US 20140213859A1

(19) **United States**
(12) **Patent Application Publication**
(10) **Pub. No.: US 2014/0213859 A1**
(43) **Pub. Date: Jul. 31, 2014**

Gilkerson et al.

(54) **SYSTEMS AND METHODS TO IDENTIFY CARDIAC DYSYNCHRONY**

(71) Applicant: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

(72) Inventors: **James O. Gilkerson**, Stillwater, MN (US); **Kenneth P. Hoyme**, Plymouth, MN (US); **James R. Kalgren**, Lino Lakes, MN (US); **David L. Perschbacher**, Coon Rapids, MN (US); **Les N. Peterson**, Woodbury, MN (US)

(73) Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

(21) Appl. No.: **14/163,087**

(22) Filed: **Jan. 24, 2014**

Related U.S. Application Data

(60) Provisional application No. 61/756,835, filed on Jan. 25, 2013.

Publication Classification

(51) **Int. Cl.**

A61B 5/024 (2006.01)
A61B 5/07 (2006.01)
A61B 5/00 (2006.01)

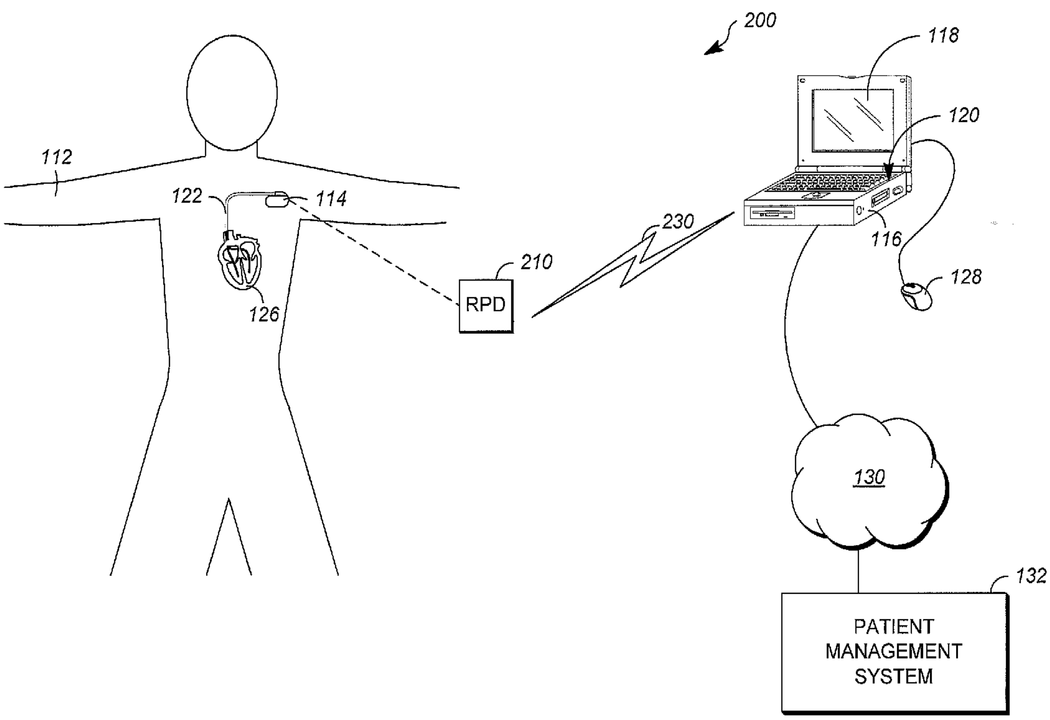
(52) **U.S. Cl.**

CPC ***A61B 5/02405*** (2013.01); ***A61B 5/746*** (2013.01); ***A61B 5/4836*** (2013.01); ***A61B 5/686*** (2013.01); ***A61B 5/7282*** (2013.01); ***A61B 5/076*** (2013.01); ***A61B 5/7475*** (2013.01)

USPC **600/302**; 600/508

(57) **ABSTRACT**

The current technology is relevant to a system having an implantable medical device, where the system is configured to identify a patient condition comprising cardiac dysynchrony, configured to notify a clinical user of the identified condition and configured to identify a therapy appropriate for the identified condition.



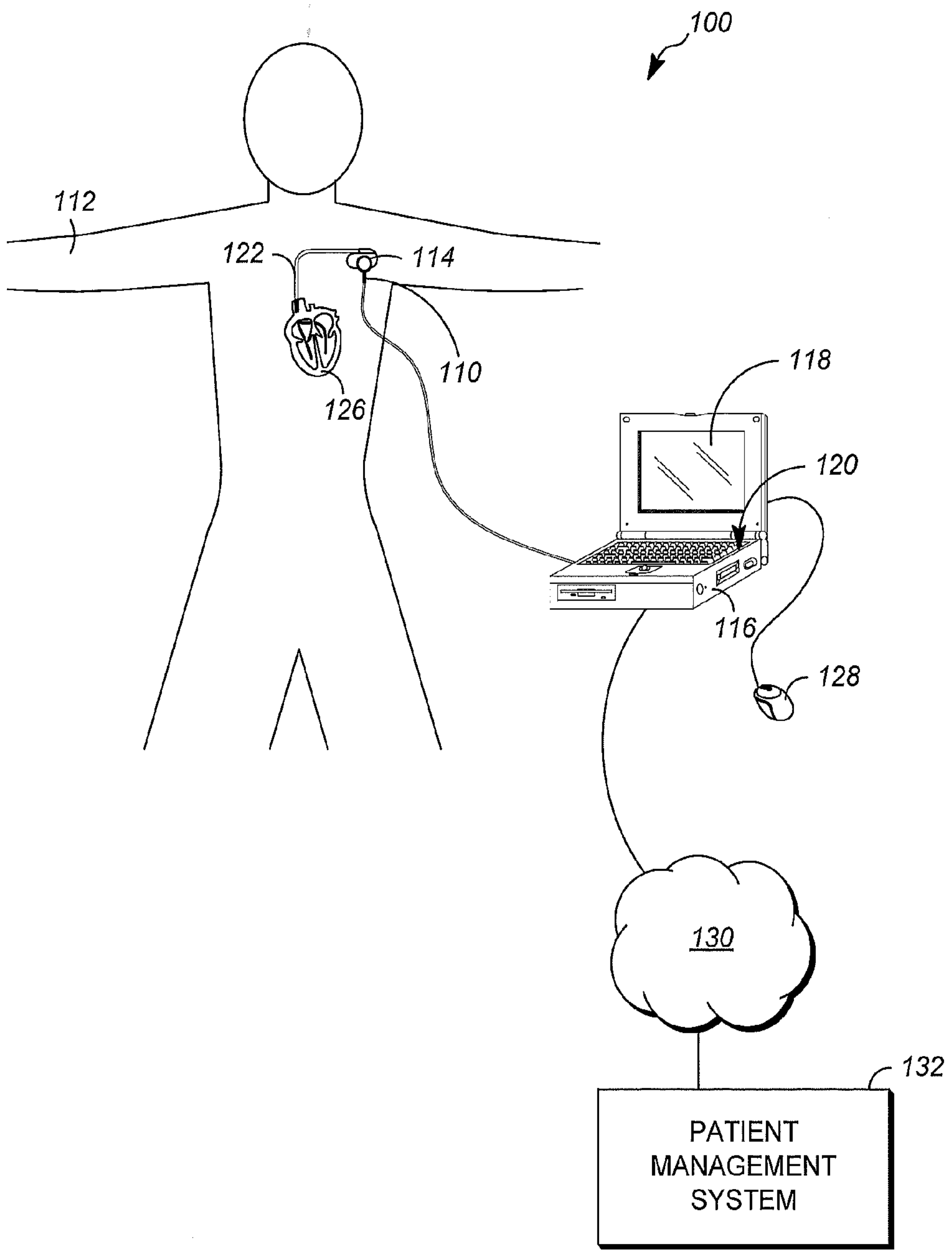

100
112
122
114
110
126
118
120
116
128
130
132
PATIENT
MANAGEMENT
SYSTEM

FIG. 1

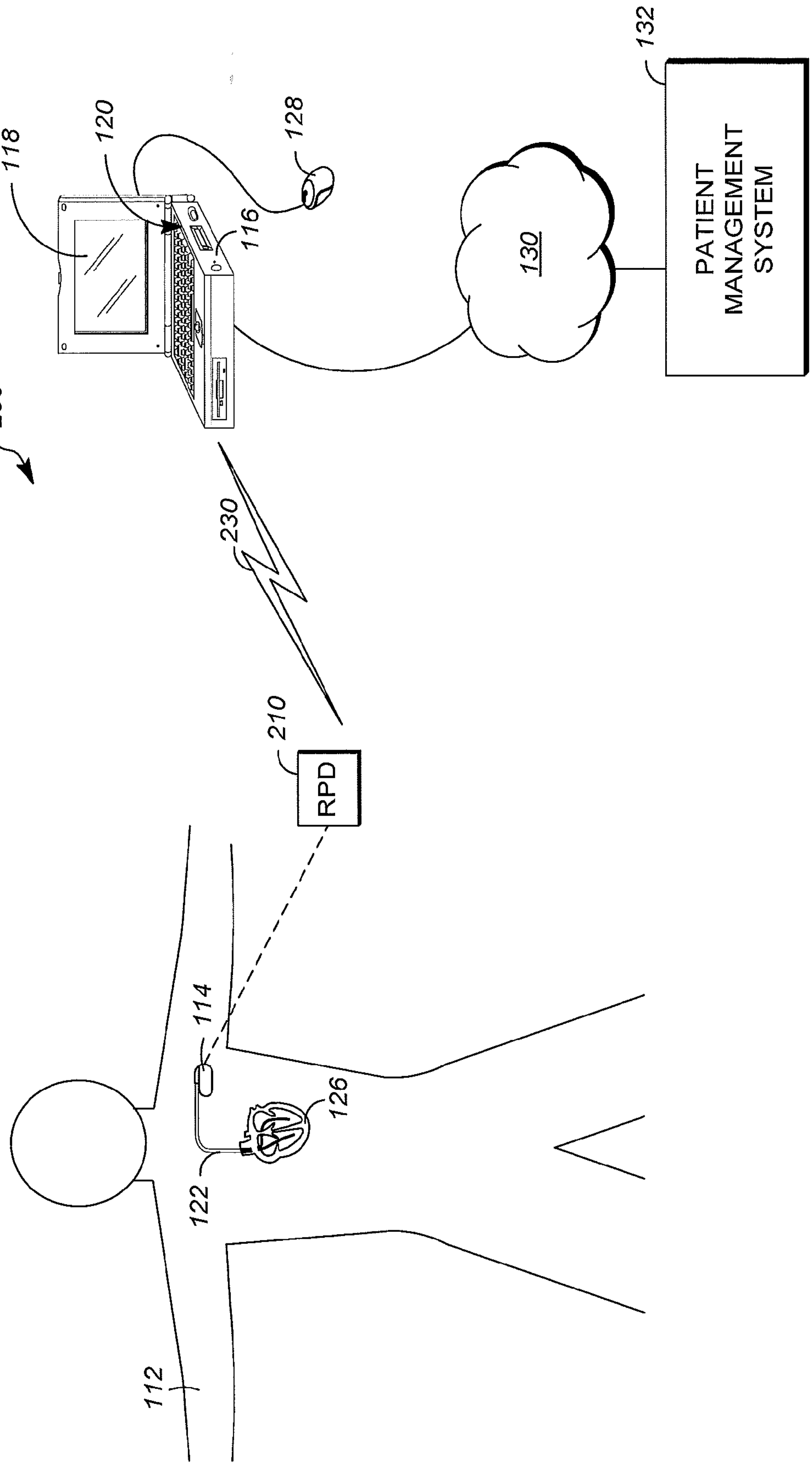

200
118
120
128
116
132
130
PATIENT MANAGEMENT SYSTEM
230
210
RPD
114
126
122
112

FIG. 2

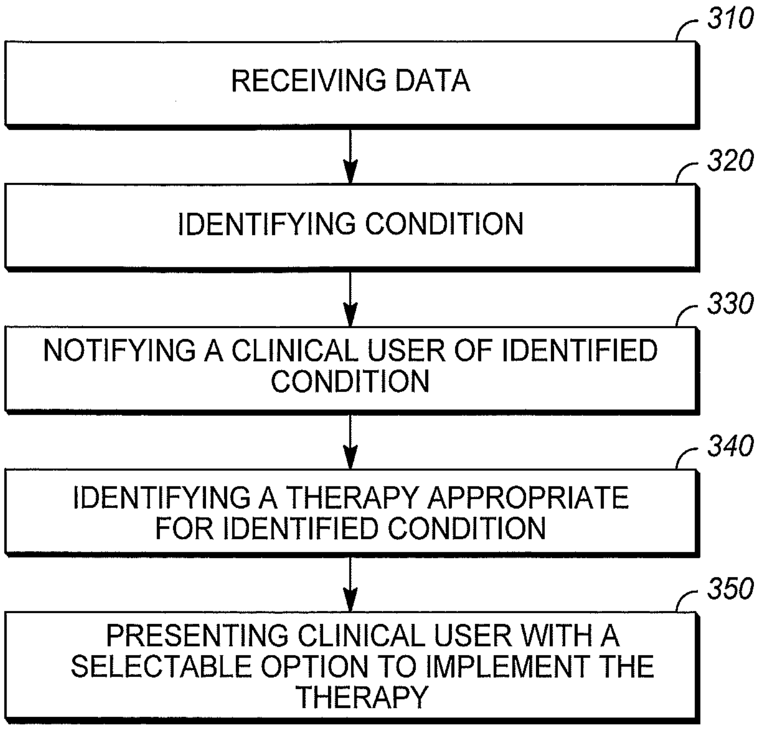

310
RECEIVING DATA
320
IDENTIFYING CONDITION
330
NOTIFYING A CLINICAL USER OF IDENTIFIED CONDITION
340
IDENTIFYING A THERAPY APPROPRIATE FOR IDENTIFIED CONDITION
350
PRESENTING CLINICAL USER WITH A SELECTABLE OPTION TO IMPLEMENT THE THERAPY

FIG. 3

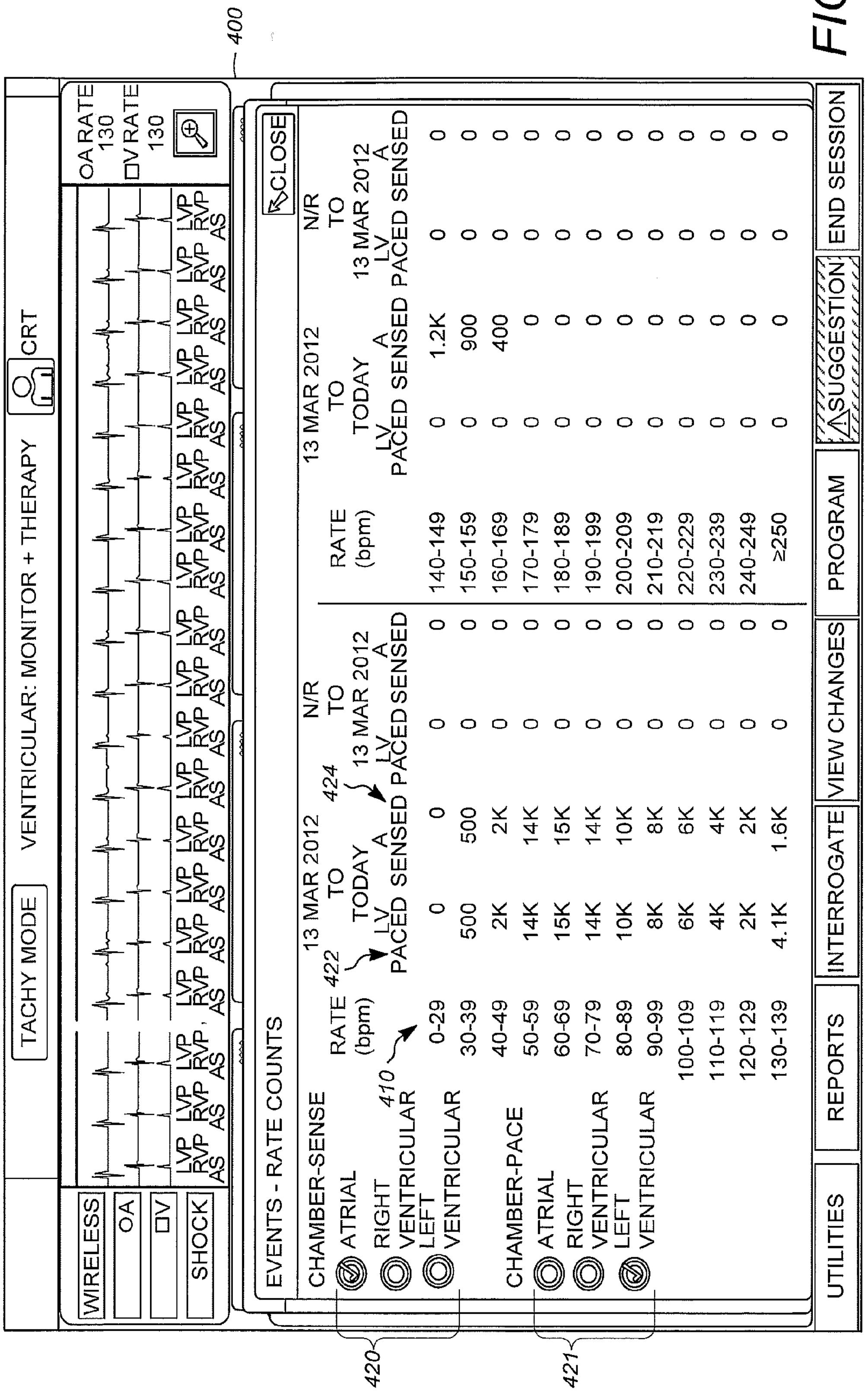
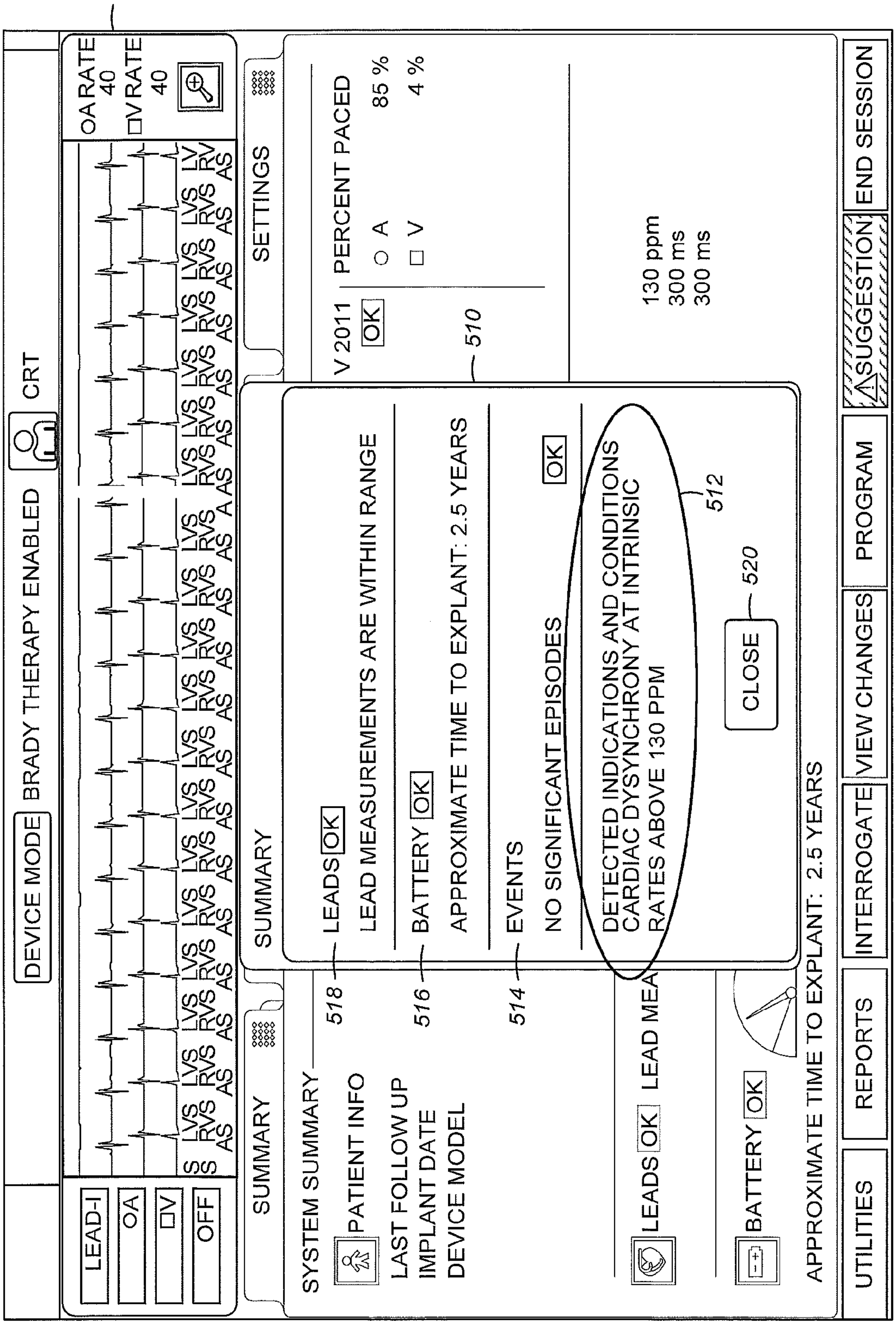

400
TACHY MODE
VENTRICULAR: MONITOR + THERAPY
CRT
WIRELESS
A
V
SHOCK
A RATE 130
V RATE 130
EVENTS - RATE COUNTS
CLOSE
CHAMBER-SENSE
ATRIAL
RIGHT VENTRICULAR
LEFT VENTRICULAR
CHAMBER-PACE
ATRIAL
RIGHT VENTRICULAR
LEFT VENTRICULAR
RATE (bpm)
13 MAR 2012 TO TODAY
N/R TO 13 MAR 2012
LV PACED
A SENSED
410
420
421
422
424
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 4



500
DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
A
V
OFF
A RATE 40
V RATE 40
SUMMARY
SETTINGS
SYSTEM SUMMARY
PATIENT INFO
LAST FOLLOW UP
IMPLANT DATE
DEVICE MODEL
V 2011
OK
PERCENT PACED
A 85 %
V 4 %
130 ppm
300 ms
300 ms
LEADS OK LEAD MEA
BATTERY OK
APPROXIMATE TIME TO EXPLANT: 2.5 YEARS
SUMMARY
518
LEADS OK
LEAD MEASUREMENTS ARE WITHIN RANGE
516
BATTERY OK
APPROXIMATE TIME TO EXPLANT: 2.5 YEARS
514
EVENTS
NO SIGNIFICANT EPISODES
OK
510
DETECTED INDICATIONS AND CONDITIONS
CARDIAC DYSYNCHRONY AT INTRINSIC
RATES ABOVE 130 PPM
512
CLOSE
520
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 5

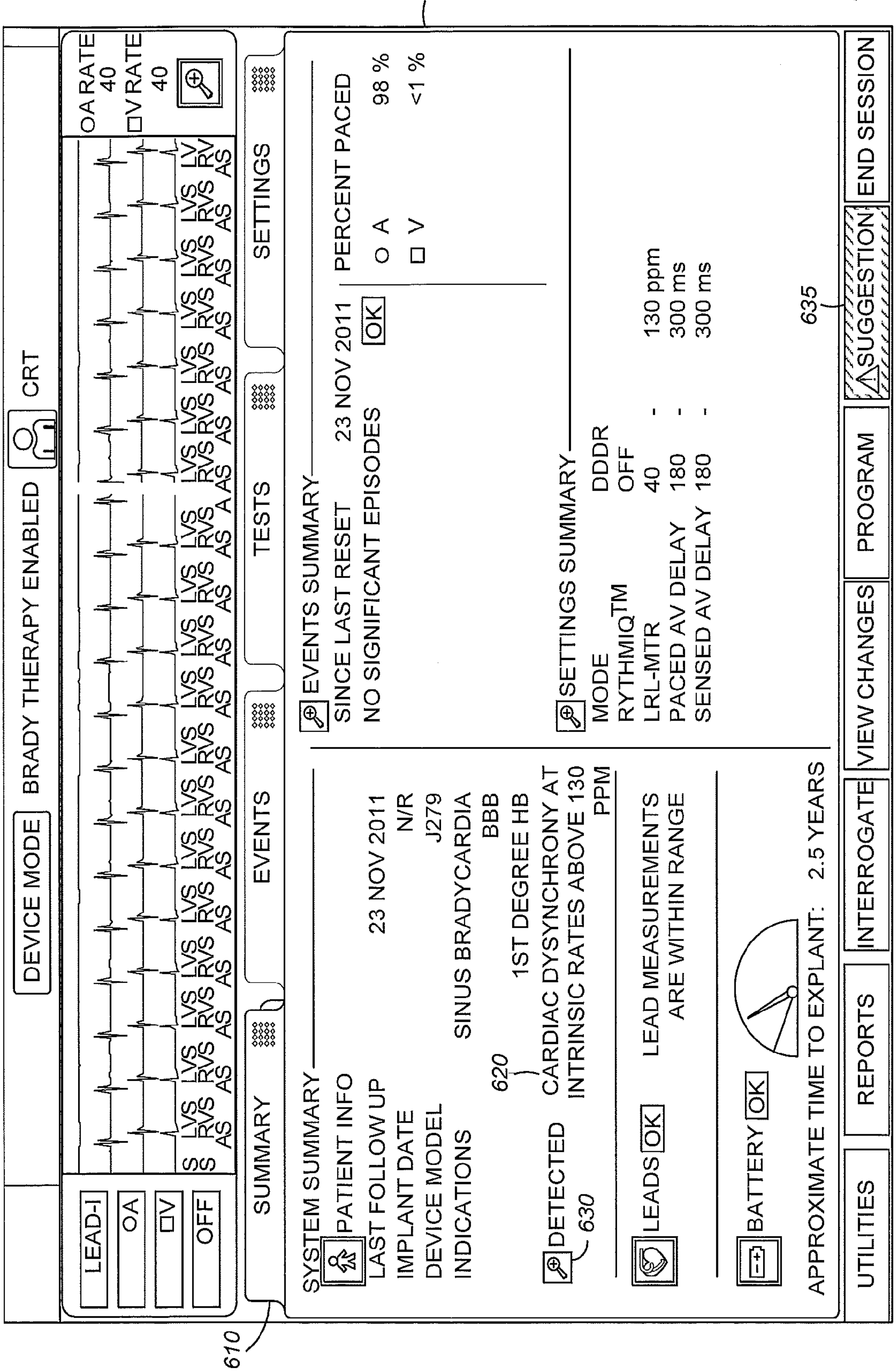

600
610
620
630
635
DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
A
V
OFF
A RATE 40
V RATE 40
LVS RVS AS
LV RV AS
SUMMARY
EVENTS
TESTS
SETTINGS
SYSTEM SUMMARY
PATIENT INFO
LAST FOLLOW UP 23 NOV 2011
IMPLANT DATE N/R
DEVICE MODEL J279
INDICATIONS SINUS BRADYCARDIA
BBB
1ST DEGREE HB
DETECTED
CARDIAC DYSYNCHRONY AT INTRINSIC RATES ABOVE 130 PPM
LEADS OK
LEAD MEASUREMENTS ARE WITHIN RANGE
BATTERY OK
APPROXIMATE TIME TO EXPLANT: 2.5 YEARS
EVENTS SUMMARY
SINCE LAST RESET 23 NOV 2011
NO SIGNIFICANT EPISODES OK
PERCENT PACED
A 98 %
V <1 %
SETTINGS SUMMARY
MODE DDDR
RYTHMIQ™ OFF
LRL-MTR 40 - 130 ppm
PACED AV DELAY 180 - 300 ms
SENSED AV DELAY 180 - 300 ms
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 6

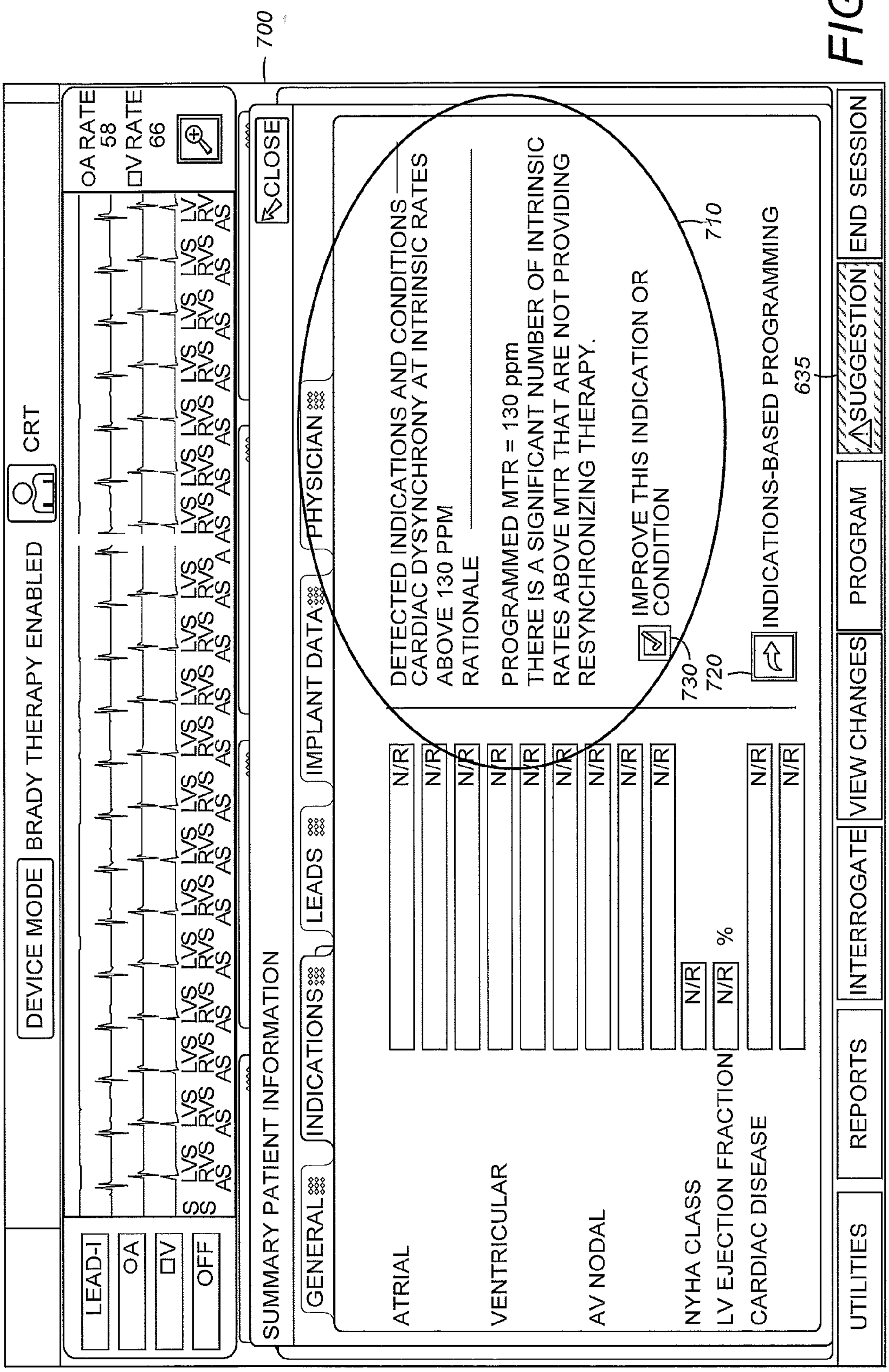

700
DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
OA
□V
OFF
OA RATE 58
□V RATE 66
S S
LVS RVS AS
LVS RVS A AS
LV RV AS
SUMMARY PATIENT INFORMATION
GENERAL
INDICATIONS
LEADS
IMPLANT DATA
PHYSICIAN
CLOSE
ATRIAL
VENTRICULAR
AV NODAL
NYHA CLASS
LV EJECTION FRACTION
CARDIAC DISEASE
N/R
%
DETECTED INDICATIONS AND CONDITIONS
CARDIAC DYSYNCHRONY AT INTRINSIC RATES ABOVE 130 PPM
RATIONALE
PROGRAMMED MTR = 130 ppm
THERE IS A SIGNIFICANT NUMBER OF INTRINSIC RATES ABOVE MTR THAT ARE NOT PROVIDING RESYNCHRONIZING THERAPY.
IMPROVE THIS INDICATION OR CONDITION
INDICATIONS-BASED PROGRAMMING
710
720
730
635
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 7

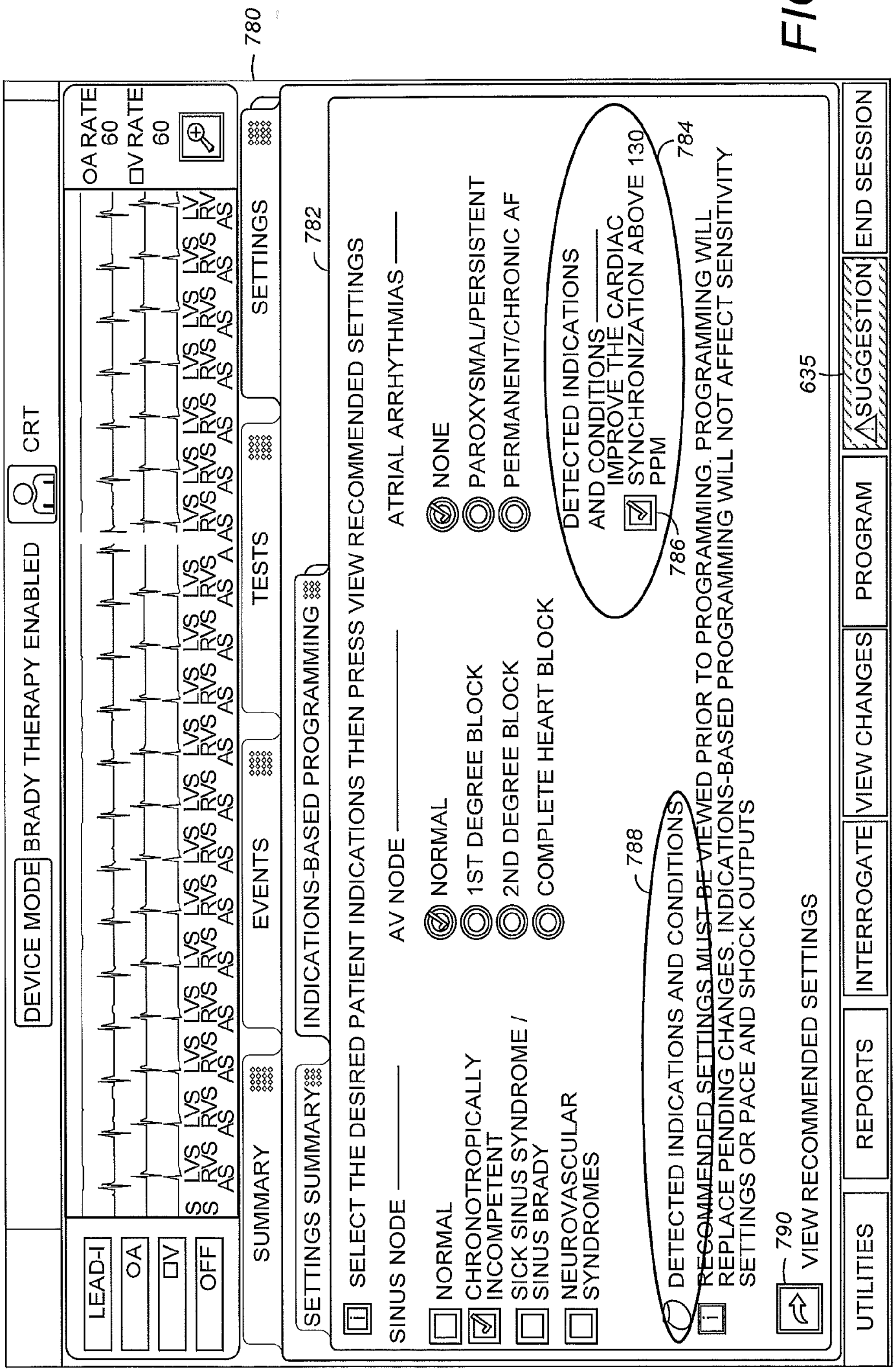

780
DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
OA
□V
OFF
OA RATE 60
□V RATE 60
SUMMARY
EVENTS
TESTS
SETTINGS
SETTINGS SUMMARY
INDICATIONS-BASED PROGRAMMING
782
SELECT THE DESIRED PATIENT INDICATIONS THEN PRESS VIEW RECOMMENDED SETTINGS
SINUS NODE
NORMAL
CHRONOTROPICALLY INCOMPETENT
SICK SINUS SYNDROME / SINUS BRADY
NEUROVASCULAR SYNDROMES
AV NODE
NORMAL
1ST DEGREE BLOCK
2ND DEGREE BLOCK
COMPLETE HEART BLOCK
ATRIAL ARRHYTHMIAS
NONE
PAROXYSMAL/PERSISTENT
PERMANENT/CHRONIC AF
DETECTED INDICATIONS AND CONDITIONS
IMPROVE THE CARDIAC SYNCHRONIZATION ABOVE 130 PPM
784
786
788
DETECTED INDICATIONS AND CONDITIONS
RECOMMENDED SETTINGS MUST BE VIEWED PRIOR TO PROGRAMMING. PROGRAMMING WILL REPLACE PENDING CHANGES. INDICATIONS-BASED PROGRAMMING WILL NOT AFFECT SENSITIVITY SETTINGS OR PACE AND SHOCK OUTPUTS
790
VIEW RECOMMENDED SETTINGS
635
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 8

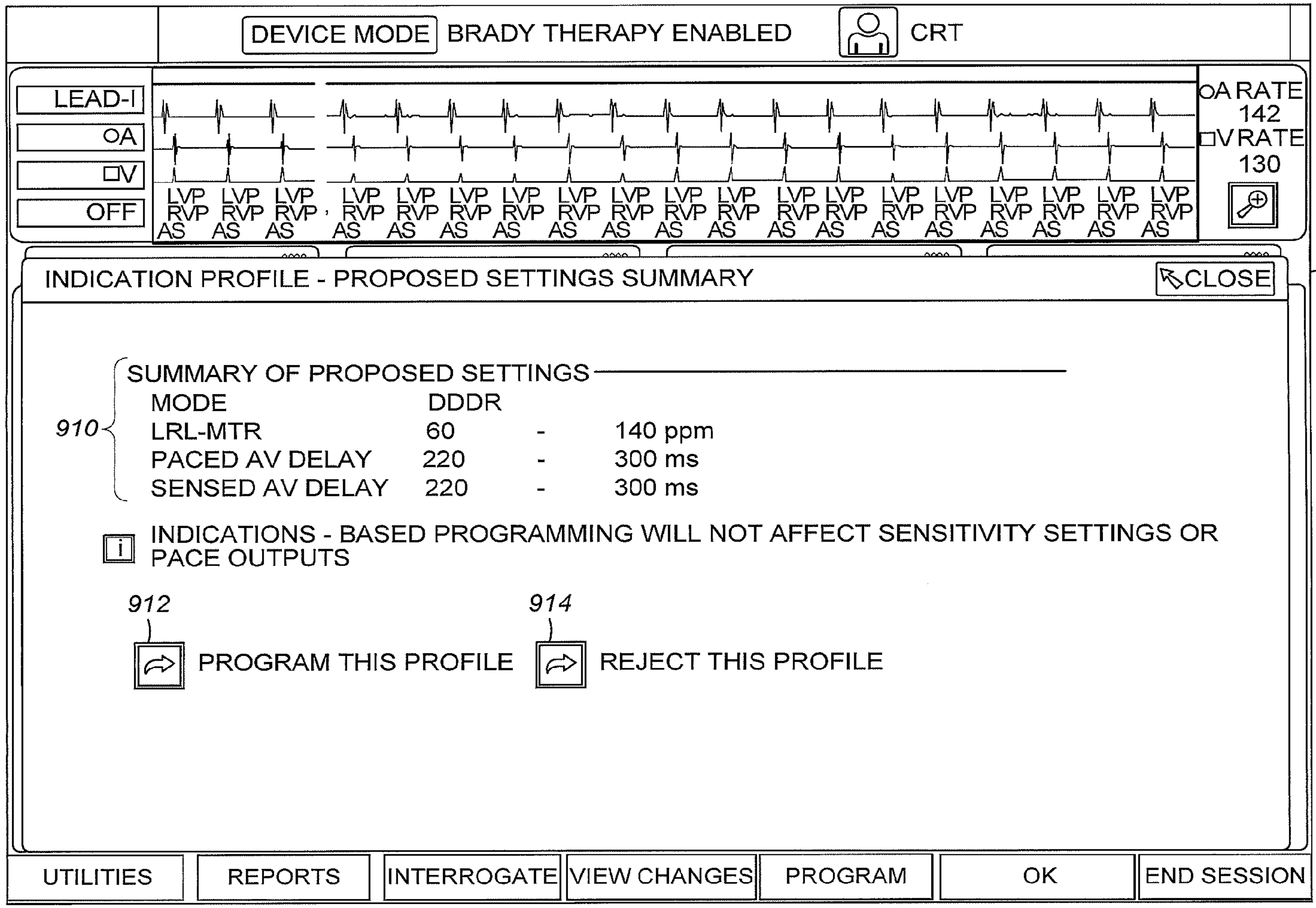

DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
A
V
OFF
LVP RVP AS
A RATE 142
V RATE 130
INDICATION PROFILE - PROPOSED SETTINGS SUMMARY
CLOSE
900
910
SUMMARY OF PROPOSED SETTINGS
MODE DDDR
LRL-MTR 60 - 140 ppm
PACED AV DELAY 220 - 300 ms
SENSED AV DELAY 220 - 300 ms
INDICATIONS - BASED PROGRAMMING WILL NOT AFFECT SENSITIVITY SETTINGS OR PACE OUTPUTS
912
PROGRAM THIS PROFILE
914
REJECT THIS PROFILE
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
OK
END SESSION

FIG. 9

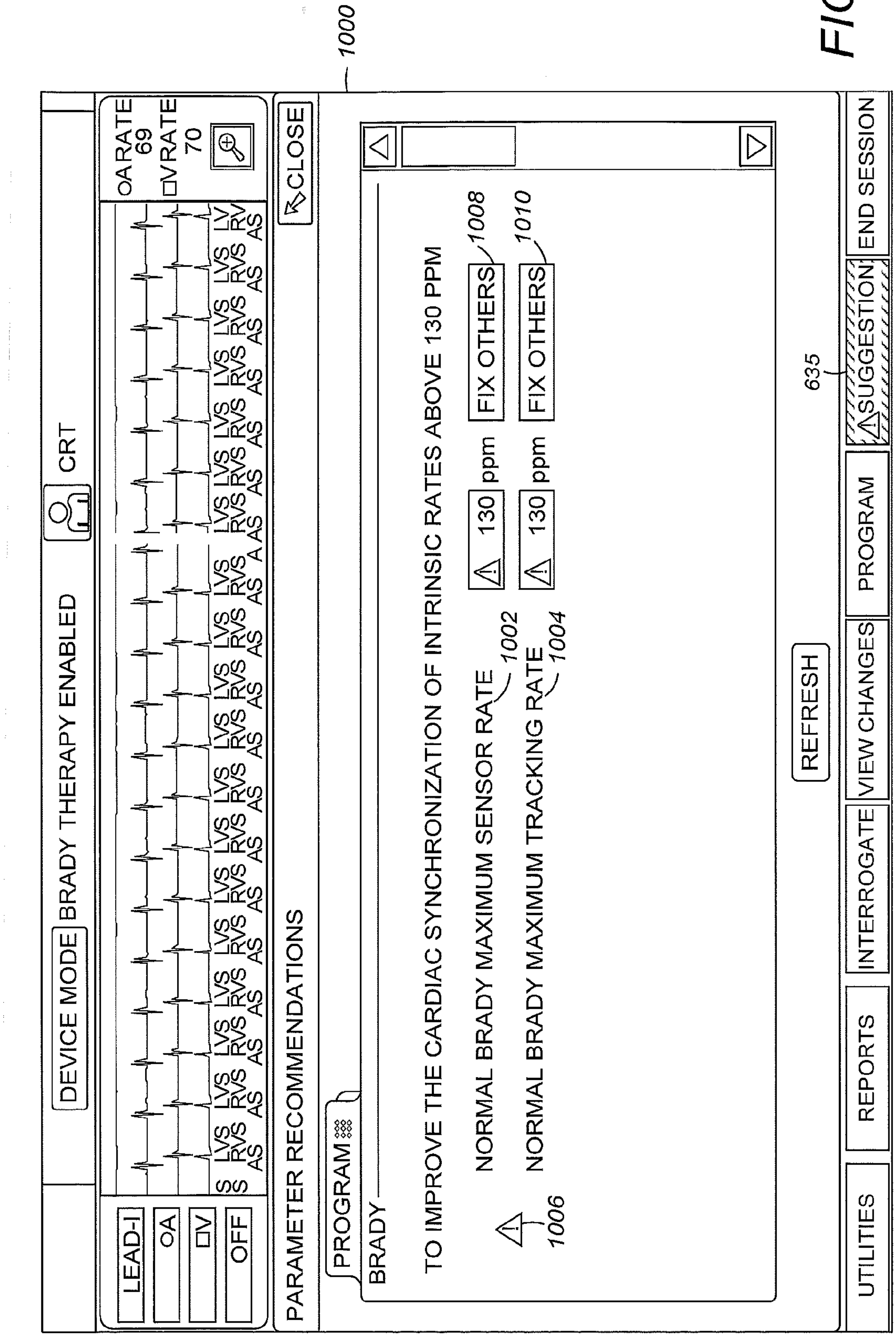

1000
DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
A
V
OFF
A RATE
69
V RATE
70
PARAMETER RECOMMENDATIONS
CLOSE
PROGRAM
BRADY
TO IMPROVE THE CARDIAC SYNCHRONIZATION OF INTRINSIC RATES ABOVE 130 PPM
NORMAL BRADY MAXIMUM SENSOR RATE
NORMAL BRADY MAXIMUM TRACKING RATE
130 ppm
130 ppm
FIX OTHERS
FIX OTHERS
1002
1004
1006
1008
1010
REFRESH
635
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 10

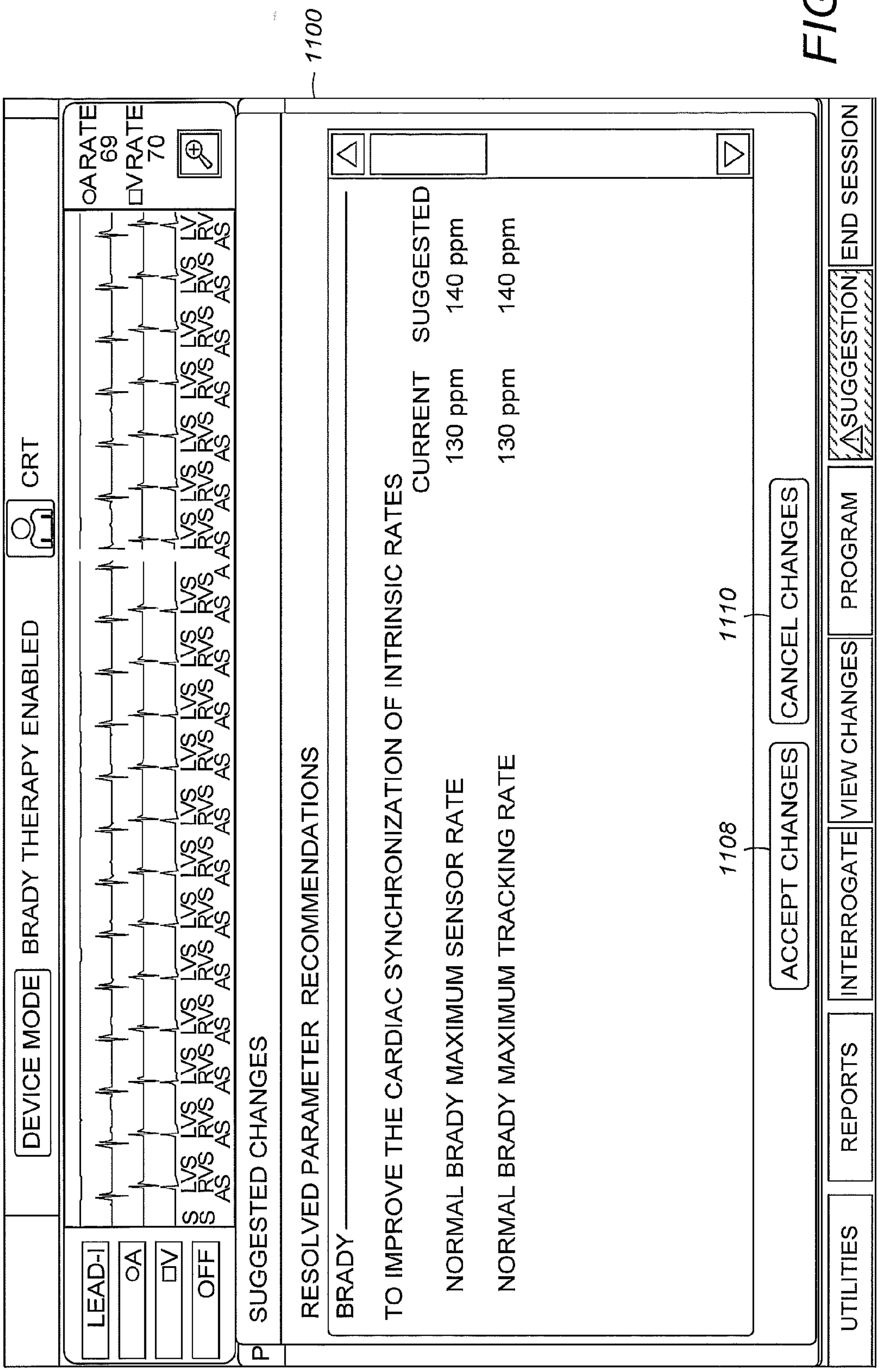
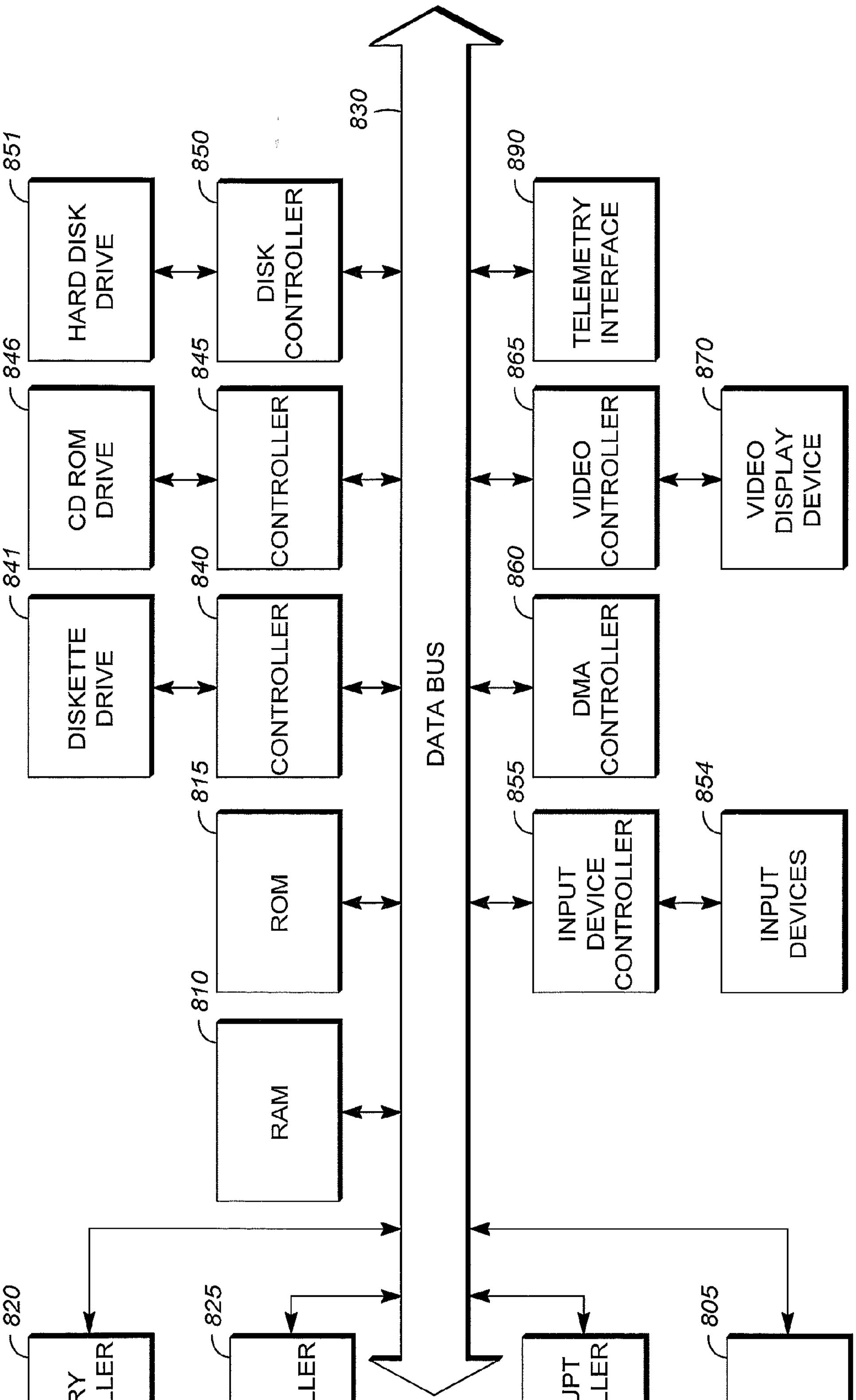

DEVICE MODE
BRADY THERAPY ENABLED
CRT
LEAD-I
A
V
OFF
A RATE 69
V RATE 70
SUGGESTED CHANGES
RESOLVED PARAMETER RECOMMENDATIONS
BRADY
TO IMPROVE THE CARDIAC SYNCHRONIZATION OF INTRINSIC RATES
CURRENT
SUGGESTED
NORMAL BRADY MAXIMUM SENSOR RATE
130 ppm
140 ppm
NORMAL BRADY MAXIMUM TRACKING RATE
130 ppm
140 ppm
ACCEPT CHANGES
CANCEL CHANGES
1100
1108
1110
UTILITIES
REPORTS
INTERROGATE
VIEW CHANGES
PROGRAM
SUGGESTION
END SESSION

FIG. 11



851
HARD DISK DRIVE
850
DISK CONTROLLER
830
846
CD ROM DRIVE
845
CONTROLLER
841
DISKETTE DRIVE
840
CONTROLLER
815
ROM
810
RAM
DATA BUS
890
TELEMETRY INTERFACE
865
VIDEO CONTROLLER
870
VIDEO DISPLAY DEVICE
860
DMA CONTROLLER
855
INPUT DEVICE CONTROLLER
854
INPUT DEVICES
820
MEMORY CONTROLLER
825
BUS CONTROLLER
835
INTERRUPT CONTROLLER
805
CPU

FIG. 12

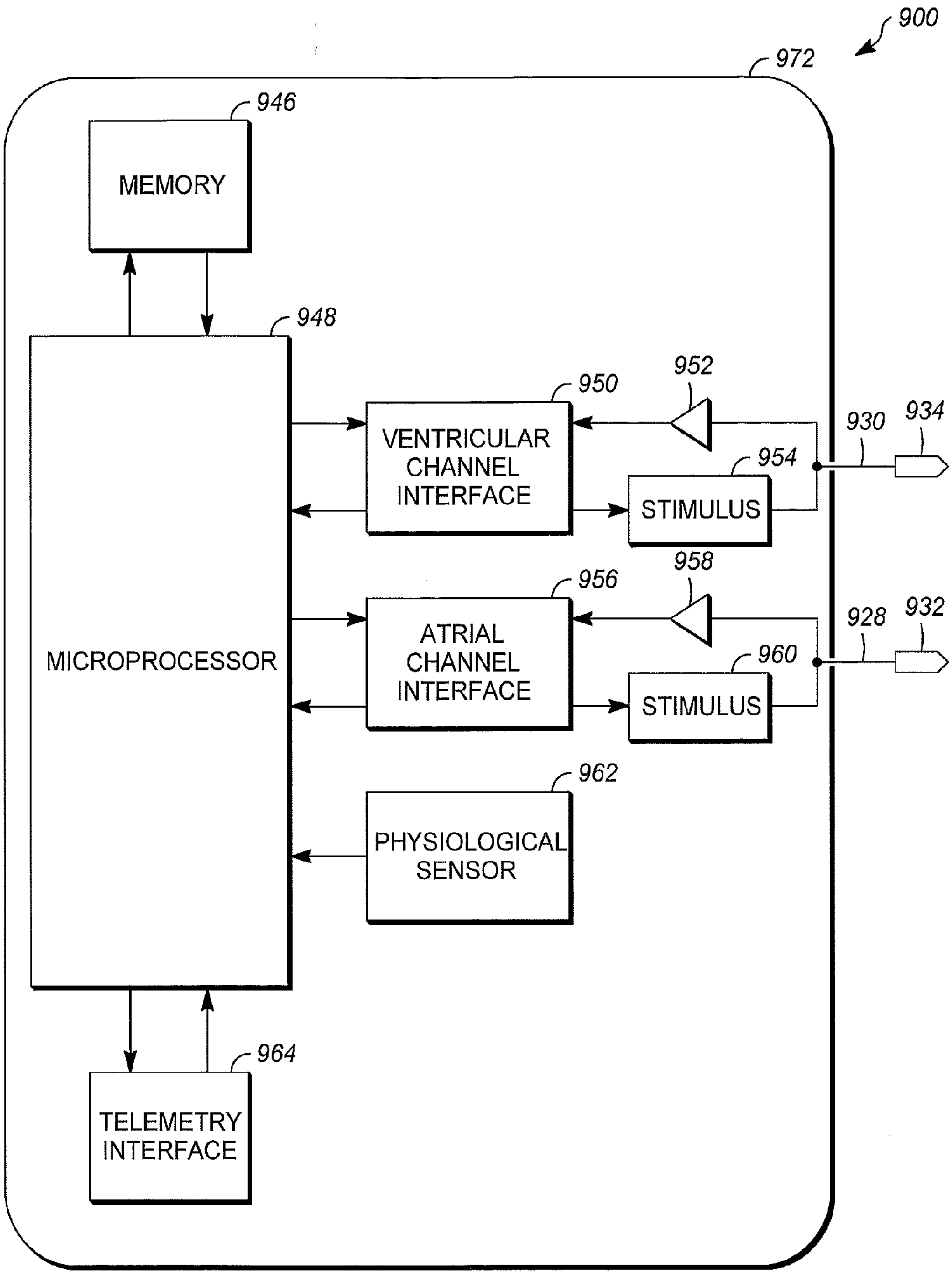

900
972
946
MEMORY
948
MICROPROCESSOR
950
VENTRICULAR CHANNEL INTERFACE
952
954
STIMULUS
930
934
956
ATRIAL CHANNEL INTERFACE
958
960
STIMULUS
928
932
962
PHYSIOLOGICAL SENSOR
964
TELEMETRY INTERFACE

FIG. 13

SYSTEMS AND METHODS TO IDENTIFY CARDIAC DYSYNCHRONY

[0001] This application claims the benefit of U.S. Provisional Application No.

[0002] **61/756,835**, filed Jan. **25**, **2013**, the contents of which are herein incorporated by reference.

FIELD OF THE INVENTION

[0003] The current technology generally relates to programming of medical devices. More specifically, the current technology relates to systems and methods of identifying and communicating appropriate programming parameters in implantable medical devices (IMDs).

BACKGROUND

[0004] Implantable medical devices (IMDs) can be used to provide pacing therapy to patients who have cardiac rhythm problems. For example, an implanted cardiac rhythm management (CRM) device can be used to provide pacing therapy to a patient with sinus node dysfunction, where the heart fails to properly initiate depolarization waves, or an atrio-ventricular conduction disturbance, where the conduction of depolarization waves through the heart tissue is impaired.

[0005] At each follow-up appointment with a patient with an IMD such as a CRM, the clinician reviews information on multiple screens and reports, analyzes the information and determines which parameters are most appropriate for the IMD. Currently, some patient management systems can provide system recommendations of programming parameters based on patient-specific medical data including sensor data. Physicians would benefit from systems that identify specific patient indications and conditions and determine whether the IMD is programmed appropriately for the patient indications and conditions.

SUMMARY OF THE INVENTION

[0006] In one embodiment, a method includes identifying a patient condition, where the patient condition includes the patient's cardiac dysynchrony at intrinsic rates higher than a threshold using an implantable medical device. The method further includes notifying a clinical user of the identified condition. The method further includes identifying a therapy appropriate for the identified condition.

[0007] In another embodiment a system includes an implantable medical device configured to collect cardiac data from a patient and a device comprising a user interface and capable of communication with the implantable medical device to collect the cardiac data. The system is configured to program the implantable medical device, to identify a patient condition comprising cardiac dysynchrony at intrinsic rates higher than a threshold using the cardiac data, and notify a clinical user of the identified condition using the user interface.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The invention may be more completely understood and appreciated in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings.

[0009] FIG. **1** is a schematic diagram of an exemplary implementation of a cardiac rhythm management (CRM) system, including an implanted CRM device, a programming device, and a patient management computer system, consistent with at least one embodiment of the technology disclosed herein.

[0010] FIG. **2** is a schematic diagram of another exemplary implementation of a cardiac rhythm management (CRM) system, including an implanted CRM device, a remote programming device, a programming device, and a patient management computer system, consistent with at least one embodiment of the technology disclosed herein.

[0011] FIG. **3** is a flow chart depicting one method consistent with the technology disclosed herein.

[0012] FIGS. **4-11** are example screenshots of a programming device consistent with the technology disclosed herein.

[0013] FIG. **12** is a schematic diagram of an implementation of the components of a programming device or user interface, in accordance with various embodiments.

[0014] FIG. **13** is a schematic view of components of an implantable medical system in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

[0015] The technology disclosed herein relates generally to a medical device system for use with patients having an implantable medical device. The system identifies a patient condition to a clinical user of the system. The system uses information from the implantable medical device, such as cardiac data, to identify the patient condition. The system notifies the clinical user of the system of the identified patient condition. The system also identifies a therapy appropriate for the identified condition.

[0016] Many patients with CRM devices have been provided with those devices to treat bradycardia, where the heart beats more slowly than normal, causing the heart to not pump enough blood to meet the body's needs. There are also many other reasons that patients can benefit from a CRM device. CRM devices are programmed to operate within a particular beat rate or heart rate (HR) range including a particular upper rate limit (URL) or maximum tracking rate (MTR). The MTR is the maximum heart rate at which the CRM will pace the heart. Often the MTR is selected conservatively and so is lower than a rate that the patient's heart would otherwise achieve during certain circumstances. The rate that the heart can achieve without pacing is referred to as the intrinsic rate. The actual proper HR range for the patient may well extend above that initially programmed. This being the case, the CRM device may repeatedly reach the URL or MTR because of naturally occurring sinus rhythms. If the CRM device does not provide the patient with a high enough HR, the patient may experience cardiac dysynchrony, where the activation of different parts of the heart is not properly timed. In a normally functioning heart, the atrium contracts to fill the ventricle while the ventricle is relaxed, so that the ventricle fills before it contracts and pumps blood out of the heart. However, when this natural synchronization does not occur, the atrium may be pumping at a faster rate than the ventricle is being paced to pump at, and as a result the ventricle is not being properly filled and less blood is delivered to the body. One way to address the issue of cardiac dysynchrony for some patients is to increase the maximum tracking rate.

[0017] As discussed above, at each follow-up appointment with a patient with an IMD such as a CRM, the clinician reviews information on multiple screens and reports, analyzes the information and determines which parameters are most appropriate for the IMD. The system described herein can identify patient conditions to the clinician, such as cardiac dysynchrony, at these follow up appointments, or at other times, and can also provide an appropriate therapy option. Some current systems are configured to recommend CRM programming parameters to a user, usually based on default settings, but the inventors are not aware of systems in use that identify patient conditions and notify the clinician of the patient condition. As used herein, a condition is a diagnosis or symptom.

[0018] While this technology can be applied to a variety of medical systems, including non-implantable devices, the implementation described herein will be with regard to implantable medical devices, particularly cardiac devices.

Medical Device Details

[0019] FIG. **1** is a schematic of an exemplary cardiac rhythm management (CRM) system **100**, consistent with at least one embodiment of the technology disclosed herein. The system **100** can include an implantable medical device **114** disposed within a patient **112**. The implantable medical device **114** can include pacing functionality. The implantable medical device **114** can be of various types such as, for example, a cardiac resynchronization pacemaker or cardiac resyncronization defibrillator device, or the like. In some embodiments, the implantable medical device **114** can include one or more leads **122** disposed in or near the patient's heart **126**. In some embodiments, the implantable medical device does not include leads. In one embodiment, the implantable medical device does not include leads and is configured to be implanted just below the patient's skin and provide electrical impulses to stimulate the heart.

[0020] The implantable medical device **114** can include one or more implantable sensors in order to gather patient **112** data. For example, the implantable medical device **114** can include an activity level sensor which can be an accelerometer, a respiration sensor, a blood pressure sensor, and/or other sensors.

Programming Device Details

[0021] The implantable medical device **114** can be in communication with a programming device **116** or user interface. The programming device **116** is also in communication with the implantable sensor of the implantable medical device **114**, and/or one or more other implantable sensors. In some embodiments, communication between the implantable medical device **114** and the programming device **116** can be via inductive communication through a wand **110** held on the outside of the patient **112** near the implantable medical device **114**. However, in other embodiments, communication can be carried out via radiofrequency transmission, acoustically, or the like. The implantable medical device **114** can be configured to store data over a period of time and periodically communicate with the programming device **116** in order to transmit some or all of the stored data.

[0022] The programming device **116** can be for example, a programmer, a programmer/recorder/monitor device, a computer, an advanced patient management system, a personal digital assistant (PDA), or the like. A programming device is one example of a user interface. As used herein, the term programming device **116** refers to a device that programs implanted devices and records data from implanted devices. The programming device may also allow monitoring of the implanted device. Exemplary programmer/recorder/monitor devices include the Model 3120 Programmer, available from Boston Scientific Corporation, Natick, Mass. The programming device **116** can include a user interface such as a keyboard **120**, a mouse **128**, a touch screen, or more than one such device to receive user input. The programming device **116** can also include a video output channel and a user interface such as a video display **118** for displaying videos, user prompts, device operation parameters, settings, recommendations, and the like. In addition, the video display **118** can also be equipped with a touch screen, making it into a user input device as well.

[0023] The programming device **116** can display real-time data and/or stored data graphically, such as in charts or graphs, and textually through the user interface screen. The programming device **116** can display parameters associated with the medical device **114**. Parameters associated with the medical device **114** can be device operational parameters, patient indications relevant to the medical device **114**, and the like. In at least one embodiment, the parameters associated with the medical device **114** can include system-recommended parameters that are formulated by the system. In addition, the programming device **116** can prompt a user for particular data. In addition, the programming device **116** can also notify a clinical user of an identified patient condition, such as the patient's cardiac dysynchrony. The notification can be in the form of an alert on the programming device screen **118**, a sound, a text display, or a combination of these. The programming device **116** can also display options for a therapy appropriate for the identified condition. The programming device **116** can display one or more selectable options for a therapy appropriate for the identified condition and can receive input from the clinical user selecting one of the options.

[0024] The programming device can also display a rationale for the conclusion that a condition has been identified. Also, in response to an input to turn off or inappropriately modify the therapy appropriate for the condition, the programming device **116** can deliver an alert to a user communicating that the requested modification is inappropriate for the identified condition.

[0025] The programming device **116** can input and store a user's response to the various programming prompts. The programming device **116** can also display indications of system confidence levels relative to particular data or operation parameters based on a variety of factors including sensor reliability, age of a patient's electronic files, past accuracy of the data or operation parameters, and the like. The programming device can also display guidance to a user regarding data accuracy.

[0026] In various embodiments, the programming device **116** is in communication with a patient management system **132**. The patient management system **132** can additionally be in communication with electronic patient medical records in a variety of embodiments. The communication link **130** between the programming device **116** and the patient management system **132** may be via phone lines, the Internet, or any other data connection. In another embodiment, the programming device **116** is not in direct communication with a patient management system **132**, but can be in indirect communication with the patient management system **132**. In another embodiment, the programming device is not in communication with a patient management system **132**.

[0027] The programming device **116** is capable of changing the operational parameters of the medical device **114**, and is therefore referred to as a programmer. Typically, programmers are used to interface with medical devices in a clinic or hospital setting. In this context, the user of the programming device **116** is a clinician, physician or trained technician.

Remote Programming Embodiment

[0028] Now referring to FIG. **2**, a CRM system **200** is illustrated which is designed for use when the programming device **116** and the patient **112** are in different locations, so that the programming device **116** is remote from the patient **112** and not physically present in the same space as the patient **112**. For example, the patient **112** may be at his or her home while the clinician and the remote programming device is at a hospital which is a few miles away or hundreds of miles away. Like reference numbers between FIG. **1** and FIG. **2** indicate like elements. In the CRM system **200** of FIG. **2**, a remote programming device **210** is in the patient **112** location and establishes communication with the implantable medical device **114**. Communication between the remote programming device **210** and the implantable medical device **114** can be carried out by radiofrequency transmission, acoustically, or by inductive communication using a wand held on the outside of the patient **112** near the device **114**.

[0029] The remote programming device **210** is in communication with a local programming device **116**. The communication link **230** between the local programming device **116** and the remote programming device **210** may be via phone lines, the Internet, or any other data connection. Other details of the programming device **116** and the implantable medical device **114** are similar to as described with respect to FIG. **1**. Whenever configurations and capabilities of a programming device are described herein, those same features can be found in the combination of a remote programming device **210** and a local programming device **116**.

Method Description

[0030] FIG. **3** is a flow chart depicting one method consistent with the technology disclosed herein. The system receives data **310**, identifies a condition of a patient **320** such as cardiac dysynchrony, notifies or displays to a clinical user of the system of the identified condition **330**, identifies to the clinical user a therapy appropriate for the identified condition **340**, and presents the clinical user with a selectable option to implement the therapy **350**.

[0031] Generally, the system can receive data **310** from a variety of sources. An implantable medical device and any implantable sensors can provide data including device operation parameters, patient indications, event counters, and any other data from the implantable medical device and/or from the implantable sensors. Examples of patient data available from a CRM device can include heart rate variability data, cardiac output data, minute ventilation data, accelerometer data, a Wenckebach counter value and other data.

[0032] The implantable medical device can also provide data regarding the programming parameters that are in use at that moment in time and in the past, such as the maximum tracking rate, and many other parameters.

[0033] The system can receive data from electronic medical records. The electronic medical records can include patient medical records, historical implantable medical device operation parameters, indications read or calculated from electronic charts and electronic medical records, user-entered indications, episodes, and trends in patient indications, as examples. The system can also receive data from a clinician. Such data can include patient symptom data or information, operation parameters, and the like.

[0034] In different embodiments, it is possible for different components of the system to carry out the steps of FIG. **3** and other steps described herein. In one embodiment, a programming device is capable of carrying out all of the steps of FIG. **3** and other steps described herein. In one embodiment, a patient management system is configured to issue an alert to the clinical user. In one embodiment, the patient management system is configured to receive data **310**, identify a condition of a patient **320** such as cardiac dysynchrony, notifies or displays to a clinical user of the system of the identified condition **330**, and identifies to the clinical user a therapy appropriate for the identified condition **340**.

[0035] In one embodiment, the implantable medical device performs the detection algorithm. In this embodiment, the implantable medical device is configured to identify a condition of a patient **320** such as cardiac dysynchrony and notify or display to a clinical user of the system of the identified condition **330** using communication with a programming device or patient management system. In one embodiment, the implantable medical device is configured to identify a therapy appropriate for the identified condition **340**, and can prompt a programming device or a patient management system to provide that information to the clinical user.

[0036] The system can identify cardiac dysynchrony in step **320** in a number of different ways.

Heart Rate Variability Data

[0037] An example of a technique to identify cardiac dysynchrony is by analyzing heart rate variability data and determining from the heart rate variability data that cardiac synchrony requires a heart rate that is greater than at least one of a programmed maximum tracking rate, maximum sensor rate and maximum pacing rate in a CRM device. Cardiac Resynchronization Therapy (CRT) devices may utilize both programmed maximum sensor and maximum tracking rates depending on the programming mode. If a device if programmed to VVIR, then the maximum sensor rate is applicable but the maximum tracking rate is not. If the device is programmed to DDD, then maximum tracking rate is applicable but maximum sensor rate is not. If the mode is DDDR, then both maximum tracking rate and maximum sensor rate are applicable.

[0038] In CRT devices, circuitry is provided for both sensing atrial and ventricular depolarization events and for pacing one or both of atrial and ventricular tissue. These CRM devices can keep a count of sensed atrial depolarizations. The counting module can be referred to as an A-sense counter. Each A-sense event can be recorded in a category according to what the patient's heart rate was at the time of the atrial contraction based on examining the atrial contractions. Also, the CRM device can track and categorize each left ventricular pace event (LV-pace), recording each LV-pace in a category according to what the patient's heart rate was at the time of the LV-pace based on examining the ventricular pacing. An example of a screen **400** displaying this type of rate count data or heart rate variability data is shown in FIG. **4**. The rate categories are listed in the column **410** titled "Rate (bpm)" and in this example, indicates the heart rate within a 10 bpm range. Selection buttons **420** and **421** allow the user to select whether to view atrial rate counts, ventricular rate counts or left ventricular rate counts for pacing and sensing. On screen

400, atrial is selected for sensing and left ventricular is selected for pacing. As a result, the screen **400** displays sensed atrial rate counts and paced left ventricular counts. The column **422** titled "LV Paced" displays the count for left ventricular pacing while the column **424** titled "A Sensed" shows the count for sensed atrial contractions.

[0039] In one embodiment, the identification algorithm compares the A-sense counts above the maximum tracking rate to the number of A-sense counts and LV-pace counts that are close to the maximum tracking rate. For example, for a maximum tracking rate of 130 paces per minute (ppm), the method would identify the number of V-pace counts around the MTR and the number of A-sense counts around and above MTR (130 bpm).

[0040] The method would also gather information about the number of LV-pace counts that are close to the upper limit of 130 ppm. In one example algorithm where MTR is programmed to 130 ppm with 1:1 tracking, if the sum of A-sense between 110 and 140 bpm is at least 15% greater than the sum of the LV-pace beats between 110 and 140 bpm, and at least 85% of the sum of the A-sense beats between 110 and 150 bpm, then the system would suggest considering raising the MTR to 140 ppm.

[0041] In gathering the number of A-sense counts, no premature atrial contractions (PACs) should be counted in the total. If the number of A-sense counts gradually decreases at heart rates below and above MTR, then the MTR will be recommended to be increased. In one example shown in FIG. **4**, MTR is 130 ppm, and over a rate range below and above MTR, such as 110-150 bpm and the A-sense counts gradually decrease: 110 bpm (4000), 120 bpm (2000), 130 bpm (1600), 140 bpm (1200), 150 bpm (900). In this situation, the MTR will be recommended to be increased. If the number of A-sense counts above the MTR is higher than the number of A-sense counts near the MTR, then the maximum tracking rate will be recommended to be unchanged.

[0042] In a typical patient, heart rate variability usually increases, spikes and then consistently degrades as the heart rate increases. This is consistent with the example shown in FIG. **4**. There may be A-Sense counts over 180 ppm but they should not be counted, similar to the rule for not counting PACs, since these may occur for reasons unrelated to exercise or other causes for increasing heart rate. In the example of FIG. **4**, the maximum LV-Pace is at the MTR of 130 ppm. The number of A-sense counts above 130 bpm (about 2500 counts) is higher than the number of A-sense counts near 130 bpm (about 1600 counts). The combined total of A-sense counts 2500 and 1600 are about the same as the V-pace total (4100) at MTR. As a result, the MTR could be raised a little higher to allow the left ventricle to be paced at a higher rate and thereby achieve greater synchrony with the atrial activity.

Cardiac Output

[0043] In another example of a method for identifying cardiac dysynchrony, the CRM device determines the cardiac output and analyzes the result to see if it is too low. The cardiac output is the stroke volume multiplied by the heart rate. There are many different methods for using the CRM device to determine the cardiac output, such as the methods described in U.S. Pat. No. 5,190,035 to Salo et al. which use intrathoracic impedance. Other methods involve determining an aortic flow using Doppler shifting or by using perfusion sensors or other invasive and non-invasive techniques.

[0044] If cardiac output is too low according to the notification algorithm for cardiac dysynchrony, the user is notified that the patient has a lack of cardiac synchrony.

Notifying a Clinical User, Identifying a Therapy and Presenting a Therapy

[0045] Again referring to FIG. **3**, the system notifies the clinical user of the identified condition in step **320**, identifies a therapy appropriate for the identified condition at step **340** and presents the clinical user with a selectable option to implement the therapy at step **350**. FIGS. **5-11** show examples of a group of screen shots that can be used to accomplish these steps. Screen **500** of FIG. **5** shows an initial screen of a programming device. A summary dialog box **510** is presented to the user before providing access to the programming functions. The summary dialog box **510** includes a notification **512** of detected indications and conditions, and states "Cardiac Dysynchrony at Intrinsic Rates above 130 bpm" to indicate that this condition is present in the patient.

[0046] The summary dialog box **510** also includes an event notification **514**. In the example of FIG. **5**, the event notification **514** states that there have been no significant episodes. In other situations, the event notification "VF Therapy" may appear indicating that the patient has received therapy from the IMD for ventricular fibrillation. The event notification "VT Therapy" may appear indicating that the patient has received therapy from the IMD for ventricular tachycardia. The notification may indicate the zone in which the device detects therapy. The event notification "VT-1 Therapy" may appear indicating that the patient has received therapy for ventricular therapy in the VT-1 zone. The event notification "Atrial Episodes>48 hours" may appear indicating Atrial episodes lasting longer than 48 hours. The event notification "Non-Sustained Episodes" may appear indicating that episodes have occurred but that they were of a non-sustained nature.

[0047] The summary dialog box **510** also includes a battery notification **516**. In one example, battery notification **516** states a timeframe until the end of the battery life or until device removal or explant is recommended. The summary dialog box **510** also includes a lead notification **518**, such as a statement that all lead measurements are in range or a warning that a lead may be damaged. The summary dialog box **510** also includes a button **520** user input so that the user can acknowledge having viewed the notifications.

[0048] By clicking "Close" on the button **520**, the user closes the summary dialog box **510** and views other programming device screens. For example, the user can next view screen **600** shown in FIG. **6**, which displays the summary tab **610** of the programming device. The summary tab **610** includes a notification **620** of a detected patient indication or condition, in this example stating "Cardiac Dysynchrony at Intrinsic Rates above 130 bpm." A condition explanation button **630** is displayed as a part of the notification **620**, and allows the user to get more information about the notification **620**. A graphic is included on the condition explanation button **630**, such as a magnifying glass, which indicates that further information can be obtained.

[0049] At the bottom edge of FIG. **6**, many options for actions by the system or information from the system are presented to the user in the form of interactive buttons, including Utilities, Reports, Interrogate, View Changes, Program, Parameter/Alert Status (such as OK, Warning, Attention, Suggestion) and End Session. When the system has a suggestion for programming for the user that has not yet been adopted, the Suggestion button **635** is brought to the attention of the user with the use of a symbol and a special color, such as yellow, which is indicated in FIG. **6** with cross-hatching of the Suggestion button **635**.

[0050] If the user selects the condition explanation button **630**, the system displays screen **700** of FIG. **7** which provides a statement of the condition and provides a rationale for why the system concluded that the patient has the condition cardiac dysynchrony at intrinsic rates above 130 bpm in the screen portion **710**. In the example of FIG. **8**, the screen portion **710** states under the heading Detected Indications and Conditions, "Cardiac Dysynchrony at intrinsic rates above 130 bpm." In other examples, the screen portion **710** states under the heading Detected Indications and Conditions, "Cardiac Dysynchrony at intrinsic rates above MTR."

[0051] In the example of FIG. **8**, the screen portion **710** states as a rationale, "Programmed MTR=130 bpm" and "There is a significant number of intrinsic rates above the MTR that are not providing resynchronizing therapy." In another embodiment, the screen portion **710** instead states as a rationale, "There is a significant number of intrinsic rates above 130 ppm that are not providing resynchronizing therapy."

[0052] Screen **700** also includes an indications-based programming button **720** which the user can select to see selected indications and programming recommendations. Screen **700** also includes a checkbox **730** giving the user the option to improve the identified indication or condition, thereby providing the user with a selectable option to implement therapy appropriate to address the identified condition.

[0053] Screen **780** of FIG. **8** is one example of an indications-based programming display **782** where patient indications and conditions can be viewed, selected and unselected. A notification **784** of detected indications and conditions is displayed, and in this example the notification states, "Improve the Cardiac Dysynchrony at Intrinsic Rates above 130 bpm" alongside a checkbox **786**. The checkbox **786** is in a checked state to indicate that the system has detected the condition of cardiac dysynchrony at intrinsic rates above 130 bpm using an identification algorithm. The user can uncheck the checkbox **786** if the user has reached a different conclusion about the patient condition or does not want the system to present options for fixing or improving the patient condition or indication. The checkboxes and buttons described herein are all types of user input devices, and many different user input devices may be substituted for those described herein.

[0054] Screen **780** also includes a detected indications and conditions label and button **788** which allows a user to return to the more detailed information about of the patient's indications and conditions and the rationale for the detected indications and conditions of screen **700** of FIG. **7**. Also, a view recommended settings label and button **790** provides a selectable option for the user to view the specific parameter settings that are recommended by the system to address the particular patient indications and conditions.

[0055] In one example, the system recommends that an MTR value that is higher than the current MTR value be programmed for the CRM device to address the patient's cardiac dysynchrony at intrinsic rates higher than a threshold. If the user selects the "View Recommended Settings" button **790** of FIG. **8**, then screen **900** of FIG. **9** is displayed. In screen **900**, a summary of proposed settings **910** is provided including setting the MTR to be 140 paces per minute instead of 130 paces per minute as it was previously programmed as shown at the Summary of Patient Information Screen **700**. In screen **900**, the user is also presented with a Program this Profile button **912** and a Reject this Profile button **914** to allow programming or rejecting the proposed settings to the implantable medical device.

[0056] Other options also exist in the programming screens of FIGS. **5-11** to obtain more detailed information about the recommended setting changes. For example, by selecting the Suggestion button **635** of FIGS. **6-8**, the user is brought to a summary of those parameters which can be modified to improve the identified condition. FIG. **10** provides an example of such a screen **1000**, showing the Normal Brady Maximum Sensor Rate **1002** and the Normal Brady Maximum Tracking Rate **1004** at their programmed values of 130 ppm. Screen **1000** also shows a warning symbol **1006** indicating that the system has a different suggestion for these parameters.

[0057] If the user selects any of the Fix Other buttons **1008**, **1010** on the screen, the user is presented with screen **1100** of FIG. **11**, providing Resolved Parameter Recommendations parameters. Screen **1100** of FIG. **11** shows that the current values for MSR and MTR are 130 ppm, but the suggested values are 140 ppm. The user has the option to accept the suggested parameter changes by selecting button **1108** or cancel the changes using button **1110**.

[0058] In one example, in response to an input to turn off or inappropriately modify the therapy appropriate for the condition, the system delivers an alert to a user communicating that the existing therapy is appropriate for the identified condition. This alert can come in the form of the Suggestion button **635** being active and being presented to the user and brought to the user's attention with the color yellow, another color, a special symbol or more than one of these techniques. When the user presses the Suggestion button **635**, the screen **1000** of FIG. **10** identifies to the user the parameters that are in conflict with the system's suggestions. When the user has accepted the suggested parameters, the Suggestion button **635** can become a dimmed OK button as shown in FIG. **9**

[0059] FIGS. **5-11** show how the system communicates a treatment recommendation that conveys device operation parameters. Generally, the system makes a treatment recommendation based on data available to the system. The treatment recommendations will generally be consistent with recent patient indications and other data available to the system. The treatment recommendations can be communicated to a system user through a user interface, such as displayed on a screen. Other parameters associated with the medical device and the treatment recommendations can also be communicated to a system user. Each treatment recommendation can have a system confidence level associated therewith.

[0060] The system confidence level can be based on a variety of factors associated with the data, such as the reliability of a data source, historical patient data including event occurrences, past incorrectness of treatment recommendations, conflicting data, and so on. In a variety of embodiments the system provides an indication of the system confidence level of the treatment recommendations to the user, which can be expressed in a variety of ways including a percentage or number value, color code, text and so on. The treatment recommendations can be displayed for the caretaker on a user interface, who may decide to select or override one or more parameters.

[0061] The system can receive the clinical user's therapy selection through a variety of user interface devices such as a keyboard, touch screen, mouse, microphone, combinations thereof, and so on.

[0062] If the clinical user's therapy selection conflicts with system data, the system can display a notice to provide information to the user. The notice can be a warning indicating that the chosen treatment is not consistent with patient indications. The warning can also notify the system user of data that is in conflict with the therapy selection, or provide another explanation of the inconsistency. The system can also provide the user with rationale associated with the recommended parameter.

Programmer Hardware

[0063] Programming devices can include components common to many computing devices. Referring now to FIG. **12**, a diagram of various components is shown in accordance with some embodiments of the invention. However, it is not required that a programming device have all of the components illustrated in FIG. **12**.

[0064] In one embodiment, the programming device includes a central processing unit (CPU) **805** or processor, which may include a conventional microprocessor, random access memory (RAM) **810** for temporary storage of information, and read only memory (ROM) **815** for permanent storage of information. A memory controller **820** is provided for controlling system RAM **810**. A bus controller **825** is provided for controlling data bus **830**, and an interrupt controller **835** is used for receiving and processing various interrupt signals from the other system components.

[0065] Mass storage can be provided by diskette drive **841**, which is connected to bus **830** by controller **840**, CD-ROM drive **846**, which is connected to bus **830** by controller **845**, and hard disk drive **851**, which is connected to bus **830** by controller **850**. User input to the programmer system may be provided by a number of input devices **834**. For example, a keyboard, touch screen, mouse, or more than one of these, can connected to bus **830** by input device controller **855**. DMA controller **860** is provided for performing direct memory access to system RAM **810**. A visual display is generated by a video controller **865** or video output, which controls video display **870**. The external system can also include a telemetry interface **890** or telemetry circuit which allows the external system to interface and exchange data with an implantable medical device. It will be appreciated that some embodiments may lack various elements illustrated in FIG. **12**.

Implantable Device Hardware

[0066] Referring now to FIG. **13**, some components of an exemplary implantable system **900**, such as an implantable CRM device, are schematically illustrated. The implantable medical system **900** can include an implantable medical device **972** coupled to one or more stimulation leads **930** and **928**. The implantable device **972** can also include other sensors such as an activity sensor **962**.

[0067] The implantable device can include a microprocessor **948** (or processor) that communicates with a memory **946** via a bidirectional data bus. The memory **946** typically comprises ROM or RAM for program storage and RAM for data storage. The implantable device can be configured to execute various operations such as processing of signals and execution of methods as described herein. A telemetry interface **964** is also provided for communicating with an external unit, such as a programmer device or a patient management system.

[0068] The implantable device can include ventricular sensing and pacing channels comprising sensing amplifier **952**, output circuit **954**, and a ventricular channel interface **950** which communicates bidirectionally with a port of microprocessor **948**. The ventricular sensing and pacing channel can be in communication with stimulation lead **930** and electrode **934**. The implantable device can include atrial sensing and pacing channels comprising sensing amplifier **958**, output circuit **960**, and an atrial channel interface **956** which communicates bidirectionally with a port of microprocessor **948**. The atrial sensing and pacing channel can be in communication with stimulation lead **928** and electrode **932**. For each channel, the same lead and electrode can be used for both sensing and pacing. The channel interfaces **950** and **956** can include analog-to-digital converters for digitizing sensing signal inputs from the sensing amplifiers and registers which can be written to by the microprocessor in order to output pacing pulses, change the pacing pulse amplitude, and adjust the gain and threshold values for the sensing amplifiers.

[0069] It should be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise. It should also be noted that the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

[0070] It should also be noted that, as used in this specification and the appended claims, the phrase "configured" describes a system, apparatus, or other structure that is constructed or configured to perform a particular task or adopt a particular configuration. The phrase "configured" can be used interchangeably with other similar phrases such as "arranged", "arranged and configured", "constructed and arranged", "constructed", "manufactured and arranged", and the like.

[0071] One of ordinary skill in the art will understand that the modules, circuitry, and methods shown and described herein with regard to various embodiments of the invention can be implemented using software, hardware, and combinations of software and hardware. As such, the illustrated and/or described modules and circuitry are intended to encompass software implementations, hardware implementations, and software and hardware implementations.

[0072] All publications and patent applications in this specification are indicative of the level of ordinary skill in the art to which this invention pertains. All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated by reference.

[0073] This application is intended to cover adaptations or variations of the present subject matter. It is to be understood that the above description is intended to be illustrative, and not restrictive. The scope of the present subject matter should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

We claim:

1. A method comprising:

identifying a patient condition comprising cardiac dysynchrony at intrinsic rates above a threshold using an implantable medical device;

notifying a clinical user of the identified condition; and

identifying a therapy appropriate for the identified condition.

2. The method of claim **1** further comprising presenting the clinical user with a selectable option to implement the therapy appropriate for the identified patient condition.

3. The method of claim **1**, further comprising, in response to an input to enable, disable or modify the therapy appropriate for the condition, delivering an alert to a user communicating that the requested modification is inappropriate for the identified condition.

4. The method of claim **1**, wherein identifying the condition comprises detecting a cardiac condition using a cardiac rhythm management device.

5. The method of claim **1**, wherein notifying a clinical user of the identified condition comprises presenting an alert on a programmer.

6. The method of claim **1**, wherein the threshold for intrinsic rates is the maximum tracking rate.

7. The method of claim **1**, where identifying the cardiac dysynchrony comprises analyzing heart rate variability data and determining from the heart rate variability data that cardiac synchrony requires a heart rate that is greater than at least one of a programmed maximum tracking rate, a programmed maximum sensor rate and a programmed maximum pacing rate in a cardiac rhythm management device.

8. The method of claim **1** where identifying the cardiac dysynchrony comprises analyzing cardiac output data and determining from the cardiac output data that cardiac synchrony requires a heart rate that is greater than at least one of a programmed maximum tracking rate, a programmed maximum sensor rate and a programmed maximum pacing rate in a cardiac rhythm management device.

9. The method of claim **1** further comprising receiving data comprising at least one of patient symptom data, electronic medical record data and current programming parameters for the implantable medical device.

10. The method of claim **1** wherein notifying the clinical user of the identified condition further comprises displaying a rationale for the conclusion underlying the identified condition.

11. A system for identifying a patient condition comprising:

an implantable medical device configured to collect cardiac data from a patient;

a device comprising a user interface and capable of communication with the implantable medical device to collect the cardiac data, wherein the system for identifying a patient condition is configured to program the implantable medical device, to identify a patient condition comprising cardiac dysynchrony at intrinsic heart rates over a threshold using the cardiac data, and notify a clinical user of the identified condition using the user interface.

12. The system of claim **11** wherein the device is further configured to identify a therapy appropriate for the identified condition.

13. The system of claim **11** wherein the device is a programming device and is further comprising to present the clinical user with a selectable option to implement the therapy appropriate for the identified condition on the user interface.

14. The system of claim **13**, the programming device further configured to, in response to an input to turn off or modify the therapy appropriate for the condition, deliver an alert to a user communicating that the requested change in therapy is inappropriate for the identified condition.

15. The system of claim **11** wherein the threshold for intrinsic rates is the maximum tracking rate.

16. The system of claim **11** wherein the device is configured to analyze heart rate variability data and determining from the heart rate variability data that cardiac synchrony requires a heart rate that is greater than at least one of a programmed maximum tracking rate, a programmed maximum sensor rate and a programmed maximum pacing rate in a cardiac rhythm management device in order to identify cardiac dysyncrony.

17. The system of claim **11** wherein the device is configured to analyze cardiac output data and determine from the cardiac output data that cardiac synchrony requires a heart rate that is greater than at least one of a programmed maximum tracking rate, a programmed maximum sensor rate and a programmed maximum pacing rate in a cardiac rhythm management device in order to identify cardiac dysynchrony.

18. The system of claim **11** wherein the device is configured to receive data comprising at least one of patient symptom data, electronic medical record data and current programming parameters for the implantable medical device.

19. The system of claim **11** wherein the device is configured display a rationale for the conclusion underlying the identified condition.

20. The system of claim **11** wherein the device is one of a patient management system, a programming device and a remote programming device.

* * * * *

专利名称(译)	识别心脏不同步的系统和方法		
公开(公告)号	US20140213859A1	公开(公告)日	2014-07-31
申请号	US14/163087	申请日	2014-01-24
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器，INC.		
当前申请(专利权)人(译)	心脏起搏器，INC.		
[标]发明人	GILKERSON JAMES O HOYME KENNETH P KALGREN JAMES R PERSCHBACHER DAVID L PETERSON LES N		
发明人	GILKERSON, JAMES O. HOYME, KENNETH P. KALGREN, JAMES R. PERSCHBACHER, DAVID L. PETERSON, LES N.		
IPC分类号	A61B5/024 A61B5/07 A61B5/00		
CPC分类号	A61B5/02405 A61B5/746 A61B5/4836 A61B5/7475 A61B5/7282 A61B5/076 A61B5/686 A61N1/3627		
优先权	61/756835 2013-01-25 US		
其他公开文献	US9357935		
外部链接	Espacenet USPTO		

摘要(译)

当前技术与具有可植入医疗设备的系统相关，其中该系统被配置为识别包括心脏不同步的患者状况，被配置为向临床用户通知所识别的状况并且被配置为识别适合于所识别的状况的治疗。