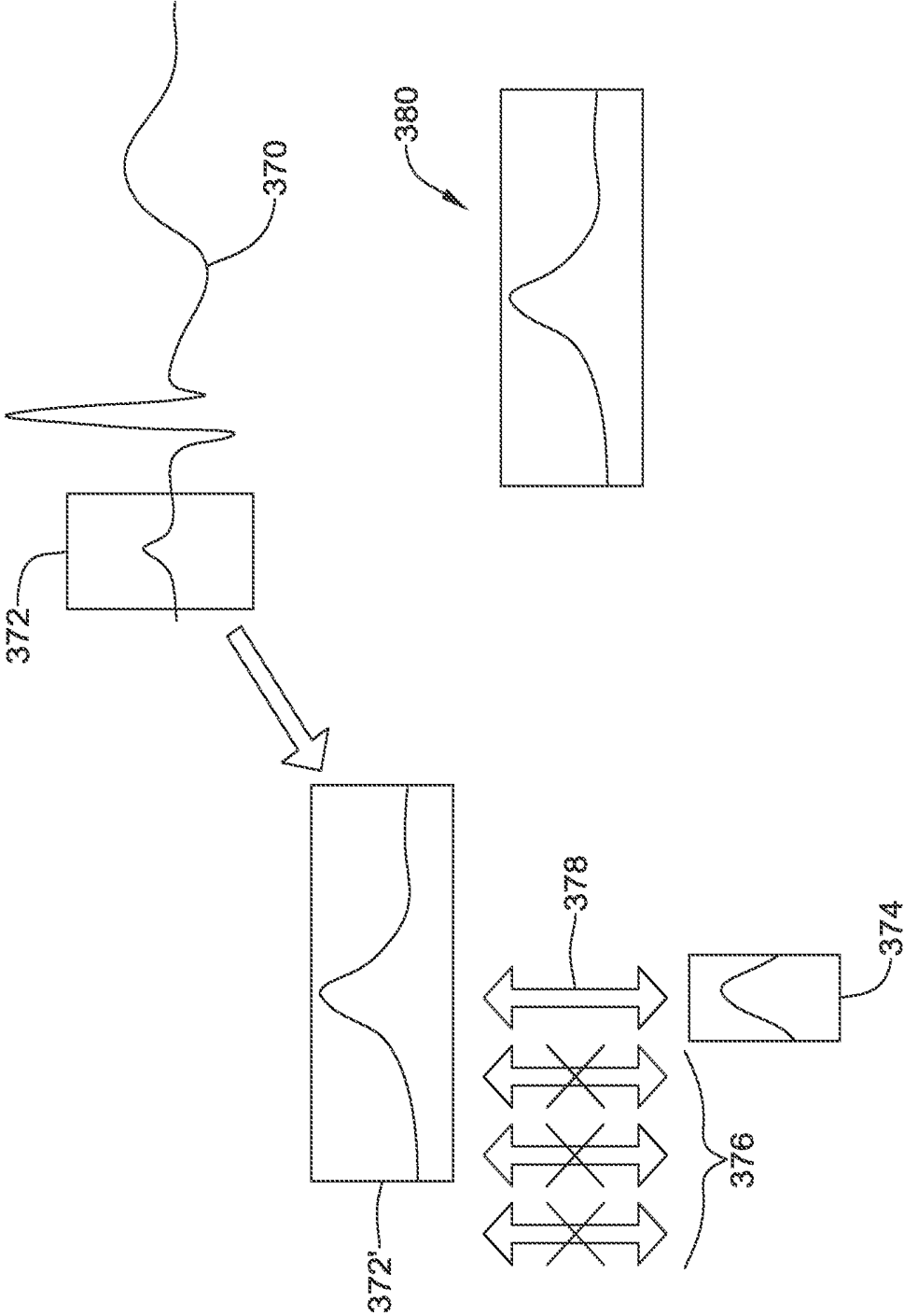


Figure 12

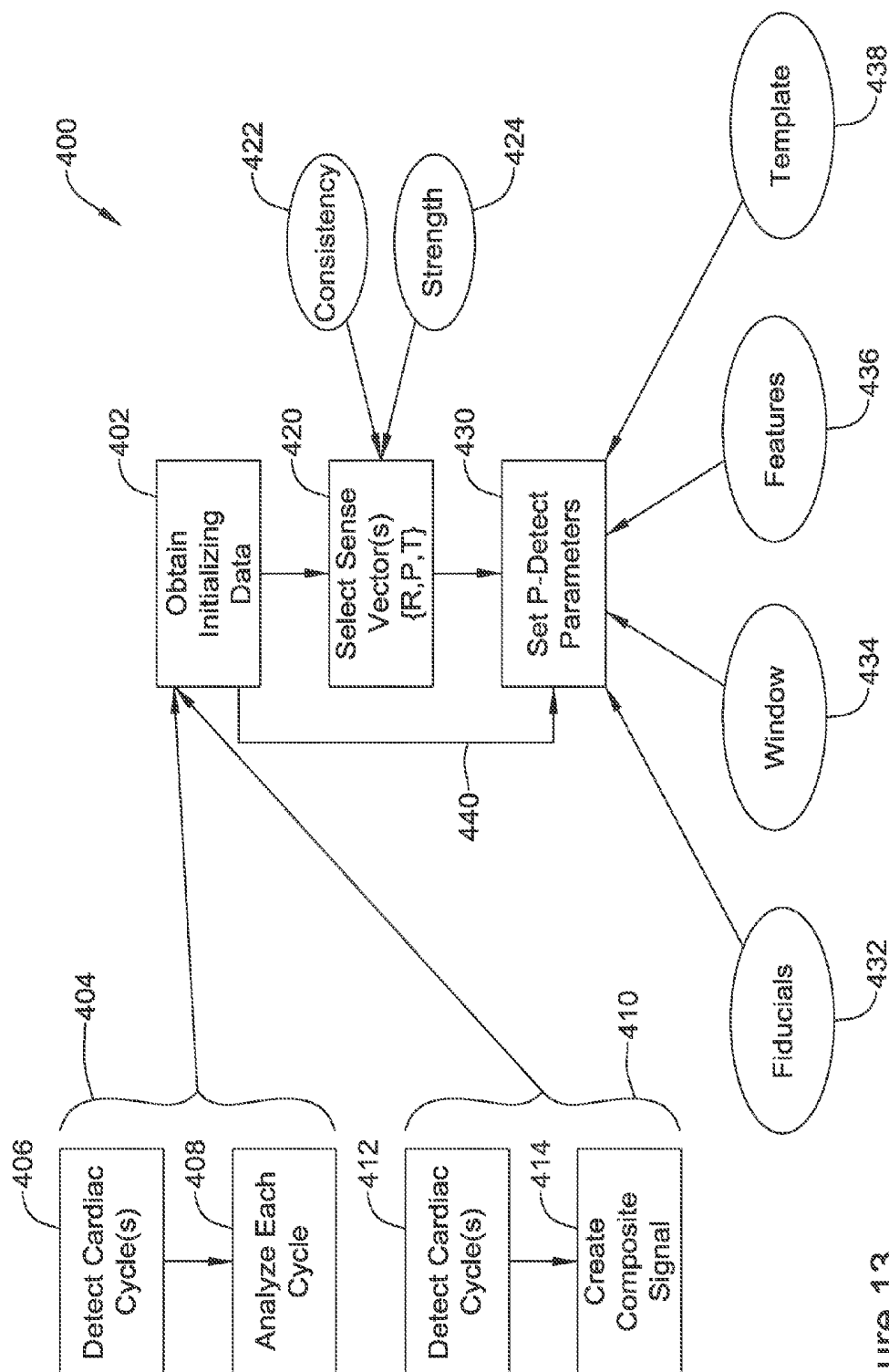


Figure 13

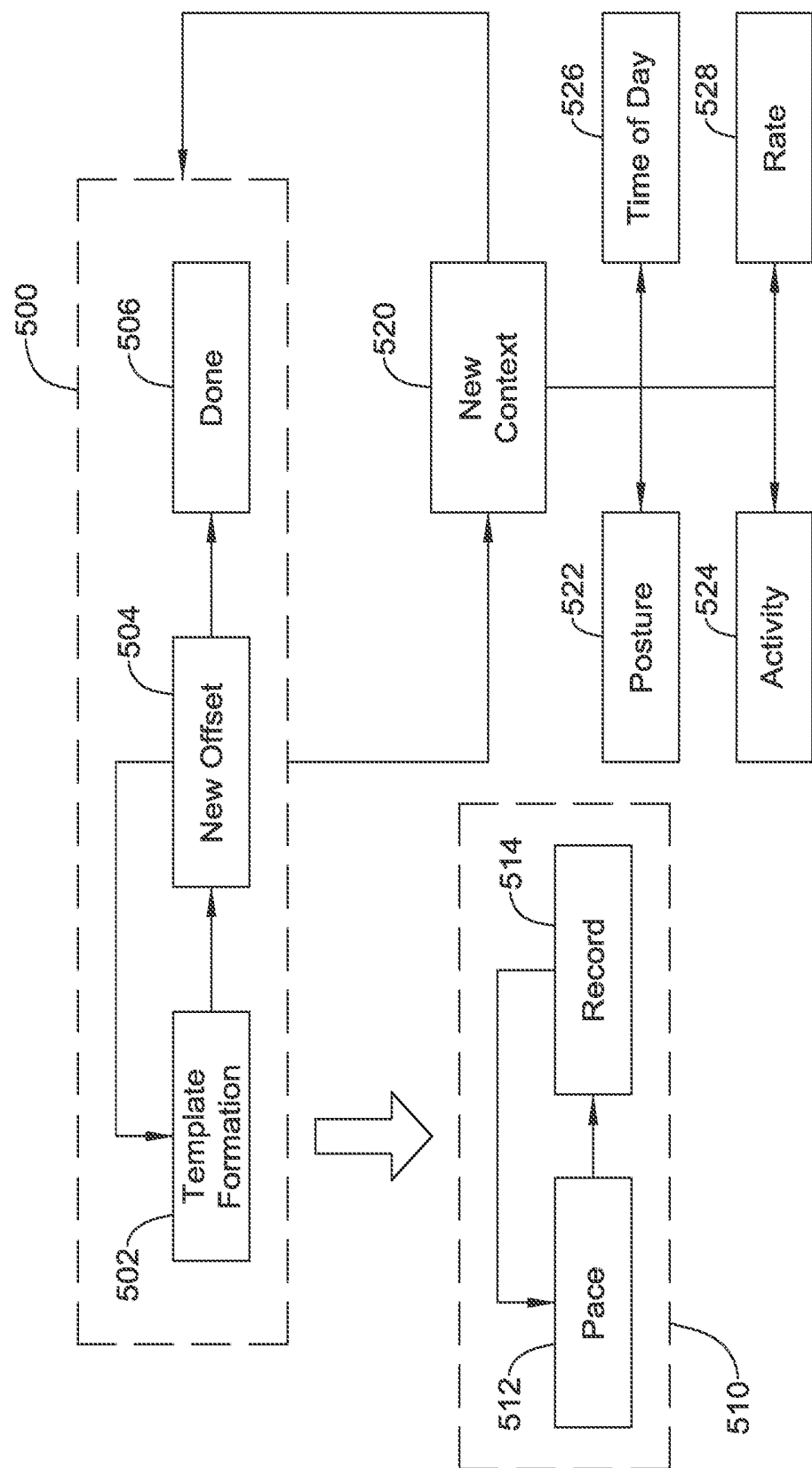


Figure 14

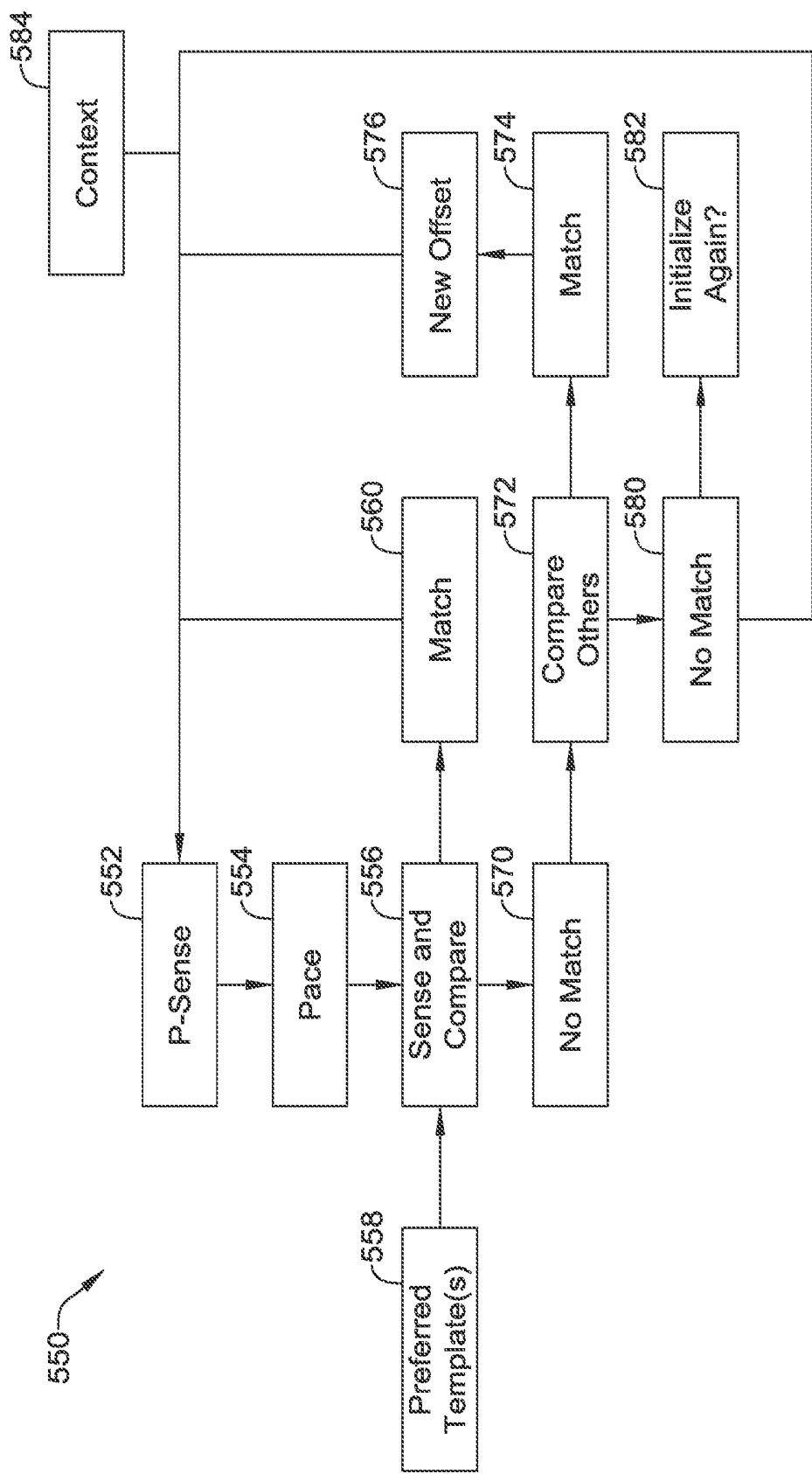


Figure 15

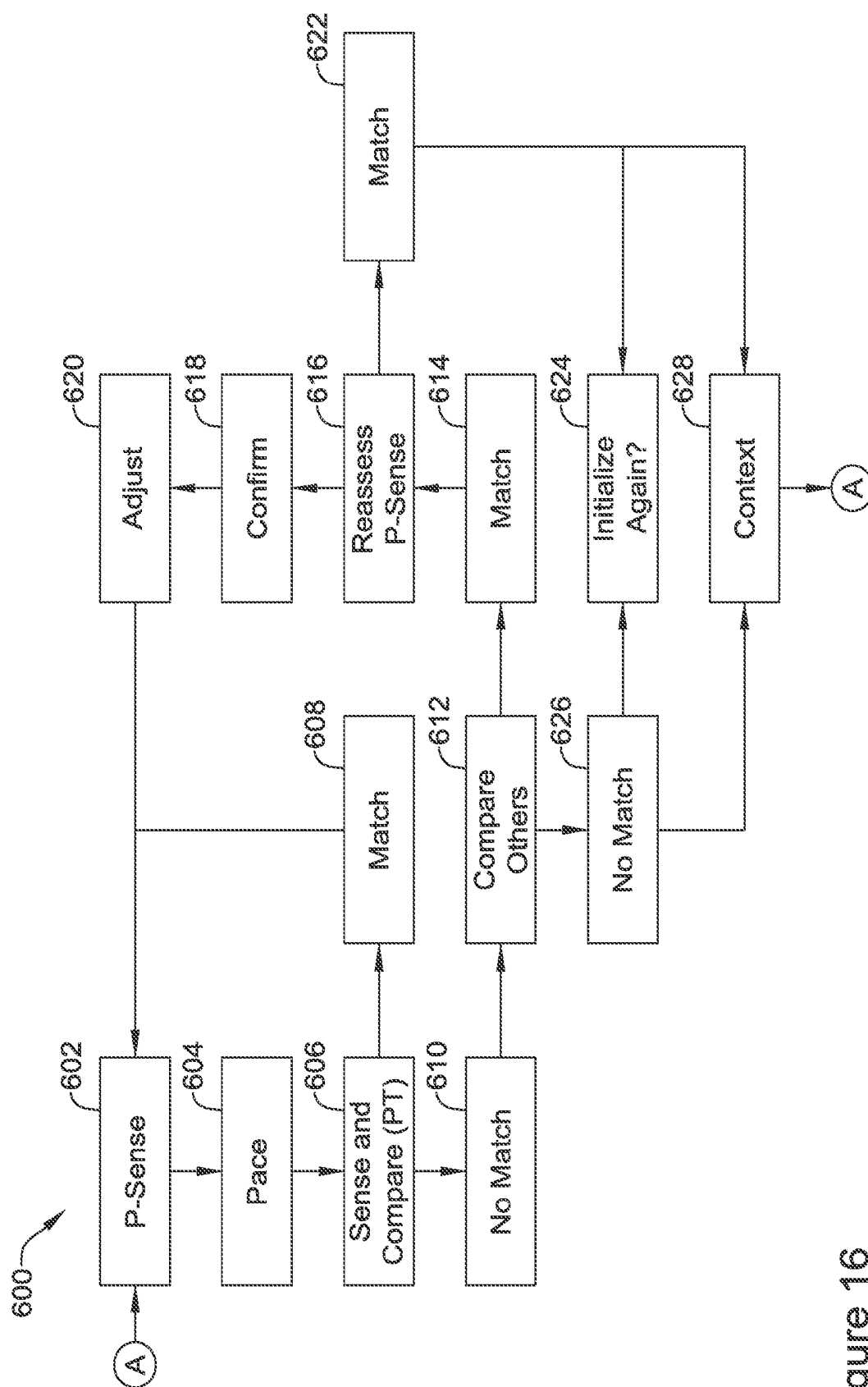


Figure 16

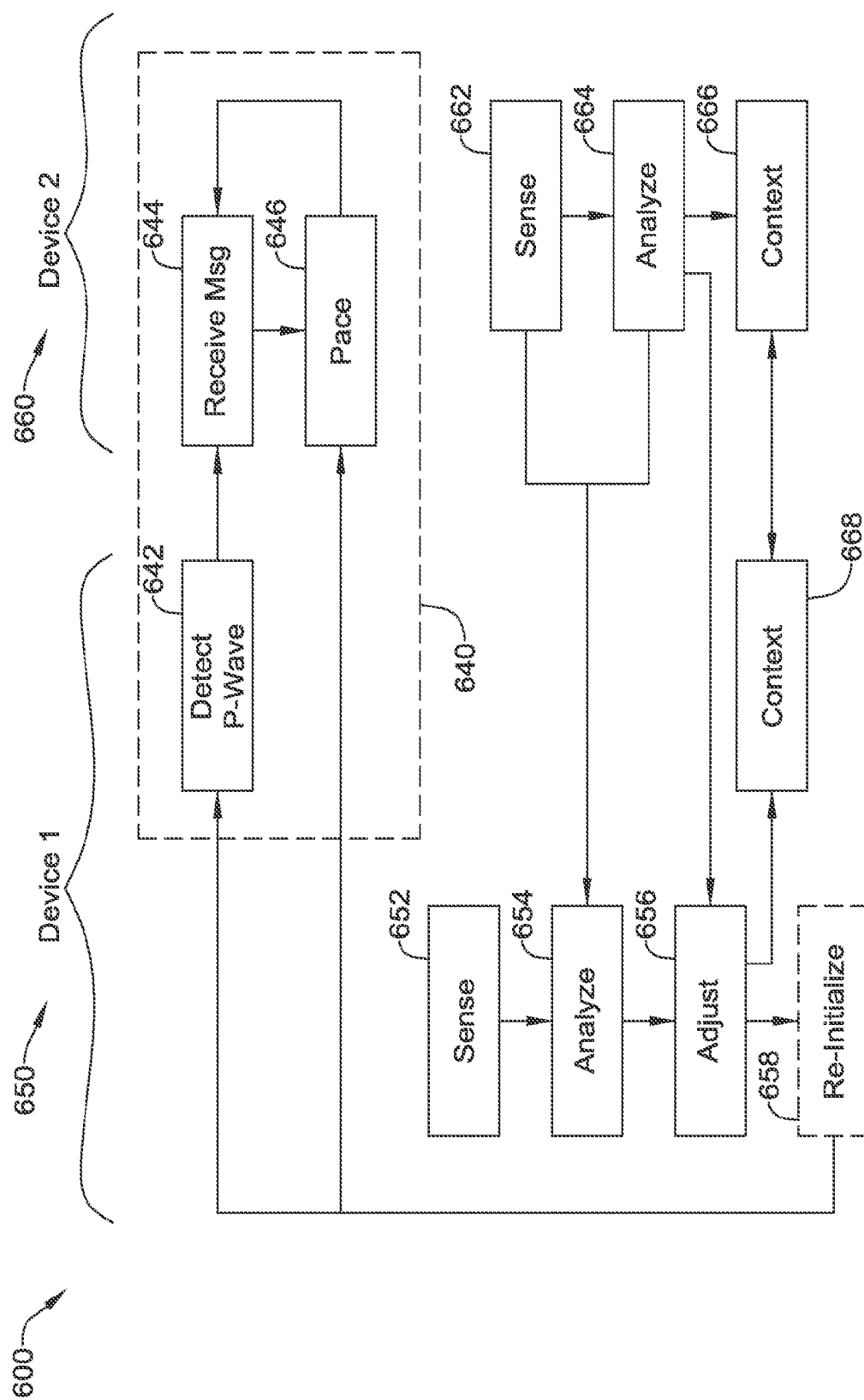


Figure 17

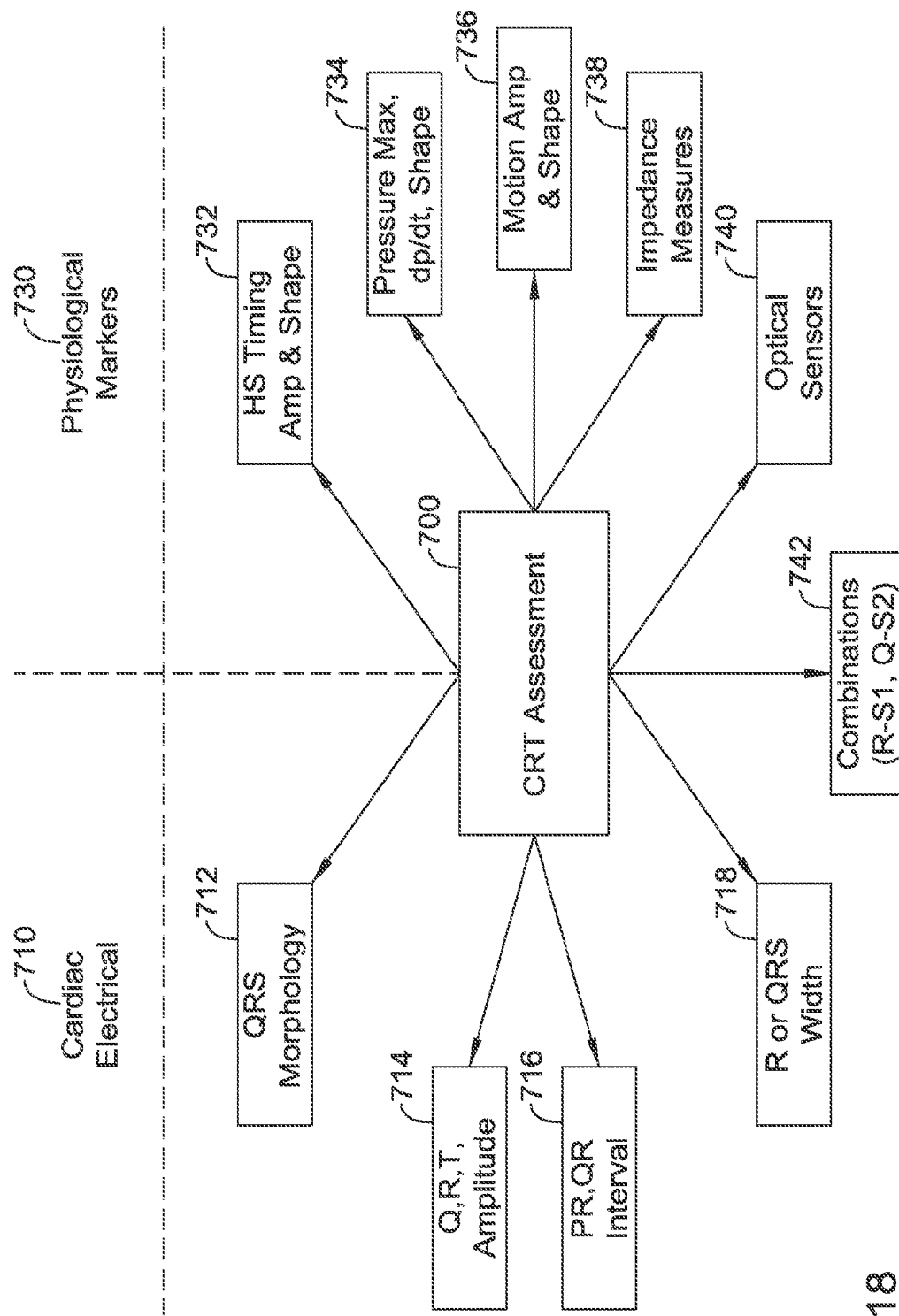


Figure 18

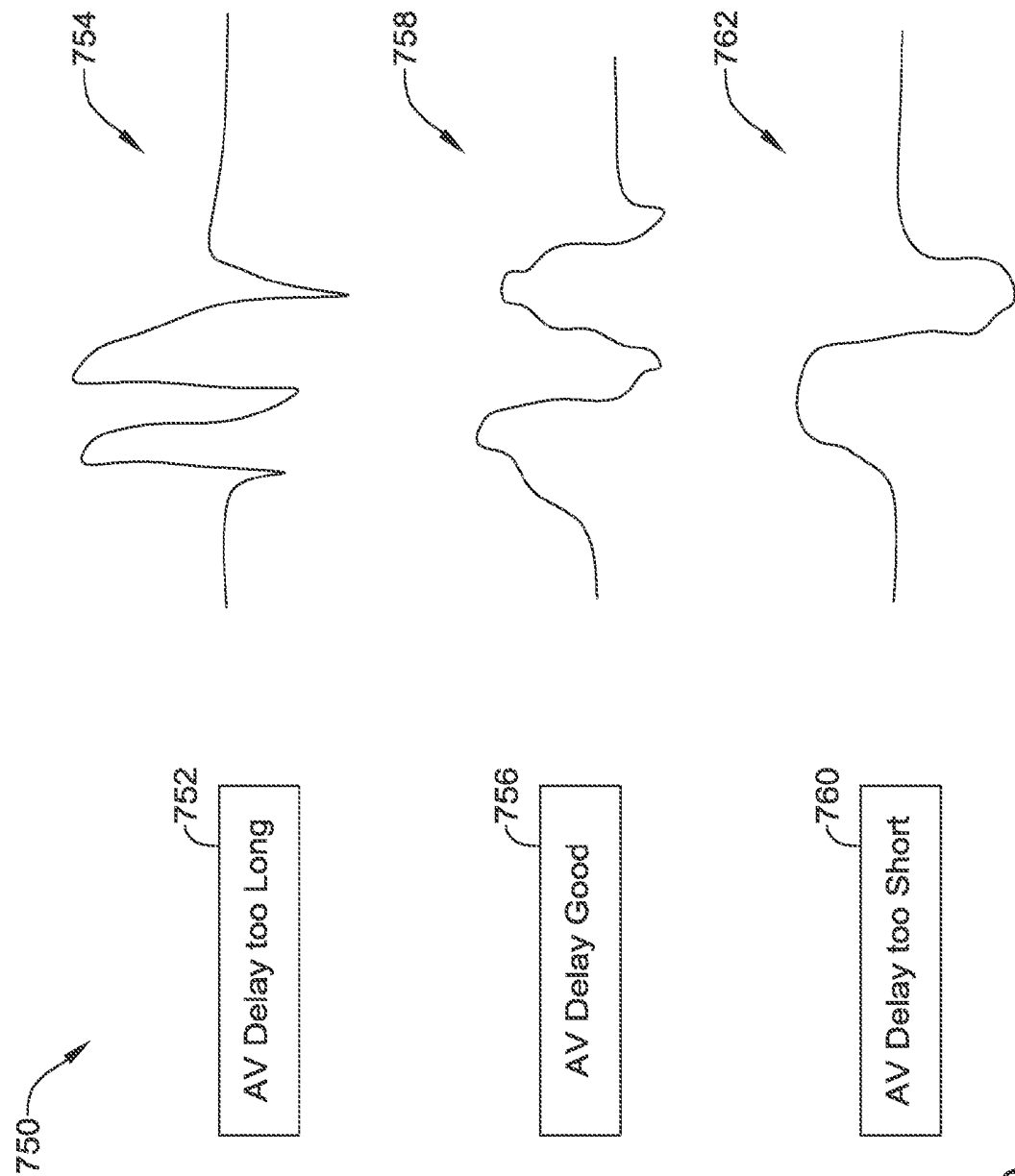


Figure 19

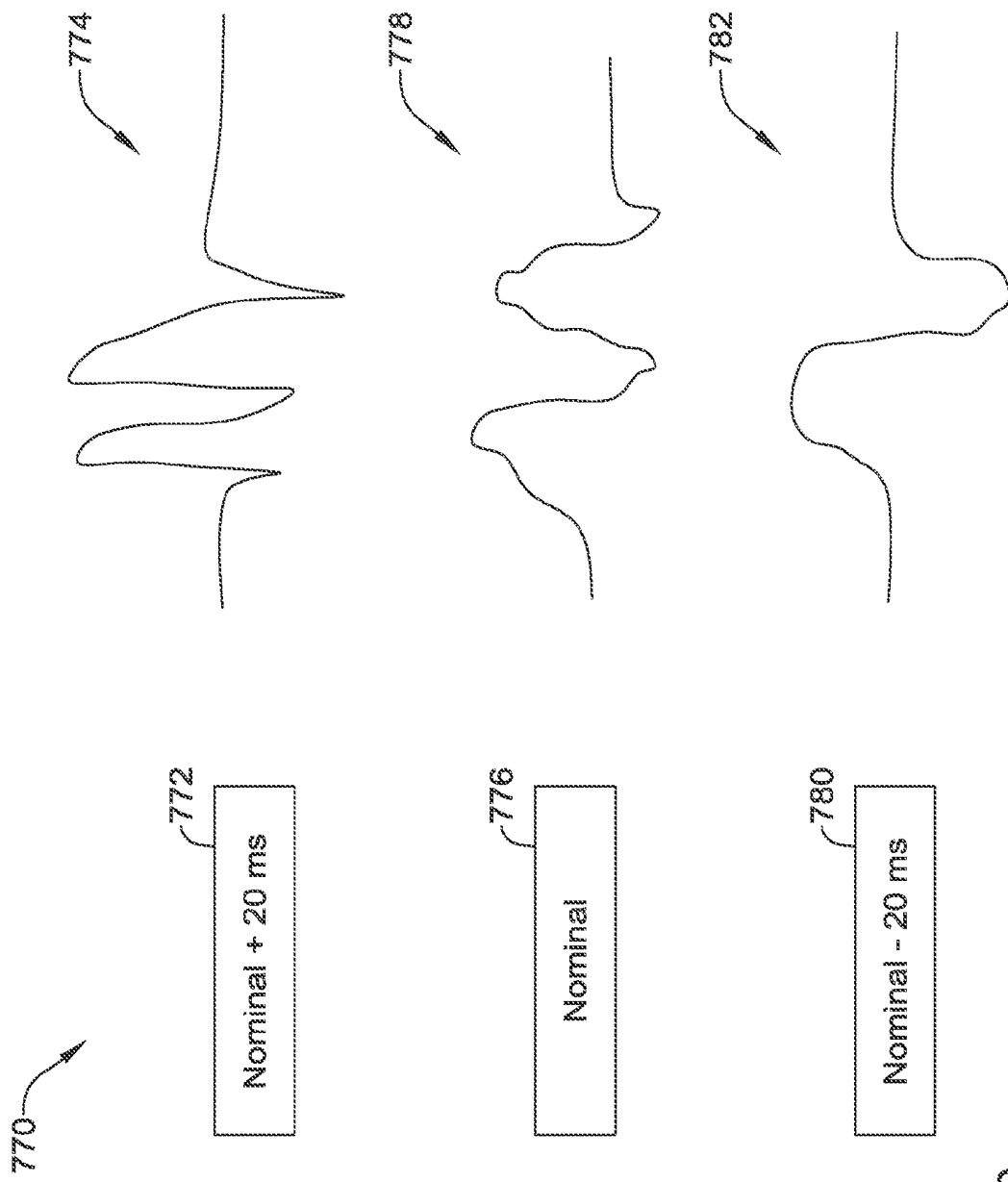


Figure 20

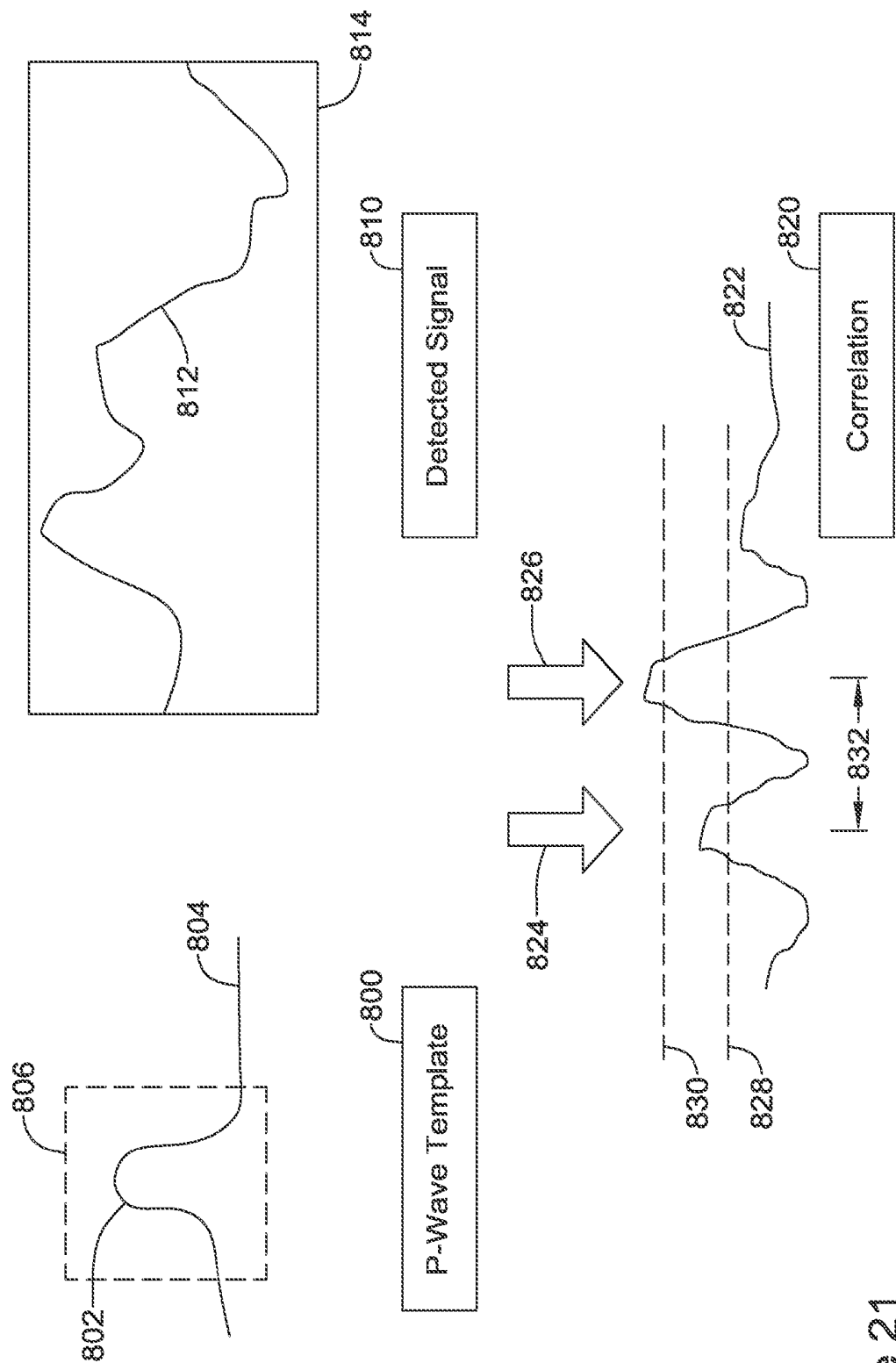


Figure 21

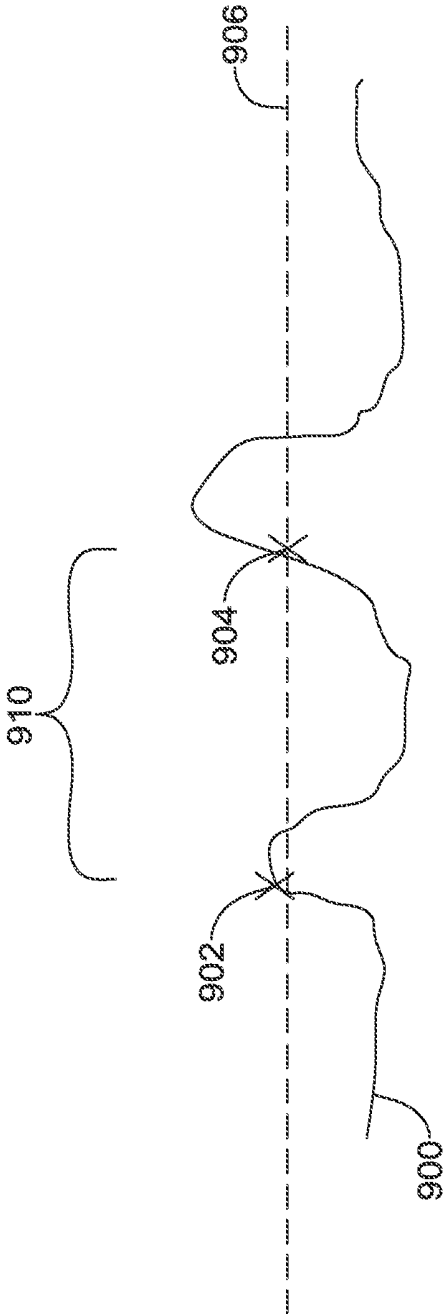


Figure 22

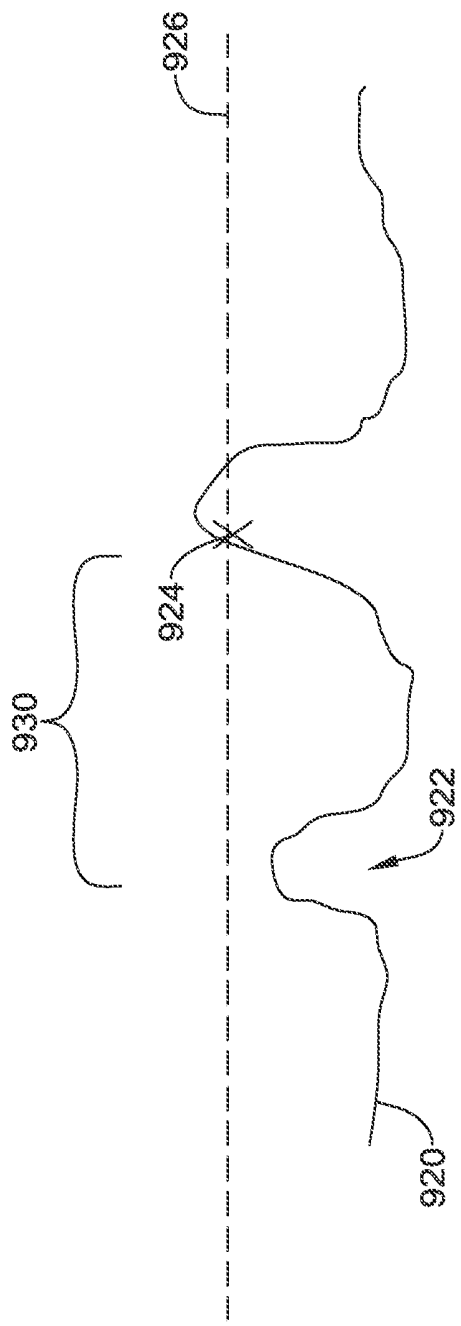


Figure 23

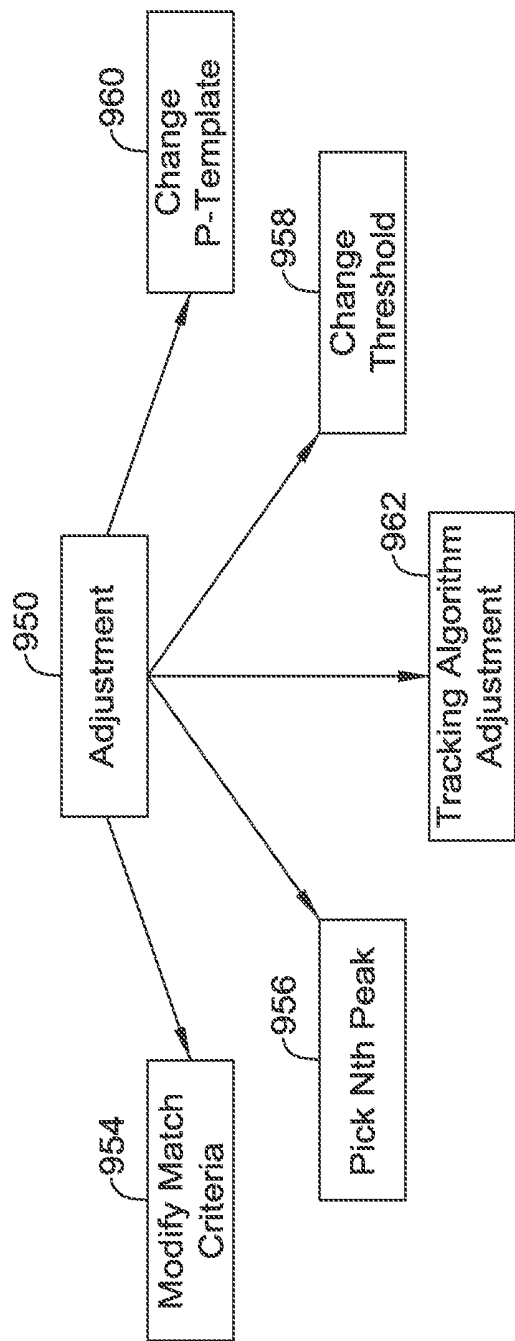


Figure 24

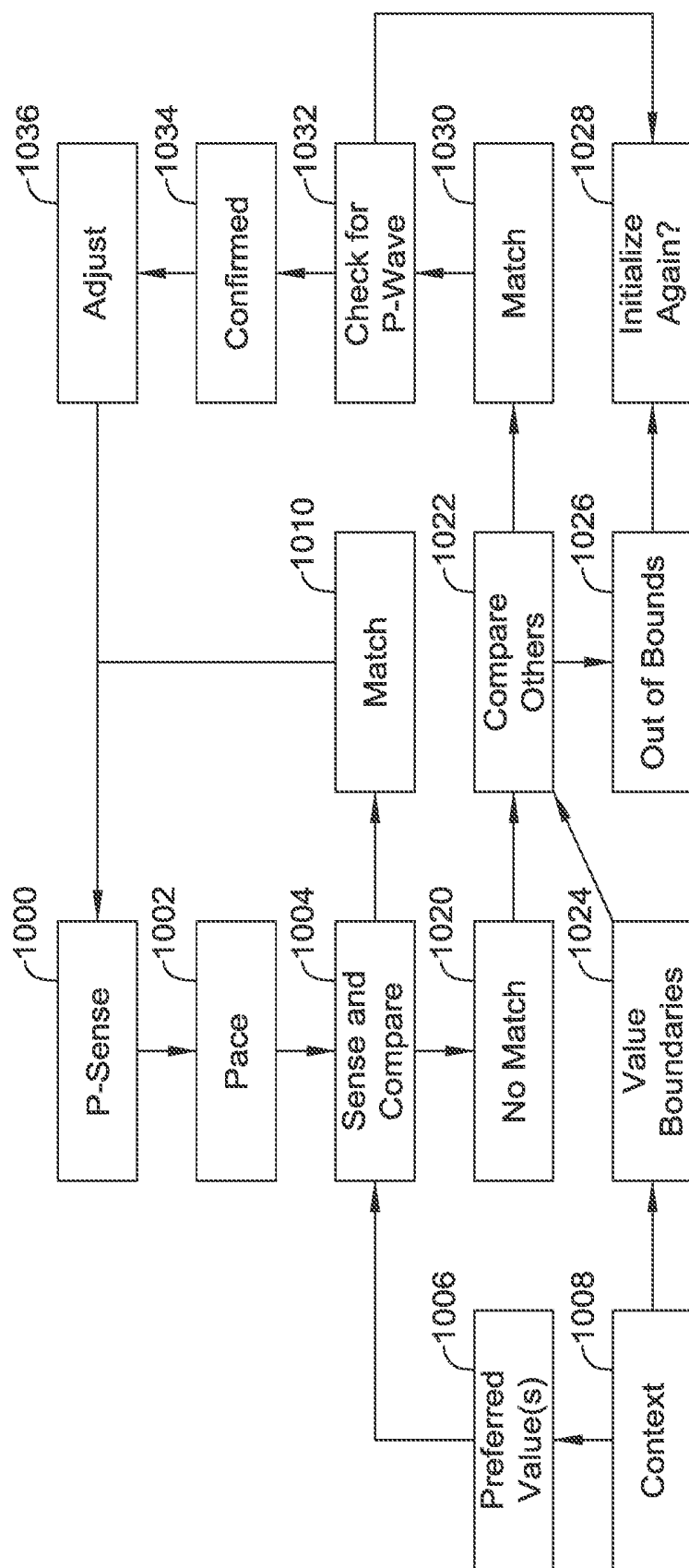


Figure 25

MULTI-DEVICE CARDIAC RESYNCHRONIZATION THERAPY WITH TIMING ENHANCEMENTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of and priority to U.S. Provisional Patent Application Ser. No. 62/413,624, filed on Oct. 27, 2016, and titled MULTI-DEVICE CARDIAC RESYNCHRONIZATION THERAPY WITH TIMING ENHANCEMENTS, the disclosure of which is incorporated herein by reference.

BACKGROUND

[0002] Cardiac resynchronization therapy (CRT) modifies the electrical activation and contractions of the heart's chambers to enhance pumping efficiency. Benefits may include increased exercise capacity and reduced hospitalization and mortality. More particularly, CRT devices operate by affecting the timing of contraction of one or more cardiac chambers relative to one or more other cardiac chambers. For example, contractions of one or more of the ventricle(s) may be timed relative to contraction of the atria, or contractions of the left and right ventricles may be timed relative to one another.

[0003] A "fusion" beat occurs when multiple activation signals affect the same cardiac tissue at the same time. For example, electrical fusion between pacing of one ventricle with spontaneous activation of another ventricle (for example, paced left ventricular (LV) activation and intrinsic right ventricular (RV) activation) produces a fusion beat. The generation of fusion beats is a goal of CRT in many circumstances.

[0004] Prior systems generally include intracardiac electrodes coupled via transvenous leads to an implanted pulse generator. The leads of such systems are widely known as introducing various morbidities and are prone to eventual conductor and/or insulator failure. Such issues likely reduce usage of CRT within the indicated population of heart failure patients.

[0005] Such prior lead systems typically include ventricular and atrial components to facilitate sensing of atrial and ventricular events to enhance CRT timing. For example, in some patients, CRT may be achieved by pacing the left ventricle at a specific time relative to detection of an atrial event. The atrial signal may conduct to the right ventricle (RV) via natural conduction to generate an RV contraction, with paced LV contraction occurring at a desirable time relative to the RV contraction to yield a fusion beat. The interval from the atrial sensed event to the LV pace may be adjusted to enhance cardiac response in prior systems.

[0006] Newer generation pacemakers include the leadless cardiac pacemaker (LCP), which can be implanted entirely within the heart and does not require a transvenous (or any) lead. Such devices are commercially available on a limited basis, but are currently indicated for and capable of use in only bradycardia pacing. With further enhancements, the LCP also presents an opportunity to provide an alternative to traditional CRT using transvenous leads. New and alternative systems, devices and methods directed at providing CRT using the LCP are desired.

Overview

[0007] The present inventors have recognized, among other things, that a problem to be solved is that the absence of an intracardiac lead makes detection of an atrial event for purposes of CRT potentially difficult for a system using one or more ventricular LCP devices. A second implantable device, such as a subcutaneous cardiac monitor (SCM), a subcutaneous implantable cardiac defibrillator (SICD), or a substernal variant of the SICD, may be used to assist in the timing of delivery of LCP CRT pacing. Such a second device may in some examples be referred to as an extracardiac device. There are various ways the second device can assist with achieved desired timing of the CRT, but each has shortcomings. The present inventors have identified new and/or alternative approaches to determining whether CRT in such a system is being provided appropriately and making adjustments to enhance CRT efficacy.

[0008] A first non-limiting example takes the form of an implantable medical device (IMD) system comprising: a leadless cardiac pacemaker (LCP) having a plurality of LCP electrodes, pacing circuitry configured to issue cardiac pacing outputs via the plurality of LCP electrodes, LCP communication circuitry configured to communicate to a second device, and operational circuitry configured to control the pacing circuitry to generate cardiac resynchronization therapy (CRT) using data received with the communication circuitry, the LCP further comprising a sensing input circuit to receive one or more biological signals to determine whether the CRT is achieving a desired result; an extracardiac device (ED) comprising: a plurality of electrodes for sensing cardiac signals; ED communication circuitry configured to communicate with at least the LCP communication circuitry; and ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity. In this first illustrative non-limiting example, the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal using a set of P-wave detection parameters, and use the ED communication circuitry to communicate to the LCP timing information related to the P-wave to assist in the CRT, such that the ED serves as a second device for purposes of the LCP communication circuitry, and the ED and LCP are configured to cooperatively adjust the P-wave detection parameters.

[0009] A second non-limiting example takes the form of an IMD system as in the first non-limiting example, wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters by: at a first time including at least a first cardiac cycle: the ED detecting a P-wave using first P-wave detection parameters and using the ED communication circuitry to communicate to the LCP first timing information related to the detected P-wave; the LCP using the first timing information to deliver one or more CRT pacing therapies; the LCP determining that a delivered CRT pacing therapy has failed to achieve the desired result; and the LCP communicating the failure to achieve the desired result to the ED. Further in the second non-limiting example, in response to the LCP communicating failure to achieve the desired result, the ED adjusts the P-wave detection parameters to second P-wave detection parameters. Still further in the second non-limiting example, at a second time following the first time, the second time including at least a second cardiac cycle: the ED detecting a P-wave using second

P-wave detection parameters and using the ED communication circuitry to communicate to the LCP second timing information related to the detected P-wave; and the LCP using the second timing information to deliver one or more CRT pacing therapies.

[0010] A third non-limiting example takes the form of an implantable medical device (IMD) system comprising: a leadless cardiac pacemaker (LCP) for delivering cardiac resynchronization therapy (CRT), the LCP comprising: a plurality of electrodes for delivering pacing therapy; a sensing input circuit to receive one or more biological signals; a pacing output circuit; LCP communication circuitry; and LCP operational circuitry configured to receive and analyze signals from the sensing input. The IMD system of this third non-limiting example also includes an extracardiac device (ED) comprising: a plurality of electrodes for sensing cardiac signals; ED communication circuitry configured to communicating with at least the LCP communication circuit; and ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity. Further in the third non-limiting example, the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal, and use the ED communication circuitry to communicate to the LCP that the P-wave has been detected; and the LCP operational circuitry is configured to determine from its analysis of signals received from the sensing input whether the ED is incorrectly detecting the P-wave.

[0011] A fourth non-limiting example takes the form of an implantable medical device (IMD) system comprising: a leadless cardiac pacemaker (LCP) for delivering cardiac resynchronization therapy (CRT), the LCP comprising: a plurality of electrodes for delivering pacing therapy; a sensing input circuit to receive one or more biological signals; a pacing output circuit; LCP communication circuitry; and LCP operational circuitry configured to receive and analyze signals from the sensing input. The system of the fourth non-limiting example further comprises an extracardiac device (ED) comprising: a plurality of electrodes for sensing cardiac signals; ED communication circuitry configured to communicating with at least the LCP communication circuit; and ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity. Further in the system of the fourth non-limiting example, the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal, and use the ED communication circuitry to communicate to the LCP that the P-wave has been detected; wherein the LCP operational circuitry is configured to use the pacing output circuit to deliver pace therapy and to use the sensing input circuit to determine whether a cardiac response to the pace therapy matches a desired metric; and the LCP operational circuitry is configured to communicate to the ED operational circuitry to indicate that the pace therapy does not match the desired metric.

[0012] A fifth non-limiting example takes the form of an implantable medical device (IMD) system comprising: a leadless cardiac pacemaker (LCP) having a plurality of LCP electrodes, pacing circuitry configured to issue cardiac pacing outputs via the plurality of LCP electrodes, LCP communication circuitry configured to communicate to a second device, and operational circuitry configured to control the

pacing circuitry to generate cardiac resynchronization therapy (CRT) using data received with the communication circuitry, the LCP further comprising a sensing input circuit to receive one or more biological signals to determine whether the CRT is achieving a desired result. The fifth non-limiting example further includes an extracardiac device (ED) comprising: a plurality of electrodes for sensing cardiac signals; ED communication circuitry configured to communicating with at least the LCP communication circuitry; and ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity. Further in the fifth non-limiting example, the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal, and use the ED communication circuitry to communicate to the LCP timing information related to the P-wave to assist in the CRT; and the LCP operational circuitry is configured to communicate to the ED operational circuitry to indicate whether the CRT is achieving the desired result.

[0013] Additionally or alternatively, the ED may be configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the ED may be configured to adjust the P-wave detection parameters by adjusting a match criteria.

[0014] Additionally or alternatively, the ED may be configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the ED may be configured to adjust the P-wave detection parameters by changing the template.

[0015] Additionally or alternatively, the ED may be configured to detect a P-wave by identifying a peak among a set of peaks in a set of P-wave indicia; further wherein the ED may be configured to adjust the P-wave detection parameters by storing a parameter for selecting an Nth peak of the set of peaks.

[0016] Additionally or alternatively, the ED may be configured to detect a P-wave by comparing a set of P-wave indicia to a P-wave detection threshold; further wherein the ED may be configured to adjust the P-wave detection parameters by adjusting the P-wave detection threshold.

[0017] Additionally or alternatively, the P-wave indicia may comprise a series of samples of cardiac electrical data, or may comprise a series of correlation results generated by comparing a P-wave template to a cardiac electrical signal at a series of points in time.

[0018] Additionally or alternatively, the ED may be configured to detect a P-wave using a tracking analysis to track P-wave detections among a set of P-wave data captured for a series of cardiac cycles; further wherein the ED may be configured to adjust the P-wave detection parameters by adjusting the tracking analysis.

[0019] Additionally or alternatively, the LCP operational circuitry may be configured to determine whether the CRT is achieving a desired result and to communicate to the ED operational circuitry to indicate whether the CRT is achieving the desired result, wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters in response to the LCP determining that the CRT is not achieving the desired result.

[0020] Additionally or alternatively, the LCP operational circuitry may be configured to determine whether the CRT

is achieving a desired result by: storing one or more templates for a physiological signal sensed by the sensing input circuit, at least one of the templates representing the physiological signal corresponding to a preferred pace timing; and determining whether a test physiological signal captured in relation to a CRT pace therapy matches the template representing the physiological signal corresponding to the preferred pace timing. Additionally or alternatively, the one or more templates may comprise at least one offset template each representing the physiological signal corresponding to a known offset from the preferred pace timing; and the LCP may be configured to determine whether the test physiological signal matches one of the at least one offset templates and, if so, to communicate to the ED that an offset template match has occurred.

[0021] Additionally or alternatively, the ED may be configured, in response to the LCP communicating that an offset template match has occurred, to analyze the cardiac signal to determine whether a P-wave may have occurred at an offset relative to the detected P-wave, and, if so, making an adjustment to P-wave detection criteria.

[0022] Additionally or alternatively, the ED may be configured, in response to the LCP communicating that an offset template match has occurred, to reanalyze the cardiac signal to determine whether one or more adjustments to a P-wave detection criteria would result in detection of a P-wave correlated to the offset of the offset template that matched the test physiological signal.

[0023] Additionally or alternatively, the ED may be configured, in response to the LCP communicating that an offset template match has occurred, to make an adjustment to P-wave detection criteria using the offset.

[0024] Additionally or alternatively, if the test physiological signal does not match any of the one or more templates, the LCP may be configured to communicate that no template match occurred to the ED and further wherein, if the LCP finds at least a threshold quantity of test physiological signals fail to match any of the one or more templates, the IMD system may be configured to perform a re-initialization of one or more CRT system settings.

[0025] Additionally or alternatively, the one or more templates may include different templates for each of a plurality of system contexts. Additionally or alternatively, the plurality of system contexts may define a context for each of a plurality of cardiac rate zones. Additionally or alternatively, the plurality of system contexts may define a context for each of a plurality of postures, and at least one of the ED or the LCP may comprise a sensor to determine posture.

[0026] Additionally or alternatively, the LCP sensing input circuit to receive one or more biological signals may comprise a heart sound detector, and the one or more templates may include templates of heart sound signals. Additionally or alternatively, the LCP sensing input circuit to receive one or more biological signals may comprise a cardiac electrogram sensor, and the one or more templates may include templates of QRS morphology. Additionally or alternatively, the LCP sensing input circuit to receive one or more biological signals may comprise a pressure detector, and the one or more templates may include templates of pressure waveforms. Additionally or alternatively, the LCP sensing input circuit to receive one or more biological signals may comprise a motion detector, and the one or more templates may include templates of motion detector outputs over time. Additionally or alternatively, the LCP sensing

input circuit to receive one or more biological signals may comprise an impedance measuring circuit, and the one or more templates may include templates of impedance changes over time. Additionally or alternatively the LCP sensing input circuit to receive one or more biological signals may comprise an optical sensor, and the one or more templates may include templates of optical sensor output over time.

[0027] Additionally or alternatively, the LCP may be configured to deliver CRT pacing output in response to communication of timing information related to the P-wave from the ED.

[0028] Additionally or alternatively, the LCP may be configured to deliver CRT pacing output according to a calculated interval relative to a prior CRT pacing output, such that the LCP is configured to use the communication of timing information related to the P-wave to adjust the calculated interval.

[0029] Additional embodiments may take the form of methods of providing CRT to a patient using any of these above non-limiting examples. In some such methods, an LCP may deliver the CRT pacing and observe a response to the pacing to determine whether desirable CRT results are occurring, and acts cooperatively with an ED in order to correct pace timing in the event that the desirable CRT results are not occurring.

[0030] This overview is intended to provide an introduction to the subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The detailed description is included to provide further information about the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] In the drawings, which are not necessarily drawn to scale, like numerals may describe similar components in different views. Like numerals having different letter suffixes may represent different instances of similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

[0032] FIG. 1 illustrates a patient having a plurality of implantable medical devices;

[0033] FIG. 2 shows an illustrative implantable medical device;

[0034] FIG. 3 shows an illustrative implantable leadless cardiac pacemaker;

[0035] FIG. 4 shows an overall method of use of a system;

[0036] FIGS. 5-8 show a number of illustrative approaches to pacing and pace timing for a multi-device implantable system;

[0037] FIG. 9 highlights certain features of a cardiac electrical signal;

[0038] FIG. 10 illustrates setting of a P-wave detection window;

[0039] FIGS. 11-12 show a use of a P-wave detection window;

[0040] FIG. 13 illustrates a method of configuring sensing in one or more devices;

[0041] FIG. 14 illustrates a method for setting templates in an illustrative example;

[0042] FIGS. 15-16 show methods of monitoring and enhancing P-wave detection;

[0043] FIG. 17 shows an example allocating certain functions among a multi-device system;

[0044] FIG. 18 illustrates a number of signal types useful in various examples;

[0045] FIGS. 19-20 illustrate physiological signal templates for illustrative examples; and

[0046] FIGS. 21-23 show examples of P-wave detection methods and issues that can arise in each leading to mis-detection of the P-wave;

[0047] FIG. 24 shows a number of different adjustments to P-wave detection methods that may be used; and

[0048] FIG. 25 illustrates a method of monitoring an enhancing P-wave detection using value boundaries rather than templates.

DETAILED DESCRIPTION

[0049] The following description should be read with reference to the drawings. The description and the drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the disclosure.

[0050] FIG. 1 illustrates a patient 10 with a first implanted medical device, shown as a leadless cardiac pacemaker (LCP) 14 implanted inside the heart 12, in the left ventricle for illustrative purposes. The LCP 14 may be implanted in other chambers, such as the right ventricle or in the atrium, and more than one LCP may be provided.

[0051] A second medical device in the form of a subcutaneous implantable defibrillator (SICD) having a left axillary canister 16 and a lead 18 is also present. The illustrative lead 18 is shown with a defibrillation coil 22 and sensing electrodes 24, 26 distal and proximal of the coil 22. The lead 18 may optionally include a bifurcation 28 to provide an additional set of sensing or stimulus providing electrodes, if desired.

[0052] In some embodiments the lead may be as shown, for example, in U.S. Pat. No. 9,079,035, titled ELEC-TRODE SPACING IN A SUBCUTANEOUS IMPLANT-ABLE CARDIAC STIMULUS DEVICE, the disclosure of which is incorporated herein by reference. Rather than bifurcation, plural leads may be provided as shown, for example, in U.S. Pat. No. 7,149,575, titled SUBCUTANEOUS CARDIAC STIMULATOR DEVICE HAVING AN ANTERIORLY POSITIONED ELECTRODE. Any suitable design for single, multiple, or bifurcated implantable leads may be used.

[0053] The lead 18 may be implanted entirely subcutaneously, such as by extending across the anterior or posterior of the chest, or by going partly across the chest in a lateral/medial direction and then superiorly toward the head along the sternum. Some examples and discussion of subcutaneous lead implantation may be found in U.S. Pat. No. 8,157,813, titled APPARATUS AND METHOD FOR SUBCUTANEOUS ELECTRODE INSERTION, and US PG Publication No. 20120029335, titled SUBCUTANEOUS LEADS AND METHODS OF IMPLANT AND EXPLANT, the disclosures of which are incorporated herein by reference. Additional subcutaneous placements are discussed in U.S. Pat. No. 6,721,597, titled SUBCUTANEOUS ONLY IMPLANTABLE CARDIOVERTER DEFIBRILLATOR AND OPTIONAL PACER, and the above mentioned U.S. Pat. No. 7,149,575, the disclosures of which are incorporated herein by reference.

[0054] A substernal placement may be used instead, with one finger 18/20 or the entire distal end of the lead (that is, the end distant from the canister 16) going beneath the sternum. Some examples of such placement are described in US PG Patent Pub. No. 2017/0021159, titled SUBSTER-NAL PLACEMENT OF A PACING OR DEFIBRILLAT-ING ELECTRODE, the disclosure of which is incorporated herein by reference. Still another alternative placement is shown in U.S. patent application Ser. No. 15/667,167, titled IMPLANTATION OF AN ACTIVE MEDICAL DEVICE USING THE INTERNAL THORACIC VASCULATURE, the disclosure of which is incorporated herein by reference.

[0055] The devices 14 and 16 may communicate with one another and/or with an external programmer 30 using conducted communication, in some examples. Conducted communication is communication via electrical signals which propagate via patient tissue and are generated by more or less ordinary electrodes. By using the existing electrodes of the implantable devices, conducted communication does not rely on an antenna and an oscillator/resonant circuit having a tuned center frequency or frequencies common to both transmitter and receiver. RF or inductive communication may be used instead. Alternatively the devices 14 and 16 may communicate via inductive, optical, sonic, or RF communication, or any other suitable medium.

[0056] The programmer 30 may optionally use a wand (not shown) and/or skin electrodes 32 and 34 to facilitate communication. For example, skin electrodes 32 and 34 may be used for conducted communication with an implantable device. For other communication approaches such as RF or inductive communication, the programmer 30 may use a programming wand or may have an antenna integral with the programmer 30 housing for communication. Though not shown in detail, the programmer 30 may include any suitable user interface, including a screen, buttons, keyboard, touchscreen, speakers, and various other features widely known in the art.

[0057] Subcutaneous implantable defibrillators may include, for example, the Emblem S-ICD System™ offered by Boston Scientific Corporation. Combinations of subcutaneous defibrillators and LCP devices are discussed, for example, in US PG Patent Publication Nos. 20160059025, 20160059024, 20160059022, 20160059007, 20160038742, 20150297902, 20150196769, 20150196758, 20150196757, and 20150196756, the disclosures of which are incorporated herein by reference. The subcutaneous defibrillator and LCP may, for example, exchange data related to cardiac function or device status, and may operate together as a system to ensure appropriate determination of cardiac condition (such as whether or not a ventricular tachyarrhythmia is occurring), as well as to coordinate therapy such as by having the LCP deliver antitachycardia pacing in an attempt to convert certain arrhythmias before the subcutaneous defibrillator delivers a defibrillation shock. In addition, the two systems may coordinate as set forth herein to provide cardiac resynchronization therapy (CRT).

[0058] In some examples, rather than a therapy device such as the SICD shown in FIG. 1, a second implantable medical device may take the form of an implantable monitoring device such as a subcutaneous cardiac monitor (SCM). An SCM may be, for example, a loop monitor that captures data under select conditions using two or more sensing electrodes on a housing thereof and/or attached thereto with a lead. Such monitors have found use to assist

in diagnosing cardiac conditions that may be infrequent or intermittent, or which have non-specific symptoms. In the context of the present invention, an SCM, or even a wearable cardiac monitor, may be used in place of the SICD as described in any of the following examples.

[0059] Several examples focus on using a left ventricular LCP **14**. However, some examples may instead use a right ventricular LCP **40**, and other examples may include both the left ventricular LCP **14** and right ventricular LCP **40**. In other examples, a three implant system may include two LCP devices **14**, **40**, as well as a subcutaneous device such as the SICD **16**. In still other examples, an atrial-placed LCP (not shown) may also be included or may take the place of one of the ventricular LCP devices **14**, **40**.

[0060] FIG. **2** illustrates a block diagram of an implantable medical device. The illustration indicates various functional blocks within a device **50**, including a processing block **52**, memory **54**, power supply **56**, input/output circuitry **58**, therapy circuitry **60**, and communication circuitry **62**. These functional blocks make up the operational circuitry of the device. The I/O circuitry **58** can be coupled to one or more electrodes **64**, **66** on the housing of the device **50**, and may also couple to a header **68** for attachment to one or more leads **70** having additional electrodes **72**.

[0061] The processing block **52** will generally control operations in the device **50** and may include a microprocessor or microcontroller and/or other circuitry and logic suitable to its purpose. A state machine may be included. Processing block **52** may include dedicated circuits or logic for device functions such as converting analog signals to digital data, processing digital signals, detecting events in a biological signal, etc. The memory block may include RAM, ROM, flash and/or other memory circuits for storing device parameters, programming code, and data related to the use, status, and history of the device **50**. The power supply **56** typically includes one to several batteries, which may or may not be rechargeable depending on the device **50**. For rechargeable systems there would additionally be charging circuitry for the battery (not shown).

[0062] The I/O circuitry **58** may include various switches or multiplexors for selecting inputs and outputs for use. I/O circuitry **58** may also include filtering circuitry and amplifiers for pre-processing input signals. In some applications the I/O circuitry will include an H-Bridge to facilitate high power outputs, though other circuit designs may also be used. Therapy block **60** may include capacitors and charging circuits, modulators, and frequency generators for providing electrical outputs. A monitoring device may omit the therapy block **60** and may have a simplified I/O circuitry used simply to capture electrical or other signals such as chemical or motion signals.

[0063] The communication circuitry **62** may be coupled to an antenna **74** for radio communication (such as Medradio, ISM, Bluetooth, or other RF), or alternatively to a coil for inductive communication, and/or may couple via the I/O circuitry **58** to a combination of electrodes **64**, **66**, **72**, for conducted communication. Communication circuitry **62** may include a frequency generator/oscillator and mixer for creating output signals to transmit via the antenna **74**. Some devices **50** may include a separate or even off-the shelf ASIC for the communications circuitry **62**, for example. For devices using an inductive communication output, an inductive coil may be included. Devices may use optical or acoustic communication, and suitable circuits, transducers,

generators and receivers may be included for these modes of communication as well or instead of those discussed above.

[0064] As those skilled in the art will understand, additional circuits may be provided beyond those shown in FIG. **2**. For example, some devices **50** may include a Reed switch, Hall Effect device, or other magnetically reactive element to facilitate magnet wakeup, reset, or therapy inhibition of the device by a user, or to enable an MRI protection mode. A device lacking a lead may have plural electrodes on the housing thereof, as indicated at **64**, **66**, but may omit the header **68** for coupling to lead **70**. In one example, a leadless device may use a header to couple to an electrode support feature that is attached to or wraps around the device housing.

[0065] FIG. **3** shows an illustrative LCP design. The LCP **100** is shown as including several functional blocks including a communications module **102**, a pulse generator module **104**, an electrical sensing module **106**, and a mechanical sensing module **108**. In some examples, the electrical sensing module **106** and mechanical sensing module **108** may be configured to sense a biological signal for use in assessing CRT efficacy.

[0066] A processing module **110** may receive data from and generate commands for outputs by the other modules **102**, **104**, **106**, **108**. An energy storage module is highlighted at **112** and may take the form of a rechargeable or non-rechargeable battery, or a supercapacitor, or any other suitable element. Various details of the internal circuitry, which may include a microprocessor or a state-machine architecture, are further discussed in US PG Patent Publications 20150360036, titled SYSTEMS AND METHODS FOR RATE RESPONSIVE PACING WITH A LEADLESS CARDIAC PACEMAKER, 20150224320, titled MULTI-CHAMBER LEADLESS PACEMAKER SYSTEM WITH INTER-DEVICE COMMUNICATION, 20160089539, titled REFRACTORY AND BLANKING INTERVALS IN THE CONTEXT OF MULTI-SITE LEFT VENTRICULAR PACING, and 20160059025, titled, MEDICAL DEVICE WITH TRIGGERED BLANKING PERIOD, as well as other patent publications. Illustrative architectures may also resemble those found in the Micra™ (Medtronic) or Nanostim™ (St. Jude Medical) leadless pacemakers.

[0067] The device is shown with a first end electrode at **114** and a second end electrode at **116**. A number of tines **118** may extend from the device in several directions. The tines **118** may be used to secure the device in place within a heart chamber. Another attachment structure is shown at **120** and may take the form of a helical screw, if desired. In some examples, tines **118** are used as the only attachment features. Tissue attachment and retrieval features may be included in the LCP including those features shown in US PG Patent Publications 20150051610, titled LEADLESS CARDIAC PACEMAKER AND RETRIEVAL DEVICE, and 20150025612, titled SYSTEM AND METHODS FOR CHRONIC FIXATION OF MEDICAL DEVICES, the disclosures of which are incorporated herein by reference. Fixation and retrieval structures may instead resemble that of the Micra™ (Medtronic) or Nanostim™ (St. Jude Medical) leadless pacemakers.

[0068] FIG. **4** shows an overall method of use of a system. The method **200** in this case goes back, optionally, to pre-implant screening, as indicated at **210**. For example, the implantation of an SICD may occur following pre-implant screening for cardiac signal amplitude and/or signal to noise

ratio, and/or to determine whether the patient's routine cardiac rhythm will be well managed using an SICD. Some example screening tools, metrics and methods discussed in U.S. Pat. No. 8,079,959, titled PATIENT SCREENING TOOLS FOR IMPLANTABLE CARDIAC STIMULUS SYSTEMS, and/or US Patent Application PG Pub. No. 20160296131, titled AUTOMATED SCREENING METHODS AND APPARATUSES FOR IMPLANTABLE MEDICAL DEVICES, the disclosures of which are incorporated herein by reference.

[0069] Pre-implant screening may also determine whether the patient is well suited to have a combined LCP/SICD or LCP/SCM system for CRT by assessing the presence or absence of a P-wave. P-wave related screening may be optional with the present invention, as various examples rely on SICD or SCM analysis of the QRS complex (or other cardiac signal) to confirm fusion, rather than the appearance or timing of the P-wave, to enhance or control CRT to attain desirable fusion.

[0070] The system(s) are then implanted at **212**. Implantation may include the placement of an LCP on or in the heart, as well as placement of an SCM or SICD elsewhere in the patient such as between the ribs and the skin. The system may undergo intraoperative testing as is known in the art for each of LCP, SCM and SICD devices, to ensure adequate sensing configurations and/or therapy capability.

[0071] Next, the system undergoes initialization, at **220**. Initialization may include, for example, the setting of various sensing and other parameters. Examples of initialization may include selecting of a sensing vector or combination of sensing vectors, such as in U.S. Pat. No. 7,783,340, titled SYSTEMS AND METHODS FOR SENSING VECTOR SELECTION IN AN IMPLANTABLE MEDICAL DEVICE USING A POLYNOMIAL APPROACH, and U.S. Pat. No. 8,483,843 SENSING VECTOR SELECTION IN A CARDIAC STIMULUS DEVICE WITH POSTURAL ASSESSMENT, the disclosures of which are incorporated herein by reference. Related concepts surrounding the use of multiple vector sensing are also disclosed in US PG Patent Pub. Nos. 2017/0112399, 2017/0113040, 2017/0113050, and 2017/0113053, the disclosures of which are incorporated herein by reference. Methods as discussed in US PG Patent Pub. No. 2017/0156617, titled AUTOMATIC DETERMINATION AND SELECTION OF FILTERING IN A CARDIAC RHYTHM MANAGEMENT DEVICE, the disclosure of which is incorporated herein by reference, may be used as well for setting filtering characteristics.

[0072] Initialization for an LCP may also include the setting of parameters for therapy including, for example, selecting pace shape, pulsewidth and/or amplitude. If plural LCPs are included in a system, the relative timing between pace deliveries amongst the plural LCPs, and other suitable features, may be set as well. Initialization may also include identifying a P-R interval for the patient, which can be done and used as discussed below relative to FIG. 6.

[0073] Once initialization **220** is completed, normal operation can occur as indicated at **222**. Such operation may include CRT delivery in which a first device delivers pacing pulses for CRT purposes with the assistance of a second device such as an SICD or SCM.

[0074] FIGS. 5-8 show a number of illustrative approaches to pacing and pace timing for CRT in a multi-device implantable system. Such approaches are referred to herein as modes of pacing for CRT. Different modes use

different inputs or criteria for determining whether and/or when a pace therapy (a single pace impulse of a monophasic, biphasic, or other shape voltage or current controlled therapy output associated with a single cardiac cycle) is to be delivered. Any of the modes of pacing for CRT shown in FIGS. 5-8 may be used as a "normal operation" at **222** in FIG. 4, though different modes of pacing for CRT may have different initialization needs. Multiple pace therapies, as used herein, means multiple individual paces, as opposed to pacing via different configurations or for different purposes.

[0075] Some of the following examples call for each of an extracardiac device, such as an SICD or SCM, to provide information or commands to an implanted LCP such as an LCP placed in the left ventricle of a patient. Some examples instead call for the LCP to perform its own assessments to perform pacing as needed. The aim in several examples is to provide effective CRT. In keeping with the spirit of the present invention, other modes than those shown may be used.

[0076] FIG. 5 shows a mode in which an extracardiac device, such as an SICD or SCM, or a second implantable LCP, performs sensing for an atrial event **230**, detects the atrial event and communicates to the LCP at **232**. The LCP receive the communication and delivers pacing at **234**. The LCP may be located in the left ventricle. The communication may take the form of a command to pace, or may instead simply provide information such as a notification that an atrial event has been sensed.

[0077] The atrial event may be an electrical signal detection, such as a P-wave, or likely P-wave, has been detected. See, for example, U.S. patent application Ser. No. 15/633,517, titled CARDIAC THERAPY SYSTEM USING SUBCUTANEOUSLY SENSED P-WAVES FOR RESYNCHRONIZATION PACING MANAGEMENT, the disclosure of which is incorporated herein by reference, for examples using a second device to detect an atrial electrical signal for use in CRT pacing. The atrial event may be a mechanical event instead, indicating atrial contraction. See, for example, U.S. patent application Ser. No. 15/642,121, titled METHOD AND SYSTEM FOR DETERMINING AN ATRIAL CONTRACTION TIMING FIDUCIAL IN A LEADLESS CARDIAC PACEMAKER SYSTEM, the disclosure of which is incorporated herein by reference, for examples of the LCP or a second device detecting an atrial mechanical signal for use in CRT pacing. For example, the S4 heart sound, which indicates atrial contraction may be detected and relied upon. In another example the A-wave, a pressure wave indicating atrial contraction, may be detected and relied upon.

[0078] The electrical P-wave or other atrial event sensing may be difficult in some environment such as a noisy environment, or may be difficult in certain patients due to abnormal conduction, placement of sensing electrodes, etc. P-wave or other atrial event sensing may also be difficult if a patient has an atrial arrhythmia that prevents such sensing, for example, if a patient starts to experience atrial fibrillation. Patient movement and/or the patient's environment may affect the ability to sense a mechanical signal as well. Thus accommodations to adjust for any changes, as well as the capacity to identify a need for adjustments, may be useful.

[0079] FIG. 6 shows another illustrative example in which sensing is performed by an extracardiac device such as an SICD or SCM or by a second LCP, as indicated at **240**,

across an interval of time during which a pace therapy is then delivered at **242** by an LCP which may be a left ventricular LCP. The sensed signal from block **240** is then analyzed and adjustments may then be made to the interval used for pace timing at block **242**. For example, an interval from the pace therapy delivery to the R-wave, to the QRS complex, or from the P-wave to the pace therapy, may be calculated and/or assessed retrospectively to then make adjustments to tailor the desired timing. See U.S. patent application Ser. No. 15/684,366, titled INTEGRATED MULTI-DEVICE CARDIAC RESYNCHRONIZATION THERAPY USING P-WAVE TO PACE TIMING, the disclosure of which is incorporated herein by reference, for retrospective analysis of such features. Rather than an electrical signal analysis, the sensing at **240** may use mechanical sensors (an accelerometer, or pressure sensor for example) to find the timing of an atrial mechanical event.

[0080] FIG. 7 shows another illustrative example of a pace timing mode. Here, an LCP senses an atrial event at **250** and delivers pacing using a trigger sensed by the LCP itself, as indicated at **252**. A second device, such as a second LCP or an extracardiac device such as an SICD or SCM then analyzes the signals and calculates adjustments as indicated at **254**. For example, the second device may reference an electrical signal (cardiac electrical signal), a mechanical signal (motion or pressure/sound sensor), or a physiological measure (pulse oxygenation) to perform analysis, and the analysis may include measuring outcomes (fusion morphology, or desired amount of motion or pressure change, volume change, or sounds) or parameters (the P-wave to Pace or Pace to R-wave duration, for example). In some alternative examples, the device that paces at **252** may also perform the analysis and adjustments at **254**.

[0081] FIG. 8 shows an example in which the LCP senses an atrial event, either using mechanical or electrical signals, as indicated at **260**. In response, the same LCP delivers a pace therapy at a time selected relative to the atrial event, as indicated at **262**. For example, the LCP may rely on a heart sound (such as showing valve opening or closing in response to an atrial motion), a pressure waveform (such as a change in pressure based on atrial contraction), an electrical cardiac signal (such as sensing a P-wave), a motion signal (such as sensing movement caused by atrial contraction), an impedance measurement (such as sensing a change in impedance cause by a change in cardiac volume), or an optical signal (such as sensing blood motion due to atrial contraction).

[0082] FIG. 9 highlights certain features of a cardiac electrical signal. A far field representation (that is, a signal captured using only electrodes that are neither in nor on the heart) is shown with trace **300**. The trace **300** is marked using standard convention with the P-wave, R-wave (which, when combined with preceding Q-wave and following S-wave may be referred to as the QRS complex), and later T-wave. The P-wave represents atrial depolarization associated with atrial contraction to load the ventricles, the R-wave or QRS complex (the unmarked downward deflections) represents ventricular depolarization of the ventricles contracting to pump blood to the body and lungs, and the T-wave is associated with the electrical activity that repolarizes the ventricular muscle in preparation for a next beat. With heart failure and/or dysynchrony, the timing of these individual events may be anomalous or abnormal, and the shape of depolarization waves can be different from that

shown, for example, by having a much wider QRS complex or R-wave as the left and right ventricles depolarize in a poorly coordinated manner.

[0083] With traditional CRT systems having transvenous leads, the intracardiac electrodes are placed to detect the atrial depolarization while also delivering resynchronizing pacing therapy to one or both ventricles. As a result, the circuitry of a single device would directly receive information for the P-wave, allowing delivery at a timed interval of a pacing pulse to the ventricle. This can be done to achieve fusion—synchrony of the electrical signals arriving in the ventricles, to resynchronize contractions and improve pumping efficiency. However, with a system as in FIG. 1, the LCP may be unable to identify the P-wave generated in the atria from an implanted location in the ventricle. Therefore the LCP, in several embodiments of the present invention, relies on a second medical device such as a subcutaneous cardiac monitor or SICD to determine whether and when the P-wave occurs.

[0084] The SICD (or subcutaneous cardiac monitor or other extracardiac device (ED)) may be optimized for detection of R-waves and/or QRS complexes, in order to ensure that deadly arrhythmias (ventricular fibrillation and/or polymorphic ventricular tachycardia) can be appropriately and quickly identified. P-waves may be detected using separate parameters and/or analysis from R-wave detection for such a device. In some examples, a time window for P-wave detection is defined during which the ED may specifically look for the P-wave. Such windows may be defined by analysis of the cardiac signals obtained from a patient using, for example, a ventricular event such as the R-wave/QRS complex or the T-wave as the starting point for timing delays **302**, **304** shown in FIG. 9. Durations **302**, **304** may be dynamic to adjust to the overall beat rate of the patient using data gathered from a patient or using a formula or accepted relationship.

[0085] The ED may use a dedicated sensing configuration to separately detect ventricular events and a second, separately defined dedicated sensing configuration to separately detect atrial events. For example, the Emblem™ S-ICD system performs vector selection to identify a sensing vector having optimal R-wave amplitude and signal to noise ratio as a default vector for sensing the patient's cardiac rhythm, as disclosed for example in U.S. Pat. No. 7,783,340, titled SYSTEMS AND METHODS FOR SENSING VECTOR SELECTION IN AN IMPLANTABLE MEDICAL DEVICE USING A POLYNOMIAL APPROACH, and U.S. Pat. No. 8,483,843 SENSING VECTOR SELECTION IN A CARDIAC STIMULUS DEVICE WITH POSTURAL ASSESSMENT, the disclosures of which are incorporated herein by reference. Related concepts are also disclosed in US PG Patent Pub. Nos. 2017/0112399, 2017/0113040, 2017/0113050, and 2017/0113053, the disclosures of which are incorporated herein by reference. In an example, a second vector selection and/or sensing configuration process may be used to determine how the P-wave will be detected by a given device.

[0086] In further examples, filtering, gain, or other characteristics may be selected specific to P-wave detection. For example, if a ventricular event sensing channel uses a first passband, a P-wave sensing channel passband may be set to a different passband. For example, the R-wave or ventricular event passband may be set in the range of 3-40 Hz, or 9-40 Hz, or other setting. The P-wave passband may be set to a

different range, for example, 0.5 to 20 Hz. Such band setting and selection may be partly contingent on reviewing the captured signal of either or both of ventricular and/or atrial events. Methods as discussed in US PG Patent Pub. No. 2017/0156617, titled AUTOMATIC DETERMINATION AND SELECTION OF FILTERING IN A CARDIAC RHYTHM MANAGEMENT DEVICE, the disclosure of which is incorporated herein by reference, may be used to select a sensing channel passband(s). In another example, a passband may be varied until signal amplitude for the desired atrial or ventricular feature begins to drop, at which an edge or corner of the passband may be set, to achieve a targeted, narrow passband. Thus a P-wave sensing or atrial sensing configuration may use a different frequency band than a corresponding R-wave sensing or ventricular event filter. Alternatively, a single passband may be set for use in each of atrial and ventricular sensing, or different pre-set ranges may be used for each of atrial and ventricular sensing.

[0087] Setting the sensing configuration for detecting P-waves may thus include either or both of setting a detection window and/or selecting filter or vector configurations. In addition, the actual manner of detecting the P-wave is defined in some illustrative examples as part of the sensing configuration. For example, the P-wave may be detected by comparing a detected signal to a fixed or time-varying amplitude threshold. In another example, the P-wave may be detected by comparing segments of captured signal to a template until a match is found or at timeout occurs. When a match is found a P-wave detection can be declared; if a timeout occurs, it may be concluded that the P-wave was not present or simply not seen. In some examples, more than one method of identifying P-waves may be available for use, and a most effective approach for a given patient may be selected. For example, if amplitude threshold and template match approaches to P-wave detection are available, a patient having highly variable amplitude signals may have his or her device configured to use the template match approach rather than an amplitude based approach.

[0088] In some examples, a possible P-wave is confirmed as such prior to generating an output communication. For example, a template of the P-wave may be defined and used to confirm whether a detected signal that crosses an amplitude threshold is in fact a P-wave by comparing the detected signal to the template. Such templates may be static and stored in memory, may be matched from one beat to the next by comparing a first in time P-wave to a next in time possible P-wave, or may be a hybrid of a stored template and fully dynamic template as by, for example, averaging in newly detected P-waves to a template.

[0089] In some examples, patients may be pre-screened for P-wave availability with the second medical device that is to be used for synchronizing LCP pacing. For example, it may well be that due to anatomical variations or other factors, some patients will have a well-defined P-wave providing a ready fiducial for the SICD or subcutaneous cardiac monitor to rely upon to prompt CRT therapy by an LCP. In other patients, the P-wave may be difficult to detect consistently. Thus a pre-screening process may be performed, either as an in-clinic test, or by having a patient use a Holter monitor or by implanting a subcutaneous cardiac monitor to ensure that the P-wave is readily identified consistently.

[0090] FIG. 10 illustrates setting of a P-wave detection window showing at least one of the above concepts in

action. Here, a trace is shown at **310** and includes the features indicated in FIG. 9 for two cardiac cycles. An R wave and QRS complex are identified at **312**. The device uses an interval **314** to then trigger a P-wave detection window **316** for identifying the P-wave **318** of the cardiac signal. As illustrated here, the P-wave detection window **316** is useful insofar as the P-wave is smaller than other cardiac features, but also occurs after a relatively quiet time period following the T-wave. The P-wave detection window **316** may alternatively be triggered from the T-wave **330**, using an interval **332**, if desired. The intervals based on T-wave or R-wave detection may start from an inflection point, a peak, a threshold crossing, or any other desired, preferably repeatable, fiducial point of the underlying T-wave or R-wave.

[0091] Detection of the P-wave **318** is used to trigger another interval **320**, after which a ventricular pace therapy is delivered at **322**. Interval **320** may be variable and is used to trigger the pace therapy to allow fusion—whereby the natural conduction signals of the heart reach one ventricle at about the same time as the pace therapy is delivered to the other ventricle, for example, to allow coordinated ventricular contraction.

[0092] In some examples, an ED detects the P-wave **318**, and the interval **320** is consumed, at least in part, by the time required to communicate to an LCP and trigger the LCP to deliver the pace **322**, such as discussed in U.S. patent application Ser. No. 15/633,517, titled CARDIAC THERAPY SYSTEM USING SUBCUTANEOUSLY SENSED P-WAVES FOR RESYNCHRONIZATION PACING MANAGEMENT, the disclosure of which is incorporated herein by reference.

[0093] In some examples, the LCP delivers the pace therapy **322** using a calculated interval relative to, for example, a prior delivered pace therapy or a prior detected fiducial such as the R-wave **312**, and the ED and/or LCP detect cardiac signal features such as the P-wave in order to manipulate the calculated interval to achieve a desired P-wave to Pace interval **320**. See U.S. patent application Ser. No. 15/684,366, titled INTEGRATED MULTI-DEVICE CARDIAC RESYNCHRONIZATION THERAPY USING P-WAVE TO PACE TIMING, the disclosure of which is incorporated herein by reference.

[0094] Looking closely at the drawing, the skilled artisan will appreciate that the unpaced QRS complex at **312** has a different morphology than the paced complex following pace therapy **322**, with the Q-wave deflection more pronounced, and the S-T interval having a different shape. Such changes can be monitored to determine whether pace therapy is having an intended effect, as explained in U.S. patent application Ser. No. 15/684,264, titled CARDIAC RESYNCHRONIZATION USING FUSION PROMOTION FOR TIMING MANAGEMENT, the disclosure of which is incorporated herein by reference. After the first pace therapy is delivered **322**, the method can shift to using a different interval, if desired, to trigger the start of the P-wave sensing window at **344**, using, for example, an interval from a prior P-wave window as indicated at **342**, or using an interval from the pace therapy **322**, or, alternatively, using the interval from the R-wave peak or T-wave peak as before.

[0095] FIGS. 11-12 show a use of a P-wave detection window. FIG. 11 shows a first example in which the trace **350** includes a paced complex **352** that is used to trigger an R-wave detection threshold **354** similar to that shown in U.S. Pat. No. 8,565,878, titled ACCURATE CARDIAC

EVENT DETECTION IN AN IMPLANTABLE CARDIAC STIMULUS DEVICE, the disclosure of which is incorporated herein by reference. It can be seen that this detection threshold 354 is configured to avoid detecting the T-wave (not marked) as well as the P-wave 364.

[0096] A P-wave detection window is provided at 360. A separate P-wave detection threshold 362 is defined within the P-wave detection window 360. The P-wave detection threshold 362 may be a flat threshold or it may vary with time, if desired. For example, a P-wave detection threshold 362 may be a percentage of the R-wave detection threshold 354.

[0097] FIG. 12 shows another example of P-wave detection. Here, a cardiac signal is shown at 370 with a P-wave detection window at 372. The signal in window 372 is expanded as shown at 372'. A P-wave template is shown at 374. To detect the P-wave, a series of comparisons are made as incoming signal is received. Once enough signal is received to perform a morphology comparison, such as by difference of area, correlation waveform analysis, wavelet transform, or principal components analysis, for example, a morphology comparison is made. The morphology comparison is repeated as indicated at 376 as more signal comes in, with data entering a comparison window on a first-in, first-out basis, until a match is found at 378. Match 248 is then the P-wave detection. In another example, indicated at 380, the correlation of the series of comparisons 376 can be mapped across the duration of the P-wave detection window 372, and the peak correlation may be identified to correspond to the time of the P-wave occurring.

[0098] In still further examples, a P-wave detection window 372 may be searched to identify a specific feature associated with a possible P-wave. For example, a P-wave may be identified by observing whether a slope in excess of a threshold and with a minimum pathlength occurs during the P-detection window.

[0099] FIG. 13 illustrates a method of configuring sensing in one or more devices. In the example method 400, initializing data is obtained as indicated at 402, and one or more sensing vectors are selected, as indicated at 420. Next, the detection parameters such as parameters for detecting P-waves or atrial events (P-Detect Parameters) are set, as indicated at 430. Generally speaking, steps 402, 420 and 430 may be performed by an SICD, SCM, or other ED, or by an LCP, as desired and based on which device, in a particular implementation, is to detect which of the R, P, or T waves and/or QRS complex.

[0100] The step of obtaining initializing data at 402 may include various subprocesses as indicated on the left side of FIG. 13. For example, as indicated at 404, a plurality of individual cardiac cycles may be detected at 406 in one or several sensing vectors or with one or several different sensing configurations (affecting for example, filtering and/or amplification parameters, possibly in combination with vector selection parameters). The individual detections of cardiac cycles may be analyzed 408 by, for example, binning different detected data elements from each cycle as discussed in U.S. Pat. No. 7,783,340, titled SYSTEMS AND METHODS FOR SENSING VECTOR SELECTION IN AN IMPLANTABLE MEDICAL DEVICE USING A POLYNOMIAL APPROACH. As an alternative shown at 410, a set of cardiac cycles are detected as indicated at 412 and a composite signal is generated as shown at 414. The use of a composite signal to establish sensing vector quality

metrics is discussed, for example, in US PG Patent Application Pub. No. 20170113053, titled SIGNAL QUALITY MONITORING FOR MULTIPLE SENSE VECTORS IN CARDIAC DEVICES, the disclosure of which is incorporated herein by reference.

[0101] Next, in block 420, sense vector configurations for ventricular (targeting, for example, R waves, the QRS complex, and/or T-waves) and/or atrial event detection (targeting, for example, the P-wave) are selected. The vector configuration may include selecting combinations of electrodes to use, combinations of two or more vectors to use together, and/or the setting of filtering, blanking, refractory, amplification or other parameters. Various approaches to vector selection may be used including those referenced above from other patents or patent applications, as well as those discussed herein. For example, consistency of a vector configuration may be used, as indicated at 422, to select a given vector. Consistency 422 may mean, for example, that a selected cardiac event (P, R or T waves, or the QRS complex) is consistent in shape, amplitude and/or timing, in a given vector configuration. Alternatively or in combination with consistency, strength 424 of the signal, absolute and/or relative to noise may be considered as well.

[0102] In some examples, once vector configuration is set, the parameters for identifying P-waves are set as indicated at 430. In an alternative, as indicated by the line at 440, the sensing configuration step may be bypassed, and P-Detect parameters set at 430. For example, block 420 may be performed in some embodiments only when connected to a clinician programmer to ensure that appropriate signals are obtained and/or that sensing configuration is not modified contrary to known patient history, while blocks 402 and 430 may be performed by a device independent of programmer intervention. In some examples, on the other hand, block 430 may be omitted, with the sensing vector setup performed and any suitable method of P-wave detection used by the device without necessarily performing a separate optimization at 430.

[0103] Block 430 calls for setting one or more parameters to optimize P-wave detection. In some examples, this may include selecting one or more of the fiducials from which P-wave detection is triggered, at 432, setting a window for detecting the P-wave 434, selecting the features to look for when attempting to detect a P-wave 436, or selecting a template for P-wave confirmation at 438. Any of blocks 432, 434, 436, 438 may be used in various combinations or, in some examples, standing alone.

[0104] For example, the fiducial selection at 432 may be used to select a feature (whether atrial or ventricular, such as an R-wave, a T-wave, a preceding P-wave, or other physiological, such as a heart sound, a blood pressure signal, or other timing point of reference such as delivery of a pacing pulse), that starts a blanking period during which P-waves cannot be detected, for example, to pass over the T-wave, and upon expiration of the blanking period, P-wave detection is enabled. Alternatively, the fiducial 432 may be used to trigger the initiation of an analysis window for the P-wave. The window 434 may be used as shown above in FIGS. 10-12 by, for example, determining relative to a selected fiducial point when the P-wave typically appears and then setting a window of a duration equal or longer than the P-wave for allowing P-wave detection. The window may be, for example, about 50 to 400 milliseconds. In another

example, the window may be about 100 to about 200 milliseconds. Other durations may be used.

[0105] Which features to use for identifying the P-wave is another element, as indicated at **436**. For example, a P-wave may be identified by having an amplitude of a certain range, such as greater than a threshold. A threshold may be adaptive to current patient conditions by, for example, setting it to some percentage (50% to 90%, or more or less) of a preceding P-wave or an average of several preceding P-waves, or stored information relating to typical P-waves generally or specific to a given patient. Other features may include a maximum or minimum slope amplitude or length. In an example, the P-wave may be identified by the detected signal moving in a certain direction within predefined slope parameters for at least a predetermined amplitude or period of time. Thus, for example, the signal may have an upward slope that is characteristic of the P-wave, not so steep as for the R-wave, but steeper than the T-wave, of at least a select duration to avoid noise detection. Slope analysis may take place by using the first or second derivative of the obtained signal. Other features may be used instead at block **436**.

[0106] The template **438** may also be used independent of other items to detect a P-wave. For example, the template may be compared to received data on a continuous or semi-continuous basis, and when a match is found, a P-wave may be declared (see FIG. 12, above). Alternatively, a series of comparison results may be compared to select a peak correlation. The template may be an averaged composite of prior signals, or may be simply a prior P-wave, or may be constructed in any other suitable manner. The incoming signal itself may be a signal averaged composite of several cardiac cycles having, for example, P, Q, R and S signals (and T-waves if the composite is so configured).

[0107] In an example, during a window defined using **434** based on a fiducial **432**, a template may be compared to an incoming data stream to identify a match. In other examples, the template **438** may be used to confirm a detected likely P-wave, such as a signal that crosses a defined amplitude threshold during a P-wave detection window. If the template **438** matches the likely P-wave, then P-wave detection is confirmed or, alternatively, if there is no match to the template **438**, then the threshold crossing/detection may be discarded as not being a P-wave.

[0108] FIG. 14 illustrates a method for setting templates in an illustrative example. The example includes an iterative process for generating related templates indicated at **500**, as well as a pace and record process **510**. In the illustration, a template formation block **502** is called and activates the pace/record block **510**. To form the template, one or several pace outputs **512** are generated, and an associated signal is recorded **514**. The associated signal **514** may take a variety of forms such as those indicated below in FIG. 18, including cardiac electrical, sound, pressure, motion, impedance and/or optical signals.

[0109] In one example, a single pace output is generated at block **512** and the resulting signal is recorded at **514**. In other examples, a number of pacing outputs are generated using what are considered “optimal” parameters to achieve desired outcomes, and several resulting signals are recorded at block **514** and averaged together to yield a template. If desired, statistics may be calculated associated with the template to provide indications of a range of variation that is expected. In some examples, the template may be validated by comparing several outputs to ensure similarity of

the recorded signal over each of several pace outputs; if the recorded signal at **514** varies without variation of the pacing parameters, the template is likely of little use, as it may be unable to distinguish variation due to changing pacing parameters from variation occurring within desired pacing parameters, and such a template may be discarded, generating an error message. If a template cannot be validated for a given signal type, the system may elect to use a different signal type, such as by switching from use of a motion signal to a heart sound.

[0110] Once a given template is formed at block **502**, the process **500** repeats at a new offset **504**. In some examples, a fixed offset shifting the pace therapy earlier or later in time may be used, such as by shifting 20 milliseconds in each direction around a preferred, non-offset pace timing. In some examples, a plurality of offsets may be tried, such as by adjusting in modest increments (such as by offsetting 5 milliseconds a number of times) until a template is formed that does not match the first-formed template. In some examples a one-sided approach is used by delivering the pace therapy earlier in time, or later in time, than the preferred configuration, without forming a second template. In other examples, three total templates are formed—a preferred configuration template, an early template representing an outcome that would occur if pace therapy is too early to yield a desired outcome, and a late template representing an outcome that would occur if pace therapy is delivered too late to yield a desired outcome. In still other examples, more than three templates may be formed.

[0111] When process **500** is done **506**, the results may optionally be stored in association with a specific context. The process **500** can then be repeated for a plurality of different contexts as indicated at **520**. By context, what is meant is that the device is operating in a specific physical or other circumstance that may affect the usefulness of a particular template or set of templates. For example, a given sensor output may vary in response to one or more of posture **522**, activity level **524**, time of day **526**, and/or the underlying cardiac rate **528**. As specific examples, cardiac impedance metrics may vary with patient posture **522**, and motion signals can vary with patient activity level, while pressure metrics may be affected by time of day **526**, and/or cardiac electrical metrics, including those reliant on intervals between peaks or other events, may be affected by the underlying cardiac rate **528**. Changes in patient activity may be determined by monitoring outputs of a motion sensor using known methods; changes in cardiac activity may also be determined using a temperature sensor in the patient's bloodstream, if desired; such changes may be determined or confirmed as well using the patient's intrinsic cardiac rate which may be determined by stopping CRT delivery for a number of cardiac cycles from time to time. An accelerometer output may be monitored using known methods to determine patient posture and/or changes in patient posture. The time of day may be determined from a system clock. The patient's cardiac rate may be determined using R-wave detection or other rate measurement methods such as disclosed in U.S. Pat. No. 8,565,878 and/or US PG Patent Publication Nos. 20160045136, 20160045132, and 20160045131, the disclosures of which are incorporated herein by reference as showing one or more of rate calculation and/or cardiac cycle detection.

[0112] Optionally, the process at **500** may be repeated for a plurality of different contexts **520** as those are detected or

identified. If desired, a set of contexts may be actively induced such as by having the patient change posture while template steps **500** are performed, or having the patient exercise to achieve activity **524** or rate **528** changes.

[0113] Rather than a template being formed in block **502**, target measurements or value boundaries may be gathered in another example. For example, target peak amplitudes, slopes or magnitudes, widths, maxima, minima, or intervals between detected events of similar or dissimilar types may be captured in the record step **514**. Such targets may be developed in similar fashion to that shown, with different offsets tested to establish boundaries between desirable outcomes, undesirable outcomes, and outcomes that are not within a captured range. FIG. **27** shows an example. When value boundaries are gathered, different value boundaries may be determined for different contexts as indicated at block **520**.

[0114] FIGS. **15-16** show methods of monitoring pacing outcomes and enhancing P-wave detection. The illustrative method **550** begins with sensing a P-wave, as indicated at **552**. Block **552** may be performed by an extracardiac device (ED) or by an LCP in various different examples, and the P-wave may be sensed using an electrical waveform (electrocardiogram or cardiac electrogram), for example as in U.S. patent application Ser. No. 15/633,517, or by use of a mechanical sensor as in U.S. patent application Ser. Nos. 15/642,121, 15/625,655, 15/646,999, 15/654,393, 15/635,921, and/or 15/630,677, the disclosures of which are incorporated herein by reference.

[0115] A pace output is generated at **554** by the LCP, and a sense and compare step **556** follows. The sensing may be of any of the signal types noted below in FIG. **18**, and may be performed by the LCP or the ED. In several embodiments, the LCP performs sensing using an intracardiac sensor circuit or circuits for one or more of sound, pressure, impedance, motion, or optical changes, or, alternatively, using a sensed cardiac electrical signal. Comparison is performed relative to a template. The template is described at **558** as a preferred template, meaning that the template used in block **556** may be a template for the sensed signal representing a preferred pacing outcome, such as a fusion beat. The comparison step is preferably performed by the same device that performs the sensing, though in some examples, a sensed signal may be communicated out to a second device that stores the templates and performs comparisons.

[0116] If block **556** yields a match **560**, the method iterates back to block **552**, as the system can conclude based on template matching that the pace therapy successfully caused a desirable cardiac outcome. If instead there is no match, the method proceeds via block **570** to compare to one or more other templates at **572**. Here the one or more "other" templates may correspond to identified outcomes generated at known offsets from an ideal pace timing. If block **572** yields no match, this suggests that neither the preferred outcome, nor identified alternative/offset outcomes have taken place, and re-initialization should be considered as indicated at **582**.

[0117] For example, re-initialization may occur after a predetermined quantity of pacing therapies end up with no match at **580**, such as if pacing fails to yield any matches for 1, 2, 5, 10, or up to 100, or more consecutive therapy cycles, or if a threshold quantity or percentage of therapy deliveries end at block **580** over a period of time. Re-initialization may

comprise interrupting pace therapy delivery to observe one or more intrinsic cardiac cycles to develop new timing criteria for use in the device. Pace therapy is then delivered using the data from the intrinsic cardiac cycles and the template formation steps shown above relative to FIG. **14** may be performed again. Re-initialization may also include issuing an alert to the patient and/or a physician, such as by use of a home monitoring apparatus or a mobile device or programmer to communicate with the implanted system, suggesting that re-initialization be observed in-clinic or otherwise checked for validity.

[0118] For some examples, re-initialization may be performed after first making other adjustments, such as increasing a pacing therapy output amplitude and/or pulse width, to ensure that the failure to match expected CRT parameters is not a result of delivering too little energy with a pacing therapy output. For example, lack of capture due to inadequate pacing amplitude and/or pulsewidth may cause the resulting heart beat to mismatch applied parameters. Pace threshold measurement, such as a pace capture optimization, may be performed prior to re-initialization triggering, if desired.

[0119] For examples that obtain context information during template formation, a conclusion of no match **580** may trigger assessment of context **584** such as by determining whether context has changed with a new patient posture, activity level, time of day, or rate. In other examples, the preferred templates **558** and other templates used in block **572** may be updated using context **584** such as by selecting different templates in response to a change in patient posture, activity level, cardiac rate, or time of day, or other contextual information.

[0120] If there is a match at block **572**, then the system takes a step to implement an offset in the P-sensing block **552** by artificially moving the "P-sense" forward or backward in time to adjust pace timing. One difficulty with such an approach is that it may not address uncertainty in P-wave sensing as well as an actual modification of P-wave sensing itself. Thus a method as in FIG. **16** may be used instead.

[0121] FIG. **16** shows another example. P-wave sensing is performed at block **602**, with pacing delivery at **604**, followed by sensing and comparison to a preferred outcome template **606**. If a match **608** is found, the method returns to **602**. If no match is found **610**, comparisons are made to other templates at **612**; if there is no match **626**, either re-initialization **624** and/or context **628** may be considered. In these respects, the method of FIG. **16** is similar to that of FIG. **15**.

[0122] However, if there is a match **614** to one of the "other" templates in the comparison at **612**, an additional sequence occurs. The system reassesses the P-wave sensing data at **616**. In particular, given the match to an offset template in block **612**, the reassessment at **616** is performed to determine whether signal(s) analyzed to sense a P-wave include a "peak" or other indication that a P-wave may have occurred but was not identified. The aim in block **616** is to determine if there is a P-wave signal that could have been missed which would accord with the offset of the matching template.

[0123] For example, an offset template used in block **612** may correspond to delivering the pace therapy 20 milliseconds earlier than desired; if there is a P-wave peak about 20 milliseconds after the detected P-wave, then an adjustment can be made to one or more settings to ensure that the

P-wave will be detected more accurately for a subsequent cardiac cycle. For example, in FIGS. 21-25, below, there are various illustrations of a P-wave signal, or a correlation signal generated from a P-wave signal, where multiple peaks, each possibly representing a P-wave, can be found. In addition, FIG. 26 shows certain illustrative adjustments that may be performed to enhance P-wave detection accuracy.

[0124] If the re-assessment 616 finds a P-wave at a time corresponding to the timing of the offset template match, this is treated as confirmation 618 of the offset template, and an adjustment 620 to P-wave sensing is made before returning to block 602. Such and adjustment 620 may be performed to accommodate the knowledge that current P-wave sensing method is not resulting in a preferred pace outcome. If the reassessment at 616 cannot confirm the offset, this is treated as a no match 622, and the method again looks at context 628 and/or re-initialization.

[0125] FIG. 17 shows an example allocating certain functions among a multi-device system. A pacing protocol is followed in this example as shown at 640. A first device 650 detects the P-wave 642 and issues a message to a second device 660, which receives the message 644 and then delivers a pace output 646 using the received message. The pace protocol may be as in any of U.S. patent application Ser. Nos. 15/633,517, 15/684,366, and/or 15/710,118, the disclosures of which are incorporated herein by reference. For example, Device 1 650 may be an extracardiac device (ED) such as an SICD or SCM, and Device 2 may be an LCP. Device 1 650 may alternatively be an LCP or an intracardiac sensor device placed to capture atrial signals.

[0126] Meanwhile, one, the other, or both devices 650, 660 may be performing additional sensing and analysis to monitor pacing efficacy. For example, sensing 652, analysis 654, and adjustments 656 may be generated by Device 1 650 by the use of methods and other examples shown in U.S. patent application Ser. No. 15/684,264, titled CARDIAC RESYNCHRONIZATION USING FUSION PROMOTION FOR TIMING MANAGEMENT, the disclosure of which is incorporated herein by reference. In various examples, however, the LCP operating as Device 2 performs one or more of sensing 662, analysis 664, and observation of context 666, communicated back to Device 1 650 for generating adjustments 656. In some examples, Device 2 660 performs sensing 662 and communicates sensing outputs for analysis 652 in Device 1 650. In other examples, Device 2 performs sensing 662 and analysis 664 to determine template matching using context 664, while Device 1 performs further analysis 654 to observe P-wave sensing data and confirm an offset, as in block 616 in FIG. 16, above. Re-initialization 658 may be triggered by either device citing persistent system difficulty obtaining indicia of desirable pacing output.

[0127] FIG. 18 illustrates a number of signal types useful in various examples. The signals can be used to verify pacing efficacy and may range from cardiac electrical signals 710 to an array of physiological markers, as well as combinations thereof, any of which may be viewed as biological signals useful in providing and/or assessing CRT. For example, CRT assessment 700 may be performed by analyzing QRS morphology 712 using for example feature analysis (shape features such as turning points, area under a curve, etc.) and/or template matching. Additionally or alternatively, CRT assessment 700 may be performed by analyzing Q-wave, R-wave, and/or T-wave amplitude, or by

relative comparison among different amplitudes, as indicated at 714. Additionally or alternatively, CRT assessment 700 may be performed by analyzing various intervals or segments of cardiac signal data such as by observing the PR interval, the QR interval, the ST interval, or other feature, as indicated at 716. Additionally or alternatively, CRT assessment 700 may include analysis of R-wave width and/or QRS width, as indicated at 718.

[0128] Physiological markers 730 may be used as well. For example, CRT assessment 700 may analyze heart sound timing, amplitude, and/or shape, as indicated at 732. Additionally or alternatively, CRT assessment 700 may include analysis of a pressure signal such as an intracardiac pressure, using for example, maximum or minimum pressure, slope of changes in pressure, a difference between minimum and maximum pressure, and/or shape. Additionally or alternatively, CRT assessment 700 may include analysis of a motion sensor output such as using a motion sensor attached to a portion of the heart as part of an LCP, or a motion sensor placed outside of the heart on an ED, and observing, for example, amplitude of the output signal, changes in the output signal, turning points in the output signal relative to time, and/or shape of the output signal of the sensor, as indicated at 736. Additionally or alternatively, CRT assessment 700 may include measurement of impedance 738 which may be determined as described in U.S. patent application Ser. Nos. 15/654,261, and 15/630,677, for example, the disclosures of which are incorporated herein by reference. Additionally or alternatively, CRT assessment 700 may include analysis of the output of one or more optical sensors, which may be used to generate cardiac timing features or pressure surrogates by, for example, observing reflected signals from blood flow; times of increased and decreased blood flow suggest various events in the cardiac cycle.

[0129] The various inputs for CRT assessment 700 can also be used in various combinations. For example, interval analysis can be useful to determine whether synchronization of cardiac contraction is occurring in a desirable manner. An interval from an R-wave onset or peak to the heart sound S1 is an example. Another example may be the interval from a Q-wave onset or peak to heart sound S2. Combinations may also take into account the timing of CRT pace delivery to various events. For example, the period from a pacing output to a motion signal indicating ventricular contraction, or to heart sound S1 indicating AV valve closure, may be observed.

[0130] In several embodiments, the LCP is configured to provide the inputs for CRT Assessment. For example, an LCP may be well placed to observe one or more of heart sounds 732, intracardiac pressure 734, motion 736, cardiac impedance 738, and/or optically observed blood flow 740. The LCP may also be used to detect one or more parts of the cardiac electrical signal 710. For example, an LCP may include a sensor for detecting one or the other of heart sounds and intracardiac pressure (the difference between a pressure signal and a sound signal being largely one of frequency), an accelerometer to obtain cardiac motion and/or overall motion indicating, for example, changes in patient posture or activity level, one or more optical sensors such as an optical device outputting an optical signal and determining reflectance thereof, and/or a sensor(s) to detect cardiac impedance as in U.S. patent application Ser. Nos. 15/654, 261, and 15/630,677, for example, the disclosures of which

are incorporated herein by reference. In a further embodiment, a motion signal may be used to determine cardiac contractility and to make adjustments as needed.

[0131] Alternatively, the ED, or both the ED and the LCP, may observe any of the noted features. For example, an ED with a lead implanted subinternally (such as in US PG Patent Pub. No. 2017/0021159, titled SUBSTERNAL PLACEMENT OF A PACING OR DEFIBRILLATING ELECTRODE) and/or in the internal thoracic vein (such as in U.S. patent application Ser. No. 15/667,167, titled IMPLANTATION OF AN ACTIVE MEDICAL DEVICE USING THE INTERNAL THORACIC VASCULATURE), may be positioned to capture heart sounds and/or cardiac motion. A subcutaneous lead and/or canister may also detect heart sounds, or other features noted in FIG. 16. Placement of a lead in the internal thoracic vein and/or in an artery if desired may allow observation of blood flow characteristics and/or pressure. A lead crossing a portion of the thorax may be useful to observe transthoracic impedance and/or volume and changes thereof.

[0132] For example, a transthoracic impedance may be monitored as a measure of heart failure status; gradual changes over time may indicate that fluid is accumulating, suggesting that pace timing may need review. In an example, a method as shown in FIG. 15 may be used to establish a new offset of the overall timing algorithm in response to a change in fluid status. Changes may be monitored over a period of time by, for example, having the “change” limited in a manner such as shown below in FIG. 25, where the change is from a measurement from a prior time period, such as one to ten minutes prior to a current measurement. If the change exceeds a preset threshold (which may not be based on measurement but instead is set, if desired, by the physician or system in advance), it may be supposed that fluid is accumulating and an offset to either reduce or increase the pacing interval can be invoked. Continued monitoring may reveal whether the change had an impact; if so, the offset would be retained; if not, the offset may be reversed and a new offset, in the other direction this time, invoked.

[0133] In another example, an offset maybe introduced using a method as in FIG. 15 by monitoring for respiratory signals and making a change if a respiratory sinus arrhythmia is identified. Respiratory signals may be observed for example by detecting using an ED for muscle signals emanating near the diaphragm and/or by monitoring for transthoracic impedance changes and/or by observing motion signals related to diaphragm motion.

[0134] In some examples, multiple different cardiac electrical and/or physiological signals may be monitored in several layers. For example, a signal maybe monitored using a method as in FIG. 15 to induce offsets of a few milliseconds one way or another to attempt to maintain a desired CRT result, meanwhile, a method as shown in FIG. 16 may be used as well to monitor for errors in P-wave sensing.

[0135] FIGS. 19-20 illustrate physiological signal templates for illustrative examples. For these examples, a heart sound has been selected as a demonstration exhibit. Other features may be used in like fashion, such as a template of the pressure waveform, a different heart sound, a template of cardiac motion from an accelerometer, a captured cardiac electrogram template from an LCP or a captured electrocardiogram from an extracardiac device, an optical interrogation/reflectance waveform representing the intensity of

reflected light relative to time during a portion or all of the cardiac cycle, or other waveforms/signals noted above.

[0136] Referring to FIG. 19, three separate templates are shown at 750. In a first example, as indicated at 752, the AV Delay is too long, that is, the period from the actual atrial activation to a pace therapy delivery is longer than desired, such that resultant cardiac contraction resembles a native beat rather than a fusion beat. In one example, an outcome template may be generated using a heart sound sensor. A heart sound, S1 (indicating AV valve closure) is captured, and has a specific shape as shown at 754. When AV Delay is within a desired range, as indicated at 756, the S1 signal provides a different template as shown at 758. Finally, when AV Delay is too short 760, the resulting cardiac contraction would resemble a paced beat for the heart failure patient and provides a still different template as indicated at 762.

[0137] In use, a tiered approach as shown above in FIGS. 15-16 may compare a captured heart sound following delivery of a pace therapy to the desired template 758 and, if there is a match, then it is concluded that pacing was delivered as desired; if no match takes place, the captured heart sound can then be compared to one, the other, or both of the other templates 754, 762. In an alternative approach, the captured heart sound may be compared to each of the templates 754, 758, 762 and the system concludes that whichever best matches (preferably within or above a preset boundary of minimum degree of match) the captured heart sound is indicative of the quality of the pace therapy.

[0138] FIG. 20 is similar to FIG. 19. Three separate templates are shown at 770, this time characterized by the offset of each from nominal or desired pacing parameters. As indicated at 772, when a pacing pulse is delivered at an interval 20 milliseconds longer than nominal P-wave to Pace delay, a first template is captured as shown at 774. When pacing is delivered at the nominal delay, as indicated at 776, a second “desired” template is formed as shown at 778. Finally, when pacing is delivered at an interval that is 20 milliseconds less than the nominal P-wave to Pace delay, as indicated at 780, a third template is captured as shown at 782. The “Nominal” delay may be in the range of 100 milliseconds, for example, though the nominal setting may vary by patient or due to other factors such as specifics of system design.

[0139] In an alternative example, rather than using a set time period as the basis for defining separate templates, a system approach may be to first form the nominal template. Next, the AV delay can be adjusted in small increments to capture new signals for comparison to the nominal template 778, until a “no match” threshold is crossed—that is, until the newly captured signal no longer matches the nominal within predetermined bounds. Then a new template may be formed at the offset from nominal (or at a larger offset up to, for example, twice the offset that generates the no-match signal) used to obtain the non-matching signal. The process may be repeated to generate a template on either side (both longer and shorter) than the nominal setting. Such a process may be used to generate templates as characterized in FIG. 19, for example.

[0140] FIGS. 21-23 show examples of P-wave detection methods and issues that can arise in each leading to misdetection of the P-wave. Referring first to FIG. 21, a P-wave template 800 is established by finding a P-wave peak 802 in a trace 804, and establishing a window 806 for the template comprising a segment of the trace/signal 804 including the

peak **802**. In order to identify a P-wave in a detected signal **810**, a window for the signal **812** is defined at **814**. The template **800** is then repeatedly compared using correlation or difference of area, or other comparison technique, to portions of the signal **812** to yield a series of comparisons. In FIG. **21** the analysis result is shown as correlation **820**, mapped at **822** for illustrative purposes. Peaks **824** and **826** represent points in time where the detected signal **810** was relatively more similar to the template **800** than at other points in time. To identify the P-wave, then, one of the peaks **824** may be selected. The first in time peak **824** may be selected or the largest peak **826** may be selected, for example. A match threshold may be set instead, if desired, as shown at **828** and/or **830**, for example.

[0141] For illustrative purposes, an interval **832** between the correlation peaks **824**, **826**. In the above examples where an offset template matches a detected response signal, this interval **832** may be used to determine whether there is an alternative P-wave detection available to the system. For example, if the system were to identify peak **824** as the P-wave and pace using peak **824** as a timing reference or fiducial, and if analysis as shown above in FIG. **16** is performed and the desired template fails to match, then offset templates would be considered. If an offset template matches a captured signal, the P-wave re-assessment would analyze where a non-selected P-wave peak, such as peak **826**, occurs at a point in time corresponding to the offset of the offset template that matches. To be more particular, assuming an offset template matches a captured signal (block **614** in FIG. **16**), and the offset corresponds to pace delivery at an AV delay 20 milliseconds shorter than nominal, then if peak **824** was identified as the P-wave, the system would respond by making an adjustment to select peak **826** instead, such as by shifting from using a match threshold **828** to match threshold **830**.

[0142] Rather than shifting the template through the entire incoming signal, the incoming signal may be analyzed to identify peaks in the signal and comparing the template to the peaks, reducing the number of calculations. In such an approach, a match may be declared if the correlation exceeds a match threshold.

[0143] FIGS. **22-23** show an alternative to FIG. **21**. Referring to FIG. **22**, the cardiac electrical signal is shown at **900**, with possible P-wave peaks at **902** and again at **904**. If a detection threshold as shown at **906** is used, then the system will detect peak **902** as a P-wave, assuming the first peak to cross the threshold **906** is deemed the P-wave. For subsequent analysis purposes (such as a reassessment in block **616** in FIG. **16**), the data may be stored to show that another peak appears and relates to another threshold crossing at **904**, with an interval between the threshold crossings as shown at **910**. The interval **910** may be used to confirm whether there is a possible P-wave in the signal **900** at an interval corresponding to a matching offset template, should there be one.

[0144] FIG. **23** is similar to FIG. **22**, with the signal at **920** and peaks at **922**, **924**. Here, the detection threshold **926** passes over the first peak **922** but not the second **924**. Again, interval **930** may be tracked for use in reassessment (such as reassessment in block **616** of FIG. **16**).

[0145] FIG. **24** shows a number of adjustments that may be made in response to a determination that P-wave sensing has encountered a difficulty. Adjustments may be used in block **620** of FIG. **16**, for example. The adjustments **950** as shown as including, for example, modifying match criteria

954. Such an adjustment may be performed to accommodate the knowledge that the current P-wave sensing method is not resulting in a preferred pace outcome. Here, for example, a match threshold used to determine whether a P-wave template matches an incoming signal, such as shown in FIG. **21** with thresholds **828**, **830**.

[0146] Another adjustment **950** may comprise picking an “Nth” peak **956** or changing which of a set of peaks are to be identified as the P-wave. That is, a system may be set up to detect peaks in the cardiac electrical signal in a P-wave window, such as signal peaks exceeding a set threshold (a preset amplitude for example) or a variable threshold (a multiple of the RMS voltage of the incoming signal, or a fraction of an R-wave detection threshold). The 1st such peak may be selected or, if desired or adjusted to do so, a 2nd, 3rd or other “Nth” peak may be selected.

[0147] Another adjustment **950** may comprise changing a P-wave detection threshold **958** to raise or lower the required amplitude. A fixed threshold as shown in FIGS. **22-23** may be used, or the threshold may vary such as by setting a P-wave detection threshold as a fraction of an R-wave detection threshold. The adjustment in block **958** may include modifying the percentage used, or the absolute amplitude, or other parameter as desired.

[0148] Another adjustment **950** may comprise changing the P-wave template **960**. For example, a system may store multiple P-wave templates for use in different contexts (as noted above in FIGS. **14-16**, for example). A change in context, or identification of P-wave sensing difficulty, can be used to prompt selection of a different P-wave template. The change in template may comprise changing the window of signal used for a template to expand the window or narrow the window.

[0149] Match criteria, thresholds and templates may be applied to P-wave indicia. As used herein, P-wave indicia may be, for example, a detected cardiac electrical signal, across an entire cardiac cycle or in a window selected to focus on the likely time of the P-wave. P-wave indicia may instead be a series of correlation results calculated over time as a P-wave template is compared to a sensed cardiac electrical signal, either over a large portion of the cardiac cycle or across a window selected to encompass P-wave occurrence. Thus P-wave indicia may be direct representations of the electrical P-wave, or may be a secondary function developed from the electrical signal.

[0150] Another adjustment **950** may comprise making a change to a tracking method **962**. For example, U.S. Pat. No. 8,332,034, the disclosure of which is incorporated herein by reference, discusses the use of heart sounds in assessing the mechanical action of a subject's heart, and discloses a heart sound recognition circuit that is configured to recognize heart sounds in a reliable and consistent manner. For example, in the U.S. Pat. No. 8,332,034 patent, a heart sound may be identified by tracking both the peak energy as well as a previously detected heart sound to establish the occurrence of the desired heart sound among several heart sound peaks. To apply this concept to the P-wave detection, a dynamic tracking method detects the most consistent and largest—or otherwise selected—peak in the underlying P-wave indicia. For example, a dynamic tracking method adapted from U.S. Pat. No. 8,332,034 can be used by initially identifying a P-wave using a first rule, such as maximum peak amplitude. As additional cardiac cycle data is captured, and as feedback from a pacing analysis method

as shown above is captured, adjustments can be made to better select a peak occurring within a selected window, or with selected rules being met. A Viterbi method approach may be taken by initially selecting a peak from a plurality of available peaks in a P-wave indicia, and applying dynamic tracking to repeatedly obtain the same peak. Using such a dynamic tracking method, the goal is not necessarily to get the exact “P-wave”, but instead to attain a P-wave detection outcome that allows for reliable CRT timing.

[0151] An adjustment 950 may be made by flagging an incorrect outcome and restarting the analysis for dynamic tracking 962 using a “more correct” peak in the P-wave indicia, and tracking to the newly selected peak. Dynamic tracking 962 may include setting, during initialization (referring briefly to FIG. 13) using fiducials 432, a window 434, specific set features 436, and/or a template 438, as by selecting a fiducial (a threshold crossing, inflection point, turning point, etc.) based on a feature (such as a rising edge) generated by comparing a template to a received signal within a window, for example. Adjustment to the dynamic tracking 962 may further specify one or more of the fiducial, window, feature, and/or template, such as by observing a peak rather than an inflection point, or observing an N+1 peak rather than an Nth peak. Thus the adjustment may be to select a different feature of the same type (selecting a different peak amongst a set of peaks), or by selecting a different feature type entirely (an inflection point rather than a peak, for example).

[0152] FIG. 25 shows an example using value boundaries rather than templates. In this example, a P-wave is sensed at block 1000 and used in one form or another to assist with managing a pace delivery 1002. A signal, such as one of the signals in FIG. 18, above, is sensed and compared 1004 to one or more preferred values 1006. In this example, device context 1008 may be used to select the one or more preferred values 1006. If the sensed signal matches 1010 the preferred values 1006, the system returns to the P-sense block 1000 for a next iteration of the method.

[0153] If the sensed signal does not match 1020 when checked at block 1004, the system next compares the sensed signal to one or more other parameters, such as a set of value boundaries 1024. The value boundaries 1024 may be set similar to how the templates are formed above. For example, the value boundaries may be set by increasing the CRT pacing interval by a set amount and measuring a sensed signal parameter, and then decreasing the CRT pacing interval by a set amount and re-measuring the sensed signal parameter to obtain high and low boundaries for the sensed signal parameter. The sensed signal parameter may be, for example, an interval between two cardiac electrical events, between two mechanical events (heart sound, motion, pressure, optical parameter peak, for example) of the same or different types, or between a cardiac electrical event and a mechanical event, between two impedance events (such as a measured maximum or minimum impedance), or an impedance event and a mechanical or cardiac electrical event. The sensed parameter may instead be, for example, a motion or heart sound peak, minimum, change, or rate of change. The sensed parameter may comprise any other signal that indicates cardiac response to a CRT pacing therapy.

[0154] If the sensed signal does not match or fall within the value boundaries 1024, it may be deemed out of bounds, as indicated at 1026. This may trigger evaluation of context

1008 if desired. Otherwise, the out of bounds 1026 result calls for the system to consider re-initializing itself, as indicated at 1028.

[0155] If, on the other hand, the sensed signal matches the value boundaries, this is deemed a match 1030. “Matching” in either of blocks 1010 and 1030 may include comparing to the actual previously measured value (or value based on an offset, referred to in the figure and elsewhere herein as a value boundary) plus or minus some margin, and/or a previously measured value (or value boundary) plus or minus a standard deviation or variance, or other statistical error margin (for example if several measurements of the sensed signal are made). In the event of a match at block 1030, the system may next check whether a P-wave has taken place at an offset time that matches an offset used when establishing a value boundary. For example, if the value boundary is based on pacing at a 30 millisecond offset relative to an ideal pace interval/timing, and there is a likely or possible P-wave identified from P-wave data (FIGS. 21-23) at a similar 30 millisecond offset from the detected P-wave, then this confirms, as indicated at 1034, an adjustment 1036 (FIG. 24) will be made prior to returning to the P-sense block 1000. If the check for P-wave block 1032 does not find a corresponding P-wave at a relevant offset, the method/device instead goes to block 1028, to consider re-initializing.

[0156] In any of the above examples, the monitoring of CRT pacing quality may be performed on a continuous basis for each pace delivered for CRT purposes. In some embodiments, checking on CRT pacing quality may be performed less frequently, such as after a predetermined number of therapy deliveries have occurred, or at a predetermined interval. For example, every fifth to one-hundredth pace delivery may be checked, or CRT pacing quality may be checked once or more for each five seconds to two minutes of therapy. Other quantities and intervals may be used. In some examples, pacing therapy quality may be checked in response to a change of context such as when the patient’s heart rate increases or decreases, or when the patient changes posture or activity level, for example, instead of or in addition to periodic checks.

[0157] A series of illustrative and non-limiting examples follows. These examples are provided for further illumination and it should be understood that other embodiments using other combinations of features are also contemplated.

[0158] A first illustrative non-limiting example takes the form of an implantable medical device (IMD) system comprising: a leadless cardiac pacemaker (LCP) having a plurality of LCP electrodes (FIG. 1, items 14, 40, FIG. 3), including: pacing means configured to issue cardiac pacing outputs via the plurality of LCP electrodes (FIG. 3, block 104 shows an LCP having a pulse generator module for generating an issuing cardiac pacing outputs via electrodes 118, 116, 120), LCP communication means configured to communicate to a second device (FIG. 3 shows a communication module 102 in an LCP), and LCP control means to control the pacing circuitry to generate cardiac resynchronization therapy (CRT) using data received with the communication circuitry (FIG. 3 shows a processing or control module 110 for controlling the pacing module 104 and communication module 102). Further in the first illustrative non-limiting example there is an extracardiac device (ED) comprising: a plurality of ED electrodes for receiving cardiac signals (the ED may be, for example and as described

above, an implantable cardiac monitor or a second LCP device or, as shown in FIG. 1, a subcutaneous defibrillator 16, 18; the inclusion of such electrodes may include as identified in FIG. 1 electrodes on canister 16 and/or lead 18 at 24, 26 or lead branch 28; FIG. 2 shows an ED with electrodes such as an active housing 50, discrete electrodes 64, 66, and/or electrodes 72 on lead 70; ED communication means configured to communicate with at least the LCP communication circuitry (ED communication as shown in FIG. 2 may include a communication block 62 using an antenna 74 and/or operably connected via I/O block 58 to housing 50 and/or electrodes 64, 66 and/or 72, as described in associated text above); and ED sensing means for sensing cardiac signals from the plurality of ED electrodes and analyzing cardiac activity to identify cardiac cycles (sensing may be performed as explained above using the housing 50 and electrodes 64, 66, and/or 72, via I/O to processing block 52).

[0159] This first illustrative, non-limiting example, may be characterized by an improvement comprising: the LCP further including LCP sensing means to receive one or more biological signals and determine whether the CRT is achieving a desired result (such as electrical sensing module 106 and/or mechanical sensing module 108 shown in FIG. 3); the ED sensing means comprises P-wave sensing means to identify occurrence of a P-wave in a cardiac signal from the ED electrodes using a set of P-wave detection parameters (various examples of P-wave sensing by the ED are shown above including the use of dedicated circuitry and/or executable instructions for using, for example, a P-wave sensing window 316 to find P-wave 318 as shown in FIG. 10, and further illustrated graphically in FIGS. 11, 12, and 21-23; P-wave sensing is illustratively performed in blocks 552 (FIG. 15), 602 (FIG. 16), 642 (FIG. 17), and at 1000 in FIG. 25); the ED communication means is configured to communicate timing information related to outputs of the P-wave sensing means to the LCP to assist in the CRT (such communication is indicated in the linkage between blocks 642 and 644 in FIG. 17, for example); and wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters in response to the LCP sensing means determines that the CRT is not achieving the desired result (such adjustment is indicated in the adjustment at blocks 576 (FIG. 15), 620 (FIG. 16), 656 (FIG. 17, which particularly illustrates the LCP and ED cooperating), and 1036 (FIG. 25); moreover, illustrative adjustments are shown graphically at FIGS. 21-23, and an overarching set of adjustments are noted in FIG. 24).

[0160] A second illustrative, non-limiting example takes the form of an IMD system as in the first illustrative non-limiting example, wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters by: at a first time including at least a first cardiac cycle: the P-wave sensing means identifying occurrence of a P-wave using first P-wave detection parameters and the ED communication means communicating to the LCP first timing information related to the identified P-wave; the LCP control means using the first timing information to cause the pacing means to deliver one or more CRT pacing therapies; the LCP sensing means determining that a delivered CRT pacing therapy has failed to achieve the desired result; the LCP communication means communicating the failure to achieve the desired result to the ED; and in response to the LCP communicating failure to achieve the desired result, the

P-wave sensing means adjusting the P-wave detection parameters to second P-wave detection parameters; at a second time following the first time, the second time including at least a second cardiac cycle: the P-wave sensing means identifying occurrence of a P-wave using the second P-wave detection parameters and the ED communication means communicating to the LCP second timing information related to the identified P-wave; and the LCP control means using the second timing information to cause the pacing means to deliver one or more CRT pacing therapies. This approach is shown in each of the methods illustrated in FIGS. 15-17 and 25, where adjustments are made in response to failure to match a preferred outcome template (see no match at 570 (FIG. 15), 626 (FIG. 16), and 1020 (FIG. 25) and/or the descriptions relative to the sense blocks 652, 662 and analysis blocks 654, 664 in FIG. 17). When the respective methods iterate, this defines a second time period for each such example.

[0161] Additionally or alternatively, the P-wave sensing means is configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the P-wave sensing means is configured to adjust the P-wave detection parameters by adjusting a match criteria (FIG. 24, block 954).

[0162] Additionally or alternatively, the P-wave sensing means is configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the P-wave sensing means is configured to adjust the P-wave detection parameters by changing the template (FIG. 24, block 960).

[0163] Additionally or alternatively, the P-wave sensing means is configured to detect a P-wave by identifying a peak among a set of peaks in a set of P-wave indicia; further wherein the P-wave sensing means is configured to adjust the P-wave detection parameters by storing a parameter for selecting an Nth peak of the set of peaks (FIG. 24, block 956).

[0164] Additionally or alternatively the P-wave sensing means is configured to detect a P-wave by comparing a set of P-wave indicia to a P-wave detection threshold; further wherein the P-wave sensing means is configured to adjust the P-wave detection parameters by adjusting the P-wave detection threshold (FIG. 24, block 958).

[0165] Additionally or alternatively the P-wave indicia comprise a series of samples of cardiac electrical data, as illustrated by the example of FIG. 11. Additionally or alternatively the P-wave indicia comprise a series of correlation results generated by the P-wave sensing means comparing a P-wave template to a cardiac electrical signal at a series of points in time, as illustrated by the example of FIG. 12.

[0166] Additionally or alternatively the P-wave sensing means is configured to detect a P-wave using a tracking analysis to track P-wave detections among a set of P-wave data captured for a series of cardiac cycles; further wherein the P-wave sensing means is configured to adjust the P-wave detection parameters by adjusting the tracking analysis (FIG. 24, block 962).

[0167] Additionally or alternatively, the LCP sensing means comprises: physiological template means for storing one or more templates for a physiological signal, at least one of the templates representing the physiological signal corresponding to a preferred pace timing; and determining means to determine whether a test physiological signal

captured in relation to a CRT pace therapy matches one of the physiological templates representing the physiological signal corresponding to the preferred pace timing. FIG. 18 shows a number of CRT assessments using physiological markers 730, including heart sounds 732, pressure signals 734, motion signals 736, impedance measures 738, optical sensors 740, and combinations of any of heart sounds, pressure, motion, impedance or optical markers with one another or with electrical signals as indicated at 742. Additionally or alternatively, the LCP sensing means may instead rely on cardiac electrical markers 710 such as QRS morphology 712, Q, R, or T-wave amplitude 714, intervals between Q, R, and/or T waves 716, width of various signals 718, and/or combinations with the physiological markers.

[0168] Additionally or alternatively the physiological template means are configured such that the one or more templates comprises at least one offset template each representing the physiological signal corresponding to a known offset from the preferred pace timing; and wherein the determining means is configured to determine whether the test physiological signal matches one of the at least one offset templates and, if so, then to use the LCP communication means to communicate to the ED that an offset template match has occurred. Offset template formation may be achieved using the methods illustrated in FIG. 14 by dedicated circuitry and/or stored executable instruction sets. Graphical illustrations of the various templates are provided as well at FIGS. 19-20.

[0169] Additionally or alternatively the P-wave sensing means comprises offset match means to determine, in response to the LCP communicating that an offset template match has occurred, whether a P-wave may have occurred at an offset relative to a detected P-wave, and, if so, to make an adjustment to P-wave detection criteria relying on the known offset. Such offset matching to criteria is indicated in the comparison at blocks 572 (FIG. 15), 612 (FIG. 16), and 1022 (FIG. 25).

[0170] Additionally or alternatively, the P-wave sensing means comprises offset detection means configured, in response to the LCP communicating that an offset template match has occurred, to reanalyze the cardiac signal to determine whether one or more adjustments to a P-wave detection criteria would result in detection of a P-wave correlated to the known offset. Such verification is indicated by blocks 616/618 (FIG. 16), and 1032/1034 (FIG. 25).

[0171] Additionally or alternatively, the P-wave sensing means comprises offset adjustment means configured, in response to the LCP communicating that an offset template match has occurred, to make an adjustment to P-wave detection criteria using the offset. FIG. 15 shows an example in which the new offset is generated at block 578 based on matching to an offset criteria.

[0172] Additionally or alternatively, the determining means is configured to determine whether the test physiological signal fails to match any of the one or more templates and, if so, to use the LCP communication means to communicate that no template match occurred, and the ED further comprises re-initialization means configured to determine, based on whether the LCP communicates that no template match occurred, whether to perform a re-initialization of one or more ED and/or LCP system settings used in the P-wave sensing means and/or LCP. Such no-match conditions and associated assessment of re-initialization are

indicated in FIG. 15 at blocks 580, 582, FIG. 16 at blocks 626, 624, and FIG. 25 at blocks 1026, 1028.

[0173] The various mean indicated may be embodied in dedicated circuitry such as dedicated blocks of logic circuitry, application specific integrated circuits, and combinations of digital logic and analog measurement or control features, as well as in executable instruction sets stored as firmware or software, as well as in other manners recognizable by the skilled artisan from the above description.

[0174] Each of these non-limiting examples can stand on its own, or can be combined in various permutations or combinations with one or more of the other examples.

[0175] The above detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the invention can be practiced. These embodiments are also referred to herein as "examples." Such examples can include elements in addition to those shown or described. However, the present inventors also contemplate examples in which only those elements shown or described are provided. Moreover, the present inventors also contemplate examples using any combination or permutation of those elements shown or described (or one or more aspects thereof), either with respect to a particular example (or one or more aspects thereof), or with respect to other examples (or one or more aspects thereof) shown or described herein.

[0176] In the event of inconsistent usages between this document and any documents so incorporated by reference, the usage in this document controls.

[0177] In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

[0178] Method examples described herein can be machine or computer-implemented at least in part. Some examples can include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods can include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code can include computer readable instructions for performing various methods. The code may form portions of computer program products. Further, in an example, the code can be tangibly stored on one or more volatile, non-transitory, or non-volatile tangible computer-readable media, such as during execution or at other times. Examples of these tangible computer-readable media can include, but are not limited to, hard disks, removable magnetic or optical disks, magnetic cassettes, memory cards or sticks, random access memories (RAMs), read only memories (ROMs), and the like.

[0179] The above description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more aspects thereof) may be used in combination with each other. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above description.

[0180] The Abstract is provided to comply with 37 C.F.R. § 1.72(b), to allow the reader to quickly ascertain the nature

of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

[0181] Also, in the above Detailed Description, various features may be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter may lie in less than all features of a particular disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description as examples or embodiments, with each claim standing on its own as a separate embodiment, and it is contemplated that such embodiments can be combined with each other in various combinations or permutations. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

The claimed invention is:

1. An implantable medical device (IMD) system comprising:

a leadless cardiac pacemaker (LCP) having a plurality of LCP electrodes, pacing circuitry configured to issue cardiac pacing outputs via the plurality of LCP electrodes, LCP communication circuitry configured to communicate to a second device, and operational circuitry configured to control the pacing circuitry to generate cardiac resynchronization therapy (CRT) using data received with the communication circuitry, the LCP further comprising a sensing input circuit to receive one or more biological signals to determine whether the CRT is achieving a desired result;

an extracardiac device (ED) comprising:

a plurality of electrodes for sensing cardiac signals;
ED communication circuitry configured to communicate with at least the LCP communication circuitry; and
ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity;

wherein the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal using a set of P-wave detection parameters, and use the ED communication circuitry to communicate to the LCP timing information related to the identified P-wave to assist in the CRT, such that the ED serves as a second device for purposes of the LCP communication circuitry; and

wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters.

2. The IMD system of claim 1 wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters by:

at a first time including at least a first cardiac cycle:
the ED detecting a P-wave using first P-wave detection parameters and using the ED communication circuitry to communicate to the LCP first timing information related to the detected P-wave;
the LCP using the first timing information to deliver one or more CRT pacing therapies;
the LCP determining that a delivered CRT pacing therapy has failed to achieve the desired result; and
the LCP communicating the failure to achieve the desired result to the ED;

in response to the LCP communicating failure to achieve the desired result, the ED adjusting the P-wave detection parameters to second P-wave detection parameters;

at a second time following the first time, the second time including at least a second cardiac cycle:

the ED detecting a P-wave using second P-wave detection parameters and using the ED communication circuitry to communicate to the LCP second timing information related to the detected P-wave; and
the LCP using the second timing information to deliver one or more CRT pacing therapies.

3. The IMD system of claim 2 wherein the ED is configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the ED is configured to adjust the P-wave detection parameters by adjusting a match criteria.

4. The IMD system of claim 2 wherein the ED is configured to detect a P-wave by comparison of a cardiac electrical signal to a template to identify a match to the template, further wherein the ED is configured to adjust the P-wave detection parameters by changing the template.

5. The IMD system of claim 2 wherein the ED is configured to detect a P-wave by identifying a peak among a set of peaks in a set of P-wave indicia; further wherein the ED is configured to adjust the P-wave detection parameters by storing a parameter for selecting an Nth peak of the set of peaks.

6. The IMD system of claim 2 wherein the ED is configured to detect a P-wave by comparing a set of P-wave indicia to a P-wave detection threshold; further wherein the ED is configured to adjust the P-wave detection parameters by adjusting the P-wave detection threshold.

7. An IMD system as in claim 2 wherein the ED is configured to detect a P-wave using a tracking analysis to track P-wave detections among a set of P-wave data captured for a series of cardiac cycles; further wherein the ED is configured to adjust the P-wave detection parameters by adjusting the tracking analysis.

8. The IMD system of claim 1 wherein the LCP operational circuitry is configured to determine whether the CRT is achieving a desired result and to communicate to the ED operational circuitry to indicate whether the CRT is achieving the desired result, wherein the ED and LCP are configured to cooperatively adjust the P-wave detection parameters in response to the LCP determining that the CRT is not achieving the desired result.

9. The IMD system of claim 8 wherein the LCP is configured to determine whether the CRT is achieving a desired result by:

storing one or more templates for a physiological signal sensed by the sensing input circuit, at least one of the templates representing the physiological signal corresponding to a preferred pace timing; and

determining whether a test physiological signal captured in relation to a CRT pace therapy matches the template representing the physiological signal corresponding to the preferred pace timing.

10. The IMD system of claim 9 wherein:

the one or more templates comprises at least one offset template each representing the physiological signal corresponding to a known offset from the preferred pace timing; and

wherein the LCP is configured to determine whether the test physiological signal matches one of the at least one offset templates and, if so, to communicate to the ED that an offset template match has occurred.

11. The IMD system of claim 10 wherein the ED is configured, in response to the LCP communicating that an offset template match has occurred, to analyze the cardiac signal to determine whether a P-wave may have occurred at an offset relative to the detected P-wave, and, if so, making an adjustment to P-wave detection criteria.

12. The IMD system of claim 10 wherein the ED is configured, in response to the LCP communicating that an offset template match has occurred, to reanalyze the cardiac signal to determine whether one or more adjustments to a P-wave detection criteria would result in detection of a P-wave correlated to the offset of the offset template that matched the test physiological signal.

13. The IMD system of claim 10 wherein, in response to the LCP communicating that an offset template match has occurred, the ED is configured to make an adjustment to P-wave detection criteria using the offset.

14. The IMD system of claim 10 wherein, if the test physiological signal does not match any of the one or more templates, the LCP is configured to communicate that no template match occurred to the ED and further wherein, if the LCP finds at least a threshold quantity of test physiological signals fail to match any of the one or more templates, the IMD system is configured to perform a re-initialization of one or more CRT system settings.

15. An IMD system as in claim 1 wherein the LCP is configured to deliver CRT pacing output in response to communication of timing information related to the P-wave from the ED.

16. An IMD system as in claim 1 wherein the LCP is configured to deliver CRT pacing output according to a calculated interval relative to a prior CRT pacing output, and the LCP is configured to use the communication of timing information related to the P-wave to adjust the calculated interval.

17. An implantable medical device (IMD) system comprising:

- a leadless cardiac pacemaker (LCP) for delivering cardiac resynchronization therapy (CRT), the LCP comprising:
 - a plurality of electrodes for delivering pacing therapy;
 - a sensing input circuit to receive one or more biological signals;

- a pacing output circuit;

- LCP communication circuitry; and

- LCP operational circuitry configured to receive and analyze signals from the sensing input;

- an extracardiac device (ED) comprising:

- a plurality of electrodes for sensing cardiac signals;

- ED communication circuitry configured to communicate with at least the LCP communication circuit;

- and

- ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity;

- wherein the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal, and use the ED communication circuitry to communicate to the LCP that the P-wave has been detected; and

- wherein the LCP operational circuitry is configured to determine from its analysis of signals received from the sensing input whether the ED is incorrectly detecting the P-wave.

18. An IMD system as in claim 17 wherein the LCP is configured to deliver CRT pacing output in response to communication of timing information related to the P-wave from the ED.

19. An implantable medical device (IMD) system comprising:

- a leadless cardiac pacemaker (LCP) for delivering cardiac resynchronization therapy (CRT), the LCP comprising:
 - a plurality of electrodes for delivering pacing therapy;
 - a sensing input circuit to receive one or more biological signals;

- a pacing output circuit;

- LCP communication circuitry; and

- LCP operational circuitry configured to receive and analyze signals from the sensing input;

- an extracardiac device (ED) comprising:

- a plurality of electrodes for sensing cardiac signals;

- ED communication circuitry configured to communicate with at least the LCP communication circuit;

- and

- ED operational circuitry configured to receive sensed cardiac signals from the plurality of electrodes and analyze cardiac activity;

- wherein the ED operational circuitry is configured to obtain a cardiac signal from the plurality of electrodes, identify occurrence of a P-wave in the cardiac signal, and use the ED communication circuitry to communicate to the LCP that the P-wave has been detected;

- wherein the LCP operational circuitry is configured to use the pacing output circuit to deliver pace therapy and to use the sensing input circuit to determine whether a cardiac response to the pace therapy matches a desired metric; and

- wherein the LCP operational circuitry is configured to communicate to the ED operational circuitry to indicate that the pace therapy does not match the desired metric.

20. An IMD system as in claim 19 wherein the LCP is configured to deliver CRT pacing output in response to communication of timing information related to the P-wave from the ED.

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摘要(译)

使用无引线心脏起搏器 (LCP) 和心外装置 (ED) 为患者提供心脏再同步治疗 (CRT) 的方法 , 系统和设备。该系统被配置为识别心房事件以用作LCP递送CRT的定时标记 , 并且进一步确定定时标记是否被错误地感测并且根据需要进行调整或呼叫重新初始化。

