Medtronic

AZURE™ MRI SURESCAN™ / ASTRA™ MRI SURESCAN™

 MR Conditional implantable pacemakers with SureScan™ technology

Reference Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

AZURE™ MRI SURESCAN™ / ASTRA™ MRI SURESCAN™

Reference Manual

A reference manual for the Azure™ MRI SureScan™ and Astra™ MRI SureScan™ families of implantable pacemakers

Contents

1   Introduction

1.1 About the product literature

This manual describes the operation and intended use of features offered by the Medtronic Azure MRI SureScan and Astra MRI SureScan families of dual and single chamber MR Conditional pacemakers.

Throughout this manual, the word "device" refers to the implanted pacemaker.

Unless otherwise noted, all device features described in this manual apply to Azure XT DR MRI SureScan devices. To determine which features are available for another model in the Azure MRI SureScan or Astra MRI SureScan family, refer to Section 1.2, "Device features per model", page 8. Any references in this manual to atrial or dual chamber operation apply to dual chamber devices only. Single chamber devices provide ventricular operation only.

The report images, button labels, and navigation instructions in this manual apply to the Medtronic Model SW030 software running on a Medtronic CareLink Model 2090 Programmer or a Medtronic CareLink Encore Model 29901 Programmer. The details of the user interface are provided for reference only and may not match those of other applications.

The names of on-screen buttons are shown within brackets: [Button Name]. Navigation paths to software screens or programmable parameters are shown with a ">" character between each step in the path (for example, Params > Additional Features… > Rate Hysteresis).

1.1.1 Product literature

Before implanting the device, it is recommended that you take the following actions:

- Read the product literature for information about prescribing, implanting, and using the device and conducting a patient follow-up session.
- Thoroughly read the technical manuals for the leads used with the device. Also read the technical manuals for other system components.
- Discuss the device and implant procedure with the patient and any other interested parties, and give them any patient information materials packaged with the device.

Additional information about the device is provided in the following documents:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Device manual – This manual contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

Programming guide – This manual explains how to use the programmer software to conduct a patient session.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

Radio regulatory compliance insert – This document provides compliance information related to the radio components of the device.

Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. The manual also provides patient education information related to sources of electromagnetic interference (EMI) at home, at work, and in other environments.

1.1.2 Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

1.2 Device features per model

The following table describes the availability of features within the Astra MRI SureScan and Azure MRI SureScan device families. Feature availability for each device model is marked with an X in the corresponding column.

Notes:

- Azure MRI SureScan devices provide wireless telemetry and Medtronic CareAlert Monitoring using a patient monitor (if available). Astra MRI SureScan devices do not provide these features.

- Only those features that vary across device model are included in the following table. All other features described in this manual are available for all Astra MRI SureScan and Azure MRI SureScan models.

Table 1. Product feature relationship

| Features | Azure MRI SureScan and Astra MRI SureScan | | | |
| | **XT DR** | **S DR** | **XT SR** | **S SR** |
	W1DR01 X1DR01	**W3DR01 X3DR01**	**W1SR01 X1SR01**	**W3SR01 X3SR01**
AT/AF Burden Observations	X	X[a]	—	—
AT/AF Detection	X	—	—	—
AT/AF Monitor	X	X	—	—
Atrial 50 Hz Burst In-Office	X	—	—	—
Atrial ATP	X	—	—	—
Atrial Preference Pacing	X	X	—	—
Atrial Rate Stabilization	X	—	—	—
Auto PVARP	X	X	—	—
Cardiac Compass	X	—	X	—
Capture Management - Atrial	X	X	—	—
Capture Management - RV	X	X	X	X
Conducted AF Response	X	—	X	—
Flashback Memory - Atrial Episodes	X	X	—	—
Flashback Memory- Ventricular Episodes	X	X	X	X
Mode Switch	X	X	—	—
Non-Competitive Atrial Pacing	X	X	—	—
Pacing modes - atrial (AAIR, AAI, AOO)	X	X	—	—
Pacing modes - dual chamber (DDDR, DDD, DDIR, DDI, DOO, ODO)	X	X	—	—
Pacing modes - MVP (AAIR<=>DDDR, AAI<=>DDD)	X	X	—	—
Pacing modes - ventricular (VVIR, VVI, VOO, OVO[b])	X	X	X	X
Patient-activated symptom log entries	X	—	X	—
PMT Intervention	X	X	—	—

Table 1. Product feature relationship (continued)

| Features | Azure MRI SureScan and Astra MRI SureScan | | | |
| | XT DR | S DR | XT SR | S SR |
	W1DR01 X1DR01	W3DR01 X3DR01	W1SR01 X1SR01	W3SR01 X3SR01
Post-Mode Switch Overdrive Pacing	X	—	—	—
PVC Response	X	X	—	—
Rate Adaptive AV	X	X	—	—
Rate Drop Response	X	X	—	—
Reactive ATP	X	—	—	—
TherapyGuide	X	X	—	—
Ventricular Rate Stabilization	X	—	X	—
Ventricular Safety Pacing	X	X	—	—

[a] AT/AF Burden Observations are available for W3DR01 devices only as clinical status alerts for the Medtronic CareAlert Monitoring feature. AT/AF Burden Observations are not available for X3DR01 devices.
[b] OVO mode is only available in single-chamber device models.

2 Patient follow-up guidelines

2.1 In-clinic follow-up appointments and remote monitoring

Schedule regular in-clinic follow-up appointments with the patient throughout the service life of the device. For patients enrolled in the Medtronic CareLink Network, remote monitoring can replace the need for some in-clinic follow-up appointments. With remote monitoring, data from a patient's implanted device is sent to the Medtronic CareLink Network, and you can review the transmitted data on the Medtronic CareLink Network website. Schedule in-clinic follow-up appointments and CareLink transmissions as follows:

- Schedule an in-clinic follow-up appointment within 72 hours of implant so that the patient can be checked for lead dislodgement, wound healing, and postoperative complications.

- Schedule an in-clinic follow-up appointment within 2–12 weeks after implant to evaluate the condition of the patient, the device, and the leads, and to verify that the device is configured appropriately for the patient.

- Schedule routine CareLink transmissions or in-clinic follow-up appointments every 3–12 months, with in-clinic follow-up appointments occurring at least annually.

- When the device battery approaches Recommended Replacement Time (RRT), schedule CareLink transmissions or in-clinic follow-up appointments every 1–3 months.

- Schedule in-clinic follow-up appointments as needed (for example, if data from a CareLink transmission indicates that the patient's device requires adjustment).

2.1.1 Remote monitoring options

Azure MRI SureScan devices provide automatic wireless remote monitoring using a Medtronic patient monitor (if available). The transmissions occur automatically at a scheduled date and time. You can schedule automatic transmissions on the Medtronic CareLink Network website. In addition, automatic, unscheduled transmissions for specific clinical or device status events are provided by the CareAlert Monitoring feature (see Section 3.2, "Medtronic CareAlert Monitoring", page 21). Patients can also send unscheduled transmissions manually.

Astra MRI SureScan devices provide remote monitoring using a Medtronic patient monitor (if available). Patients hold the monitor's telemetry head over their implanted device and initiate the transmission at the scheduled time. Patients can also send unscheduled transmissions manually.

Note: When viewing a CareLink transmission, the data collected since the last session is presented differently than it is for a programmer session. For a CareLink transmission, the last session is defined as either the last programmer session or the last CareLink transmission. During an in-clinic follow-up appointment, the programmer software defines the last session as the last programmer session.

2.1.2 Follow-up process

The process for conducting a follow-up evaluation, either during an in-clinic appointment or with a CareLink transmission, includes the following steps:

1. Review the patient's presenting rhythm.

2. Verify the status of the implanted system.

3. Verify the clinical effectiveness of the implanted system.

4. During an in-clinic follow-up appointment, adjust device parameters as necessary.

5. If evaluating data remotely, schedule an in-clinic follow-up appointment as necessary.

2.1.3 Reviewing the presenting rhythm

The presenting rhythm may indicate the presence of undersensing, far-field oversensing, or loss of capture. These are basic pacing issues that can affect the delivery of therapy. These issues can often be resolved by making basic programming changes.

Review the presenting rhythm as follows:

- During an in-clinic follow-up appointment, view the Live Rhythm Monitor and record the EGM and Marker Channel traces.

- For remote monitoring, review the EGM data that was recorded at the time of the CareLink transmission.

Viewing this information can help you identify any issues with the patient's presenting rhythm. It may be necessary to adjust the pacing parameters.

2.1.4 Verifying the status of the implanted system

Perform the following tasks to verify the status of the implanted system:

- Assess the battery status.

- Check lead measurement data.

- Review any Quick Look II Observations about the device and lead status.

2.1.4.1 Assessing the battery status

To assess the status of the device battery, review the Remaining Longevity estimate in the Quick Look II data. If the device battery has reached a replacement threshold, the associated indicator is displayed. For more detail about the battery status, including battery voltage, review the Battery and Lead Measurements data as follows:

- During an in-clinic follow-up appointment with a programmer, select the [>>] button next to the Remaining Longevity field on the Quick Look II screen.

- When evaluating a CareLink transmission, review the Battery and Lead Measurements report.

Warning: Replace the device immediately if the End of Service (EOS) indicator is displayed. The device may lose the ability to pace, sense, and deliver therapy adequately after the battery reaches End of Service.

If the Recommended Replacement Time (RRT) indicator or Elective Replacement Indicator (ERI) is displayed, or if the battery voltage is at or below the displayed RRT voltage, contact your Medtronic representative and schedule a replacement procedure with your patient. For more information about the replacement indicators, see Section 3.10, "Device and lead performance data", page 37.

2.1.4.2 Checking lead measurements and trend data

In-clinic follow-up appointment – During an in-clinic follow-up appointment, you can check the status of the implanted leads by reviewing the Impedance, Threshold, and Wave Amplitude trends on the Quick Look II screen. For a more detailed history of each measurement, select the [>>] button next to the appropriate trend graph. For more information about the automatic collection of these trends, see Section 3.10, "Device and lead performance data", page 37. If you also want to gather real-time information about the performance of the device and leads, you can perform the following tests:

- Lead Impedance Test

- Pacing Threshold Test

- Sensing Test

For more information about performing these tests, refer to the programming guide.

Evaluating a CareLink transmission – When evaluating a CareLink transmission, you can check the status of implanted leads by reviewing the most recent lead impedance, capture threshold, and sensing amplitude measurements on the Quick Look II report. Compare these values to the patient history and to the trend data provided on the Lead Trends report.

2.1.4.3 Reviewing Quick Look II Observations about the device and lead status

The Quick Look II data includes Observations that are based on an analysis of programmed parameters and collected data. Observations may include information about the status of the device and battery, the integrity of the implanted leads, or potential issues with programmed parameter settings. If Medtronic CareAlert Monitoring is enabled, any alert events detected by the device are presented as Quick Look II Observations. Review the Observations and check related reports for evidence of a problem with the device or leads.

2.1.5 Verifying the clinical effectiveness of the implanted system

Perform the following tasks to verify the clinical effectiveness of the implanted system:

- Review any Quick Look II Observations about the patient's clinical status

- Assess the effectiveness of pacing therapy

- Check tachyarrhythmia episode records for appropriate detection and therapy

2.1.5.1 Reviewing Quick Look II Observations about clinical status

The Quick Look II data includes Observations about noteworthy or abnormal patient conditions such as low patient activity, unexpectedly high rates, or high arrhythmia burden. If Medtronic CareAlert Monitoring is enabled, any alert events detected by the device are presented as Quick Look II Observations. Review the Observations and check related data to help evaluate the clinical effectiveness of the implanted system.

2.1.5.2 Assessing the effectiveness of pacing therapy

1. Review the pacing percentages in the Quick Look II data. To assess the patient's pacing and sensing history in more detail, review the Rate Histograms data. For more information, see Section 3.9, "Rate Histograms", page 36.

2. Review Cardiac Compass Trends data and compare it with the patient history. Cardiac Compass Trends data can help you to determine whether changes in the patient's activity, pacing therapies, and arrhythmias have occurred during the past 14 months. For more information about the data collected by the Cardiac Compass Trends feature, see Section 3.3, "Cardiac Compass Trends", page 24.

3. Evaluate the patient's pacing thresholds by reviewing capture threshold trend data or, for in-clinic follow-up appointments, by performing a Pacing Threshold Test. Check the programmed pacing parameters to ensure they provide an appropriate safety margin.

4. During in-clinic follow-up appointments, interview the patient to confirm that the patient is receiving adequate cardiac support for daily living activities.

2.1.5.3 Assessing tachyarrhythmia detection and therapy

1. Review the Quick Look II data for the counts of each kind of tachyarrhythmia episode.

2. Evaluate AT/AF burden by reviewing the Cardiac Compass Trends data and the Rate Histograms data. For more information, see Section 3.3, "Cardiac Compass Trends", page 24 and Section 3.9, "Rate Histograms", page 36.

3. Check tachyarrhythmia episode records to evaluate detection accuracy and the effectiveness of any delivered tachyarrhythmia therapy. For more information about the data provided in episode records, see Section 3.4, "Arrhythmia Episodes data", page 28.

2.1.6 Adjusting device parameters

Adjust the pacing, tachyarrhythmia detection, tachyarrhythmia therapy, and diagnostic data parameters as needed to address any issues identified during the follow-up appointment.

Caution: Use caution when reprogramming the detection or sensing parameters to ensure that appropriate sensing is maintained. For more information, see Section 4.1, "Sensing", page 43 .

2.1.7 Scheduling an in-clinic follow-up appointment

Data transmitted to the Medtronic CareLink Network may indicate the need to schedule an in-clinic follow-up appointment with your patient in addition to their regularly scheduled appointments. You may need to perform manual tests, adjust device parameters, or assess lead status more directly. The following table shows an example of how data from a CareLink transmission may be used to make scheduling decisions.

Table 2. Example: Responses to different kinds of CareLink transmissions

Device and lead status	Clinical status	When to schedule an in-clinic fol-low-up appointment
Normal	Normal	According to the regular schedule
Normal	Abnormal, but no urgent or emergency conditions	According to the regular schedule
Normal	Abnormal, urgent condition	Within 1 week
Normal	Abnormal, emergency condition	Immediately
Abnormal	Any	Immediately

2.2 Optimizing device longevity

Optimizing device longevity is a desirable goal because it may reduce the frequency of device replacement for patients. Optimizing device longevity requires balancing the benefit of device therapy and diagnostic features with the energy requirements placed on the battery as a result of these features.

To view the Remaining Longevity estimate for the device, refer to the Quick Look II screen.

The following sections describe strategies that may help reduce the energy requirements placed on the battery.

2.2.1 Promoting intrinsic AV conduction

Managed Ventricular Pacing (MVP) – The MVP feature promotes AV conduction by reducing unnecessary right ventricular pacing. The primary benefit of the MVP feature is therapeutic, but it may also preserve device longevity as a result of a decrease in the percentage of pacing. For more information about the MVP feature, see Section 4.5, "Managed Ventricular Pacing (MVP)", page 66.

Promoting AV conduction with longer AV intervals – Another method of promoting AV conduction is to increase the Paced AV and Sensed AV intervals. This allows intrinsic conduction to occur before a ventricular pace. Fewer pacing pulses may help to preserve device longevity. For more information, see Section 4.2, "Basic pacing", page 53.

2.2.2 Managing pacing outputs

Capture Management – The Capture Management feature provides the device with automatic monitoring and follow-up capabilities for managing pacing thresholds. This feature is designed to monitor the pacing threshold and, optionally, to adjust the pacing outputs to maintain capture. Programming the Capture Management feature allows the device to set the pacing amplitude just high enough to maintain capture while preserving battery energy. For more information, see Section 4.7, "Capture Management", page 77.

Manual optimization of amplitude and pulse width – If you choose to program the Capture Management feature to Off, you can optimize the patient's pacing output parameters manually. Perform a Pacing Threshold Test to determine the patient's pacing thresholds. Select amplitude and pulse width settings that provide an adequate safety margin above the patient's pacing threshold. These actions decrease the pacing outputs and preserve battery energy. Refer to the programming guide for more information about performing a Pacing Threshold Test.

Pacing rate – The more paced events that are delivered, the more device longevity is reduced. Make sure that you have not programmed an unnecessarily high pacing rate for the patient. Carefully consider using features that increase bradycardia pacing rate. Use

features such as Atrial Preference Pacing (APP), Conducted AF Response, and Rate Response only for patients who can receive therapeutic benefit from the feature.

2.2.3 Disabling Atrial Sensitivity

Atrial Sensitivity – When atrial monitoring is not needed due to chronic AT/AF, consider programming Atrial Sensitivity to Off before changing the mode to VVI or VVIR to preserve battery energy.

Note: When Atrial Sensitivity is programmed to Off, AT/AF monitoring is disabled.

2.2.4 Considering how diagnostic features with data storage impact longevity

Pre-arrhythmia EGM storage – Continual use of Pre-arrhythmia EGM storage reduces device longevity. For a patient with uniform tachyarrhythmia onset mechanisms, the greatest benefit of Pre-arrhythmia EGM storage is obtained after capturing a few episodes.

When Pre-arrhythmia EGM storage is on, the device collects up to 20 s of EGM data before the onset of VT Monitor or SVT episodes.

Note: The Pre-arrhythmia EGM feature does not apply to AT/AF episodes. The device stores approximately 4 s of EGM before AT/AF detection regardless of the Pre-arrhythmia EGM storage setting.

To balance the benefit of using the Pre-arrhythmia EGM storage feature with optimizing device longevity, consider the following programming options:

- Program Pre-arrhythmia EGM storage to On-1 month, On-3 months, or On Continuous to capture possible changes in the tachyarrhythmia onset mechanism following significant clinical adjustments such as device implant, medication changes, and surgical procedures. Select the setting for the shortest time period that will provide the necessary data.

- Program Pre-arrhythmia EGM storage to Off after you have obtained the data of interest.

Note: When Pre-arrhythmia EGM storage is off, the device begins to store EGM information for VT Monitor and SVT episodes after the third tachyarrhythmia event occurs. Though EGM is not recorded before the start of the arrhythmia, the device still records up to 20 s of data before the onset or detection of the episode. This data includes interval measurements and Marker Channel annotations. In addition, Flashback Memory data is stored for the most recent tachyarrhythmia episodes.

Holter telemetry – Extended use of the Holter telemetry feature decreases device longevity. The Holter telemetry feature continues to transmit EGM and Marker Channel data for the programmed time duration regardless of whether the programming head is positioned over the device.

Medtronic CareLink remote transmissions – When scheduling Medtronic CareLink remote transmissions, be aware that increasing the frequency of remote transmissions reduces implanted device service life. Refer to the device manual for more information about the estimated effect on a specific device model. To conserve battery energy, schedule the lowest frequency of remote transmissions that still allows for the desired monitoring of your patient's device.

3 Diagnostic data features

3.1 Quick Look II summary data

At the start of a patient session, it is useful to quickly view summary information about device operation and the patient's condition. This overview can help you to determine whether you need to look more closely at diagnostic data or reprogram the device to optimize therapy for the patient.

The Quick Look II data summarizes the most important indicators of system operation and the patient's condition. These indicators include device and lead status data, pacing therapy information, arrhythmia episode data, and system-defined observations.

You can view Quick Look II data on the Quick Look II screen, which is displayed on the programmer at the beginning of a patient session. To return to the Quick Look II screen from another screen, select Data > Quick Look II. For more information about using the Quick Look II screen, refer to the programming guide.

3.1.1 Quick Look II device and lead status information

The Quick Look II data includes the following information about device and lead status:

- Estimate of remaining battery longevity
- Trends of the weekly average impedance, capture threshold, and wave amplitude measurements
- Most recent measured values for impedance, capture threshold, and wave amplitude

3.1.2 Quick Look II pacing therapy information

The Quick Look II data includes the following information about pacing therapy:

- programmed values for the Mode, Lower Rate, and Upper Tracking Rate parameters
- percentage of time spent pacing since the last patient session
- an indication that the pacing mode is currently programmed to an MVP mode ("MVP On") or to another pacing mode ("MVP Off").

3.1.3 Quick Look II arrhythmia episode information

The Quick Look II data includes the following information about arrhythmia episodes since the last patient session:

- percentage of time spent in AT/AF
- number of AT/AF episodes treated with tachyarrhythmia therapy
- number of monitored VT episodes
- number of monitored Fast A&V episodes
- number of monitored AT/AF episodes

3.1.4 Quick Look II Observations

Observations are based on an analysis of programmed parameters and data collected since the last session. The following types of observations may occur:

- Device status observations inform you of conditions that affect device operation and require attention. Examples of such conditions include Recommended Replacement Time (RRT) or the occurrence of a device reset.
- Lead status observations report any potential issues with the sensing integrity of the leads, possible lead dislodgments, and abnormal Capture Management results. You may also be warned about possible inconsistencies in the programming of lead polarity.
- Parameter observations warn of any inconsistencies in the programming of detection and therapy parameters. An example is certain parameter settings resulting in a therapy being disabled.
- Diagnostic data observations report noteworthy arrhythmia episodes. Examples include arrhythmias of different types occurring together and episodes for which therapies were unsuccessful. Conditions that prevent diagnostic data from being collected effectively are also reported.
- Medtronic CareAlert observations can report system or device performance conditions and certain heart rhythm conditions. For more information, see Section 3.2, "Medtronic CareAlert Monitoring", page 21.
- Clinical status observations alert you to abnormal patient conditions, such as low activity rates, unexpectedly high heart rates, or high arrhythmia burden.

On the Quick Look II screen, if you select one of the displayed observations and more information about the selected observation is available, the [>>] button becomes active. You can use the [>>] button to look at relevant details.

Setting parameters for clinical status Observations – The Medtronic CareAlert Monitoring feature includes clinical status alerts related to high arrhythmia burden (see

Section 3.2, "Medtronic CareAlert Monitoring", page 21). For Astra XT DR MRI SureScan devices, or for Azure XT DR MRI SureScan devices with the Wireless Telemetry with Monitor parameter programmed to Off, the system provides this information as Quick Look II Observations. The device records an Observation in the Quick Look II data if either the AT/AF burden or the ventricular heart rate during AT/AF exceed a programmed threshold. The threshold parameters are programmed from the Data Collection Setup screen.

Table 3. How to navigate to parameters for clinical status Observations

Parameters	Path
AT/AF Daily Burden Avg. V. Rate During AT/AF Burden Avg. V. Rate During AT/AF V. Rate	Params > Data Collection Setup… > AT/AF Settings…

3.2 Medtronic CareAlert Monitoring

Important clinical management and system performance events may occur between scheduled patient sessions. These events may relate to clinical management data or system issues that should be investigated. The early detection and notification of these events, should they occur, enable you to intervene promptly with appropriate care for your patient.

The Medtronic CareAlert Monitoring feature automatically sends alert data about specified clinical management and system performance events to the Medtronic CareLink Network through a Medtronic patient monitor (if available). Depending on the severity of the alert condition, you can set up Medtronic CareAlert notifications through the CareLink Network to hold the alert for routine review on the CareLink website, or to notify you via email, voice message, text message, or pager.

3.2.1 Operation of Medtronic CareAlert Monitoring

If the Wireless Telemetry with Monitor parameter is programmed to On, the Medtronic CareAlert Monitoring feature is available. If a clinical or system performance event occurs and Medtronic CareAlert Monitoring is programmed to respond with an alert, the device automatically attempts to establish wireless communication with the monitor. After communication is established, the monitor receives the alert data from the device, and then transmits the alert data to the CareLink Network. The CareLink Network records the alert, and you are notified based on your preferences. If the transmission is unsuccessful at first, the device and monitor periodically repeat the process until the transmission is successfully sent.

Note: After a wireless alert signal has been successfully transmitted, the device does not retransmit data for that particular alert until the alert is cleared. This is true even if the threshold for the alert is met again in the interim.

The CareAlert notification methods (any one or a combination of voice message, text message, pager, email, or website-only) are set on a per-clinic basis according to alert urgency and time of day. You can assign the level of urgency to each alert for individual patients, so that the same alert can be high urgency for one patient and low urgency for another patient.

3.2.1.1 Clinical management event alerts

AT/AF Daily Burden > Threshold – This alert indicates that the cumulative time in AT/AF exceeds the programmed threshold.

Avg. V. Rate During AT/AF > Threshold – This alert indicates that the average ventricular rate during a selectable duration of AT/AF exceeds the programmed threshold.

Monitored VT Episode Detected – This alert indicates that one or more monitored VT episodes were detected.

Cumulative Right Ventricular Pacing > 40% – This alert indicates that the cumulative percentage of right ventricular pacing exceeded 40% for 7 consecutive days.

3.2.1.2 System performance event alerts

Low Battery Voltage Recommended Replacement Time – This alert indicates that the daily automatic battery voltage measurement has been at or below the Recommended Replacement Time voltage level for 3 consecutive days.

Lead Impedance Out of Range – This alert indicates that the daily lead impedance measurement for one of the implanted leads is out of range. This could indicate that the lead has dislodged or is improperly connected.

Capture Management High Threshold – These alerts indicate that 3 consecutive daily capture threshold measurements in the specified chamber were high.

Device Reset (nonprogrammable) – This alert indicates that the device has been reset. Diagnostic data may have been cleared and parameters may require reprogramming. Immediately contact your Medtronic representative if a device reset occurs. For device reset parameter values, see the parameter tables in the device manual for the specific device model.

3.2.2 Programming Alerts

Table 4. How to navigate to CareAlert parameters

Parameters	Path
Wireless Telemetry with Monitor	Params > Data Collection Setup
Monitored VT Episode Detected Cumulative Right Ventricular Pacing > 40% Low Battery Voltage RRT	Params > Alert…
AT/AF Burden and Rate alert parameters: AT/AF Daily Burden Enable AT/AF Daily Burden Avg. V. Rate During AT/AF Enable Avg. V. Rate During AT/AF Burden Avg. V. Rate During AT/AF V. Rate	Params > Alert… > AT/AF Burden and Rate Settings…
Lead Impedance Out of Range alert parameters: A. Pacing Enable A. Pacing Less than A. Pacing Greater than RV Pacing Enable RV Pacing Less than RV Pacing Greater than	Params > Alert… > Lead Impedance Out of Range…
Capture Management High Threshold parameters: A. Capture Enable RV Capture Enable	Params > Alert… > Capture Management High Threshold…

Programming alert parameters – The Wireless Telemetry with Monitor parameter must be set to On before you can program Medtronic CareAlert Monitoring parameters.

Repetitive alerts – If a programmable alert is triggered so often that it loses its clinical value, consider adjusting the alert threshold, programming the device to improve therapy effectiveness, or disabling the alert.

3.2.3 Evaluation of alert events

The device stores alert events in the Medtronic CareAlert Events log. For each alert event, a log entry includes the date and time of the alert, a description of the event, and the measurement or information that caused the event. Up to 15 alert events are stored.

To access alert events, select Data > CareAlert Events.

3.3 Cardiac Compass Trends

An analysis of clinical information collected over a long term can help you to follow changes in a patient's condition and correlate these changes with variations in device programming, medication, patient activity, or symptoms.

Cardiac Compass Trends data provides information about a patient's condition over the last 14 months. Graphs show trends in tachyarrhythmias, physical activity, heart rates, device therapies, and information related to heart failure. Dates and event annotations allow you to correlate trends from different graphs. The trends can also help you to assess whether device therapies or antiarrhythmic drugs are effective.

Data storage for the Cardiac Compass Trends feature is automatic. No setup is required. The device begins storing data after the device is implanted. Each day thereafter, the device stores a set of trend data. After 14 months of data are collected, the device continues storage by overwriting the oldest stored data with new data.

Note: The schedule for collecting daily measurements and the time annotations displayed in the trends are both based on the device clock.

To access Cardiac Compass Trends data, select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data].

3.3.1 Information provided by Cardiac Compass Trends

The Cardiac Compass Trends data includes the following types of information:

- Programming and interrogation event annotations
- Trend graphs related to AT/AF burden
- Trend graphs related to pacing and patient activity
- Trend graphs related to heart failure

3.3.1.1 Event information

Figure 1. Event annotations
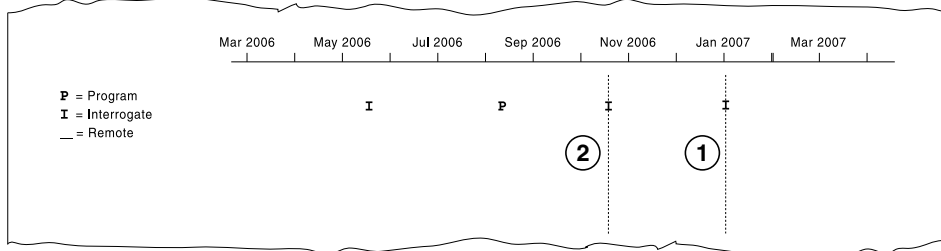
1 Current session indicator
2 Last session indicator

Programming and interrogation events – Cardiac Compass Trends data includes annotations showing when the device was interrogated or programmed to allow possible correlations between device parameter changes and other clinical trends.

When the patient is evaluated during an office visit, an "I" annotation is added for a day on which the device is interrogated and a "P" annotation is added for a day on which any programmable parameter is changed (except for temporary changes). If the device is interrogated and programmed on the same day, only a "P" is displayed.

When the patient is evaluated during a remote monitoring session, an "I" annotation with a line beneath it is added to the data.

A vertical line runs through all the graphs to indicate the beginning of the current session. If applicable, the last session is also marked with a vertical line.

3.3.1.2 AT/AF burden information

Figure 2. AT/AF arrhythmia trend graphs
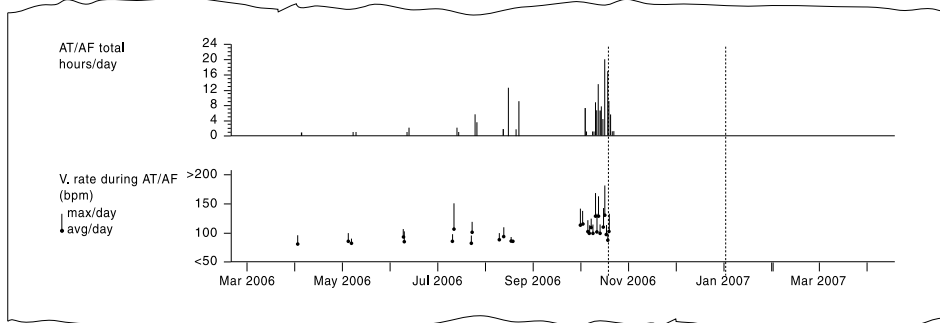
AT/AF total hours per day – This trend may help you to assess the need to adjust the patient's device or drug-based therapies. This trend may also reveal the presence of asymptomatic episodes of AT/AF.

The device records a daily total for the time the patient spent in atrial arrhythmia. The time in AT/AF is calculated from the point of AT/AF Onset. This trend may be reported in hours (0 to 24) or minutes (0 to 60) per day depending on the maximum duration per day. For more information, see Section 5.1, "AT/AF detection", page 124.

Ventricular rate during AT/AF – You can use this trend to perform the following assessments:

- Correlate patient symptoms to rapid ventricular responses to AT/AF.

- Prescribe or titrate antiarrhythmic and rate control drugs.

- Assess the efficacy of an AV node ablation procedure.

The graph plots average ventricular rates during episodes of atrial arrhythmia each day. The vertical lines show the difference between the average rate and the maximum sensed ventricular rate each day.

3.3.1.3 Pacing and patient activity information

Figure 3. Pacing and patient activity trend graphs
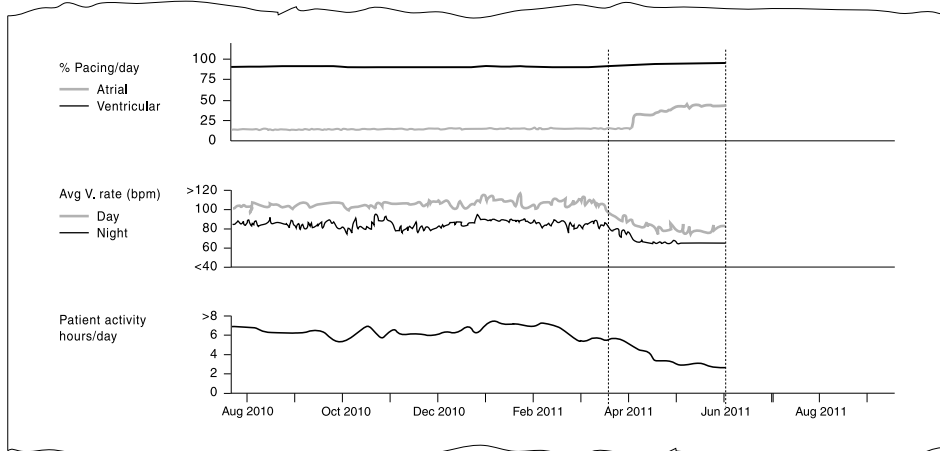
Percent pacing per day – This trend provides a view of pacing over time that can help you to identify pacing changes and trends. The graph displays the percentage of all events occurring during each day that are atrial paces and ventricular paces. The percentages are calculated from the daily counts of each event type.

Average ventricular rate – The day and night heart rates provide information that may have the following clinical uses:

- objective data to correlate with patient symptoms
- indications of autonomic dysfunction or symptoms of heart failure
- information regarding diurnal variations

For this trend, "day" is defined as the 12-hour period between 08:00 and 20:00 and "night" as the 4-hour period between 24:00 and 04:00 (as indicated by the device clock).

Patient activity – The patient activity trend may provide the following information:

- information about a patient's exercise regimen
- an objective measurement of patient response to changes in therapy
- an early indicator of progressive diseases like heart failure, which cause fatigue and a consequent reduction in activity

The patient activity trend is a 7-day average of data derived from the device rate response accelerometer. It is reported only after 14 days of data have been collected.

3.3.1.4 Heart failure information

Figure 4. Heart rate variability trend
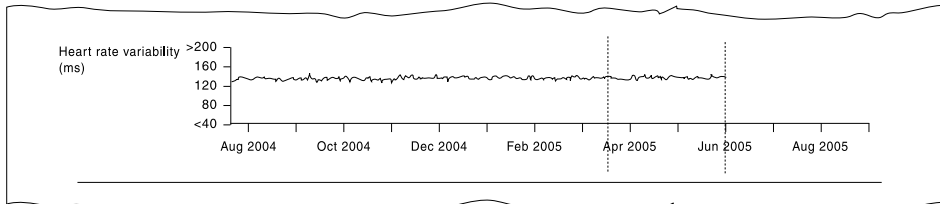
Heart rate variability – Reduced variability in the patient's heart rate may help you to identify heart failure decompensation. The device measures each atrial interval and calculates the median atrial interval every 5 min. It then calculates and plots a variability value (in ms) for each day.

Note: The heart rate variability calculation does not include events that occur during arrhythmia episodes.

3.4 Arrhythmia Episodes data

The device stores several different types of data for arrhythmia episodes. The episode log summarizes key data for each episode. Episode records include more detailed information for each episode, including an interval plot, stored EGM, and episode text.

To access Arrhythmia Episodes data, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data]. For more information about using the Arrhythmia Episodes screen, refer to the programming guide.

3.4.1 Episode log

The device stores the following summary information for each arrhythmia episode:

- type of episode
- the number of ATP sequences delivered (if any)
- whether the last therapy delivered was successful
- the date, time, and duration of the episode
- the average atrial and ventricular rates during the episode
- the maximum ventricular rate during the episode
- whether EGM data is available for the episode

Calculating the average rate – For AT/AF, VT Monitor, VT-NS, and Fast A&V episodes, the average atrial and ventricular rates are calculated from the average cycle lengths throughout the entire episode. For SVT episodes, the average atrial and ventricular rates are an average of the 4 beats at detection or just prior to withholding detection.

Display of the maximum ventricular rate – If the ventricle was paced during an AT/AF episode, the maximum ventricular rate appears in the log as VP. For VT-NS episodes, the maximum ventricular rate value is not displayed.

Patient-Activated Symptom Log entries – If the patient has a Medtronic patient assistant instrument, you can instruct them to use their patient assistant to record a Symptom entry in the arrhythmia episode log. This log entry will include the date, time, and average atrial and ventricular cycle lengths. If an arrhythmia episode is already in progress when the patient records a Symptom episode, the device does not store an additional log entry. Instead, the episode text for the ongoing arrhythmia episode is annotated with the statement "Patient Symptom detected during episode."

Notes:

- Episodes that occur during a device session are not available to view in the episode records until an interrogation is performed. The interrogation must be performed after episode termination.

- For each episode type, when the log capacity is reached, data from the most recent episodes overwrites the oldest episode data in the log.

3.4.2 Episode records

The device stores detailed information about the arrhythmia episodes recorded in the episode log. An arrhythmia episode record contains the following information:

- an interval plot
- a strip chart of the stored EGM (if available)
- a text summary
- Flashback Memory data (if available)

3.4.2.1 Episode interval plot

The device records the durations of the V-V and A-A intervals that occur during the episode. The episode interval plot graphs these interval durations versus time. The episode interval plot also includes the following information for an episode:

- programmed detection intervals
- point of onset, for AT/AF episodes

- point of detection or detection withheld
- points of therapy delivery

Note: The device may truncate data storage during an episode to conserve device memory.

3.4.2.2 Episode EGM

The device receives EGM data on three separate channels: EGM1, EGM2, and EGM3. The Source parameter for each channel defines the electrodes between which the device records the EGM signal. The Range parameters define the upper and lower amplitude limits of each recorded signal in mV. Using the Monitored parameter, you can select a set of 2 EGM channels for arrhythmia episode record storage.

The EGM data for each episode record is accompanied by the following additional information:

- Marker Channel annotations, showing the classification of cardiac events by the device
- Interval measurements
- Decision Channel annotations, identifying when tachyarrhythmia detection occurred, and which type of rhythm was detected:
    - VTM: monitored VT episode
    - VTM+SVT: monitored VT episode with SVT
    - Fast A&V: simultaneous atrial and ventricular tachyarrhythmias
    - AT/AF Detection: detected AT or AF episode
    - Fast AT/AF Detection: detected AT or AF episode with a rate in the Fast AT/AF zone

To conserve device memory, EGM data is stored only during specific parts of an episode:

- prior to episode detection
- before and after the first tachyarrhythmia therapy is delivered
- prior to episode termination

As a result, long episodes may contain gaps in the EGM between these events.

When the Pre-arrhythmia EGM feature is enabled, the device continuously collects EGM data, providing up to 20 s of EGM data for storage prior to the detection of VT Monitor, SVT, VT-NS, and Fast A&V episodes. When the Pre-arrhythmia EGM feature is programmed to Off, the device stores EGM data for these episodes starting after the third tachyarrhythmia event occurs. Though EGM is not recorded before the start of the arrhythmia, the device still records up to 20 s of interval measurements and Marker Channel annotations.

Note: The Pre-arrhythmia EGM feature does not apply to AT/AF episodes. The device stores approximately 4 s of EGM data prior to AT/AF detection, regardless of Pre-arrhythmia EGM operation.

3.4.2.3 Episode text

The device stores details with each episode record that are displayed in text form:

- episode number
- episode type
- date, time, and duration of the episode
- maximum atrial and ventricular rates during the episode
- median atrial or ventricular rate during the episode (depending on the episode type)
- patient activity at the onset of the episode, along with the calculated sensor rate associated with the level of activity
- programmed parameter settings related to sensing, tachyarrhythmia detection, tachyarrhythmia therapy, and EGM sources
- for treated AT/AF episodes, the sequence of ATP therapies and a summary of the number of ATP therapies delivered

3.4.2.4 Flashback Memory data

The episode records for the most recent VT, Fast A&V and AT/AF episodes provide Flashback Memory data. This data includes up to a total of 2000 V-V and A-A intervals and stored marker data. For more information, see Section 3.6, "Flashback Memory data", page 34.

3.4.3 Programming Arrhythmia Episodes data collection

Arrhythmia episode data collection is automatic when tachyarrhythmia detection features are programmed to On or Monitor. Parameters that control EGM data storage are available on the Data Collection Setup screen.

Table 5. How to navigate to parameters for arrhythmia episode data collection

Parameters	Path
EGM1 Source EGM1 Range EGM2 Source EGM2 Range EGM3 Source EGM3 Range Monitored Pre-arrhythmia EGM	Params > Data Collection Setup…

EGM settings and Live Rhythm Monitor – The signals displayed on the Live Rhythm Monitor for the EGM1, EGM2, and EGM3 waveform traces are controlled by the corresponding EGM Source and EGM Range parameters.

EGM source and sensing – The cardiac interval measurements of the device are always based on the signals sensed through the programmed sensing polarity (not the stored diagnostic EGM). Therefore, your selection of EGM sources does not affect bradycardia pacing or tachyarrhythmia detection.

EGM range – The EGM range setting affects the resolution of the EGM signal; the lower the setting, the higher the resolution. If the EGM signal is illegible or clipped, consider changing the range selection.

Pre-arrhythmia EGM – Pre-arrhythmia EGM storage works by keeping the EGM circuitry enabled at all times, and therefore it reduces device longevity. If you select On - 1 Month or On - 3 Months, Pre-arrhythmia EGM storage is automatically turned off after the time period expires.

3.5 Episode and therapy counters

The device stores data about the number of times VT/VF episodes, AT/AF episodes, and therapies have occurred. The counter data for ventricular episodes includes counts of ventricular episodes of different types, counts of premature ventricular contractions (PVCs), and counts of Ventricular Rate Stabilization (VRS) paces. The counter data for atrial episodes includes information about the amount of time spent in AT/AF, counts of different types of atrial episodes, and information about the time spent in atrial pacing and atrial intervention pacing. The counter data for atrial therapies includes counts of treated atrial episodes and the percentage of time the therapies successfully terminated episodes, grouped by therapy type and atrial cycle length.

To access the episode and therapy counters, select Data > Clinical Diagnostics > Counters > [Open Data].

3.5.1 VT/VF episode counters

The device records the following types of counter data related to ventricular arrhythmias since the last session, and for the lifetime of the device:

VT – The number of VT Monitor episodes.

VT-NS – The number of non-sustained ventricular tachyarrhythmias.

Fast A&V – The number of Fast A&V and SVT episodes.

PVC Runs – The average number of runs per hour of premature ventricular contractions (PVCs) in which 2, 3, or 4 consecutive ventricular events are premature.

PVC Singles – The average number of single PVCs per hour. PVCs in PVC runs are not counted as PVC singles.

Runs of VRS Paces – The average number of times per hour that 2 or more consecutive ventricular events are Ventricular Rate Stabilization (VRS) pacing pulses (VRS escape interval timeouts).

Single VRS Paces – The average number of single VRS pacing pulses (VRS escape interval timeouts) per hour. VRS paces in runs of VRS paces are not counted as single VRS paces.

3.5.2 AT/AF episode counters

The device records the following types of counter data related to atrial arrhythmias since the last session, and for the lifetime of the device:

% of Time AT/AF – The percentage of total time in AT/AF. AT/AF is defined as starting from AT/AF onset. The device additionally stores this data for the period between last session and the session prior to the last session.

Average AT/AF time/day – The average time in AT/AF per day. AT/AF is defined as starting from AT/AF onset. The device additionally stores this data for the period between last session and the session prior to the last session.

Monitored AT/AF Episodes – The average number of monitored AT/AF episodes per day. AT/AF is defined as starting from AT/AF detection.

Treated AT/AF Episodes – The average number of treated AT/AF episodes per day. AT/AF is defined as starting from AT/AF detection.

Pace-Terminated Episodes – The percentage of pace-terminated AT/AF episodes for the session. AT/AF is defined as starting from AT/AF detection.

% of Time Atrial Pacing – The percentage of time that atrial pacing was performed.

% of Time Atrial Intervention – The percentage of time that atrial pacing was performed due to atrial intervention pacing (Atrial Rate Stabilization or Atrial Preference Pacing). This is a percentage of total time, not a percentage of atrial pacing time.

AT-NS – The average number of non-sustained AT (AT-NS) episodes per day.

3.5.3 AT/AF therapy counters

The device records the following types of counter data related to atrial tachyarrhythmia therapies since the last session:

Fast AT/AF Rx – The number of episodes for which therapy was delivered (by therapy type) and the percentage of successfully terminated episodes per therapy.

AT/AF Rx – The number of episodes for which therapy was delivered (by therapy type) and the percentage of successfully terminated episodes per therapy.

Treated episodes by cycle length – The number of treated episodes and the percentage terminated, in 7 groups of cycle lengths.

ATP Sequences – The number of atrial ATP sequences that were delivered and the number that were aborted.

3.6 Flashback Memory data

Flashback Memory records atrial and ventricular intervals that occur immediately prior to tachyarrhythmia episodes or the most recent interrogation. The feature plots the interval data over time and allows you to view and print a graph of the collected data. The graphed data may help you assess the patient's heart rhythm and the performance of other features such as Rate Response.

Flashback Memory automatically records up to a total of 2000 V-V and A-A intervals and stored marker data for the following events:

- the most recent interrogation
- the most recent VT episode
- the most recent Fast A&V episode
- the most recent AT/AF episode

If 2 or more episodes are detected within 15 min, the Flashback Memory data before the episodes may be truncated.

To access Flashback Memory data for the most recent VT, Fast A&V, or AT/AF episode, select [Flashback] from the record details screen for the episode. Flashback Memory data prior to the most recent interrogation is available from the Clinical Diagnostics screen.

3.7 Rate Drop Response Episodes

Rate Drop Response is a pacing feature that monitors the heart for significant rate drops and responds by pacing the heart at an elevated rate (see Section 4.10, "Rate Drop Response", page 91). When Rate Drop Response is programmed to On, the device records data about episodes that meet the programmed rate drop detection criteria. This data is useful for analyzing Rate Drop Response episodes and the events leading up to them. You can view and print data for the last 10 episodes.

The device stores the following summary information for each Rate Drop Response episode:

- type of episode (Drop Detection or Low Rate Detection)
- date and time of the episode
- ventricular rate at the point of detection
- peak ventricular rate before detection (Drop Detection episodes only)

The following detailed information is provided for each Rate Drop Response episode:

- an interval plot showing the durations of V-V and A-A intervals that occur during the episode
- a strip chart view showing Marker Channel annotations for the events that occur during the episode
- a text summary of the Rate Drop Response settings that were in effect at the start of the programming session

To access Rate Drop Response episode data, select Data > Clinical Diagnostics > Rate Drop Response Episodes > [Open Data].

3.8 MVP Mode Switches data

The MVP pacing modes reduce unnecessary ventricular pacing by providing AAI(R) mode pacing when AV conduction is intact, and switching to DDD(R) mode if AV conduction is lost. For more information about the MVP pacing modes (AAIR<=>DDDR and AAI<=>DDD), see Section 4.5, "Managed Ventricular Pacing (MVP)", page 66.

When the device is programmed to an MVP pacing mode and switches from AAI(R) to DDD(R) mode, it records an MVP mode switch entry, which includes the following information:

- type of mode switch
- date and time when the mode switch occurred

- median ventricular rate at the time of the mode switch
- AV interval at the time of the mode switch

The device stores entries for up to the 10 most recent MVP mode switches to DDD(R) mode. The MVP Mode Switches data is displayed with annotations showing the dates of programmer and patient monitor sessions. It also includes a count of MVP mode switches since the last session.

To access the MVP Mode Switches data, select Data > Clinical Diagnostics > MVP Mode Switches > [Open Data].

3.9 Rate Histograms

Information about heart rates recorded between patient sessions can help you to monitor a patient's condition to assess the effectiveness of therapies. Rate Histograms shows the distribution of atrial and ventricular rates recorded Since Last Session and Prior to Last Session.

To access the Rate Histograms data, select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

3.9.1 Information provided by Rate Histograms

Rate Histograms report the atrial and ventricular event data stored by the device. There are histograms for 3 types of heart rate data: atrial rate, ventricular rate, and ventricular rate during AT/AF. They also report data about the patient's conduction status. The histograms include data from the current and previous collection periods. Data storage for Rate Histograms is automatic; no setup is required.

Rate histograms show the percentage of time that the device was pacing and sensing within rate ranges. There are 20 rate ranges that are each 10 bpm in length. Rates slower than 40 bpm are included in the "<40" range; rates faster than 220 bpm are included in the ">220" range.

% of Time – This section shows the percentage of the total time that the device provided pacing therapy during the collection period. This section excludes data about events that occurred during AT/AF episodes. Dual-chamber devices include data showing the percentage of time that AS-VS, AS-VP, AP-VS, and AP-VP event sequences occurred.

Notes:

- The AS-VS and AS-VP percentages include any sequences that began with an event other than an atrial paced event.

- If the patient experienced AT/AF for more than 99% of the time during the collection period, the % of Time section displays this fact instead of the event sequence percentages.

Atrial rate histogram – The atrial rate histogram shows the rate distribution of atrial sensed and paced events (including sensed events that occur during the refractory period).

Ventricular rate histogram – The ventricular rate histogram shows the rate distribution of ventricular sensed and paced events.

Ventricular rate during AT/AF histogram – The ventricular rate during AT/AF histogram shows ventricular sensed and paced events that occurred during detected atrial arrhythmias, and the total time in AT/AF[1]. This histogram may be used to monitor the effectiveness of ventricular rate control therapy and drug titration.

3.10 Device and lead performance data

The device automatically measures and records device and lead performance data every day. This information can help you assess the status of the device battery and identify issues with lead position or lead integrity. The device records the following types of performance data:

- Remaining Longevity estimate and replacement indicators

- Lead impedance measurements

- Sensing amplitude measurements

- Capture thresholds

- Sensing integrity counter

- Atrial Lead Position Check results

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[1] The time in AT/AF is calculated from the point of AT/AF Onset. For more information, see Section 5.1, "AT/AF detection", page 124.

You can access device and lead performance data from several different screens on the programmer:

- Quick Look II screen: Data > Quick Look II

- Battery and Lead Measurements screen: Data > Device/Lead Diagnostics > Battery and Lead Measurements > [Open Data]

- Lead Trends screen: Data > Device/Lead Diagnostics > Lead Impedance Trends > [Open Data]

3.10.1 Remaining Longevity estimate and replacement indicators

The device automatically measures the battery voltage several times a day. At 24:00, the device calculates the automatic daily battery voltage by averaging the measurements taken during the previous 24 hours. The device uses this data to evaluate the battery status and to calculate a Remaining Longevity estimate. This estimate is based on automatic daily battery voltage measurements, time since implant, programmed parameter settings, and device recorded events, as applied to a statistical analysis of accelerated battery discharge data.

Note: The Remaining Longevity estimate is updated when parameters are reprogrammed and when the device is interrogated.

The calculation of the Remaining Longevity estimate provides maximum, minimum, and mean values for the amount of time remaining until the device reaches the Recommended Replacement Time (RRT). The mean value is reported as the Remaining Longevity estimate. The maximum and minimum remaining longevity estimates are 95th percentile values calculated from the distribution of this data. That is, approximately 95% of devices are expected to reach RRT before the reported maximum value, and approximately 95% of devices are expected to reach RRT after the reported minimum value. When scheduling the replacement of the device, do not use the estimate of remaining longevity. Instead, schedule the device replacement after the RRT condition is reached.

The device reaches RRT when 3 consecutive automatic daily battery voltage measurements are less than or equal to the RRT voltage. After this occurs, the programmer displays the RRT symbol and the date when the battery reached RRT. Also, the programmer displays "Replace Device" instead of the Remaining Longevity estimate. If the programmer displays the RRT symbol, contact your Medtronic representative and schedule a replacement procedure with your patient. The expected service life of the device after RRT, defined as the Prolonged Service Period (PSP), is 6 months (180 days).

After the first 90 days of the PSP have passed, the device reaches the Elective Replacement Indicator (ERI) and the programmer displays the ERI symbol.[2] When the device reaches ERI, it automatically changes the pacing mode to VVI and sets the pacing rate to 65 bpm. It also sets AT/AF Detection to Monitor and disables the following features:

- Rate Hysteresis
- Ventricular Rate Stabilization
- Sleep
- Pre-arrhythmia EGM

After the 180-day PSP has expired, the device reaches End of Service (EOS), and the programmer displays the EOS symbol.[2]

Warning: Replace the device immediately if the programmer displays an EOS indicator. The device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

Note: After ERI, all pacing parameters can be programmed, including mode and rate. Reprogramming the pacing parameters may reduce the duration of the ERI to EOS period.

3.10.2 Lead impedance measurements

Every day at 03:00, the device automatically measures the lead impedance for each lead polarity on each implanted lead using subthreshold electrical pulses. These pulses are synchronized to sensed or paced events and do not capture the heart.

The daily automatic lead impedance measurements are displayed on the Lead Trends screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 60 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or sudden changes in lead impedance may indicate a problem with the lead.

If the device is unable to perform automatic lead impedance measurements, gaps are present in the trend graph.

If Lead Monitor detects a possible lead system failure, a Lead Warning annotation appears on the impedance trend graph for the affected lead. For more information, see Section 4.4, "Lead Monitor", page 64.

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[2] ERI may be indicated before the end of 90 days, and EOS may be indicated before the end of 180 days if the actual battery usage exceeds the expected conditions during the PSP. Refer to the device manual for more information about expected conditions during the PSP.

3.10.3 Sensing amplitude measurements

Every day at 02:15, the device begins to measure the amplitude of intrinsic sensed events. The device attempts to measure the amplitude of 9 normal intrinsic sensed events, and then records the median value from those events. If the device has not collected 9 amplitude measurements by 24:00, no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

The daily automatic sensing amplitude measurements are displayed on the Lead Trends screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 60 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or sudden changes in sensing amplitude may indicate a problem with a lead.

3.10.4 Capture threshold measurements

If the Capture Management feature is programmed to Adaptive or Monitor, the device automatically performs daily pacing threshold searches and records the results in the capture threshold trends data. For more information, see Section 4.7, "Capture Management", page 77.

The results of the daily pacing threshold measurements are displayed on the Lead Trends screen in the Capture Threshold trend graph. The graph displays up to 15 of the most recent measurements and up to 60 weekly summary measurements, showing minimum, maximum, and average values for each week.

The Lead Trends screen also displays programmed values for pacing output and Capture Management parameters, the last measured threshold value, and a link to a detailed view of the last 15 days of threshold measurement data. The details screen shows daily results from the last 15 days of threshold measurements. These results include the dates, times, threshold measurements, pacing amplitude values, and notes describing the results of each pacing threshold search.

The capture threshold trend data provides a way to evaluate Capture Management operation and the appropriateness of the current pacing output values. In addition, sudden or significant changes in pacing threshold may indicate a problem with a lead.

3.10.5 Sensing Integrity Counter

When the device senses high-frequency electrical noise, the result is often a large number of ventricular sensed events with intervals near the programmed value for ventricular blanking after a ventricular sense (V. Blank Post VS). The Sensing Integrity Counter records the number of ventricular events with intervals that are within 20 ms of the V. Blank Post VS parameter value. A large number of short ventricular intervals may indicate oversensing, lead fracture, or a loose setscrew. If the Sensing Integrity Counter reports more than 300 short ventricular intervals, investigate potential sensing and lead integrity issues.

3.10.6 Atrial Lead Position Check results

The device can be programmed to automatically disable atrial tachyarrhythmia therapies if the daily Atrial Lead Position Check identifies a potential problem with the lead position. The Battery and Lead Measurements screen displays the result of the most recent Atrial Lead Position Check. For more information, see Section 6.1, "Atrial therapy scheduling", page 134.

3.11 Automatic device status monitoring

The device automatically and continuously monitors internal conditions that affect device operation and require attention. If any such conditions occur, a device status indicator is recorded in memory, and a device status indicator warning is displayed on the programmer screen when the device is interrogated. Device status indicator warnings are displayed on the programmer screen and are reported as Quick Look II Observations.

Caution: Inform your Medtronic representative if a device status indicator warning is reported as a Quick Look II Observation or is displayed on the programmer screen after interrogating a device.

For more information about responding to device status indicator warnings, refer to the programming guide.

3.11.1 Operation of automatic device status monitoring

The device monitors and records device status indicators for the following conditions:

- Device reset
- Serious device memory failure
- AT/AF therapies disabled

3.11.1.1 Device reset

A device reset is a safety feature that can automatically change parameter values or clear diagnostic data in response to a problem with device memory. A device reset may occur when the device is exposed to extreme conditions, such as cold temperatures (before implant), electrocautery, external defibrillation, or intense, direct x-ray exposure.

There are two types of device reset: partial and full. A partial reset clears some or all of the diagnostic data, but the programmed parameters are not affected. A full reset clears all diagnostic data and changes programmed parameters to default reset values. These parameters provide basic device functionality (VVI pacing at 65 bpm) and are considered safe for the majority of patients. For more information about the default reset values for a device model, refer to the parameter tables in the device manual for that model.

The device records a device status indicator when a device reset occurs that requires attention. The device status indicator warning describes how data was affected by the reset. Read the message accompanying the indicator and follow the screen instructions carefully.

3.11.1.2 Serious device memory failure

In rare cases, a disruption of the device memory can occur from which the device cannot recover. If this happens, a device status indicator is recorded, and device parameters are reset to values that provide basic functionality (VVI pacing at 65 bpm). After a serious device memory failure, wireless communication is disabled, and device programming is not operational. **Immediate replacement of the device is recommended.**

3.11.1.3 AT/AF therapies disabled

The device can record a device status indicator and automatically disable atrial tachyarrhythmia therapies if any of the following situations occur:

- A ventricular episode was detected following delivery of an automatic atrial therapy prior to either redetection of AT/AF or termination of AT/AF. Atrial therapy is disabled if it appears that an atrial therapy has initiated a ventricular arrhythmia.

- The Atrial Lead Position Check failed.

- The device detected an accelerated ventricular rate during ATP therapy.

For more information about disabling atrial therapies, see Section 6.1, "Atrial therapy scheduling", page 134.

4 Pacing features

4.1 Sensing

The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver therapies appropriately. Effective sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, cross-chamber sensing, sensing far-field R-waves, sensing T-waves, noise, and interference.

Effective sensing is essential for the safe and effective use of the device. The device senses in both the atrium and right ventricle using the sensing electrodes of the leads implanted in those chambers. You can adjust the sensitivity to intracardiac signals. Each sensitivity setting represents a threshold value that defines the minimum electrical amplitude recognized by the device as a sensed event in the atrium or right ventricle.

Note: Selecting a higher value for the sensing threshold reduces the sensitivity to lower amplitude signals.

Programmable blanking periods and refractory periods help to screen out extraneous sensing or to prevent the device from responding to it. Both blanking periods and refractory periods follow pacing pulses and sensed events. Sensing is inhibited during blanking periods. The device is able to sense events that occur during refractory periods, but it marks them as refractory events. Refractory events generally have no effect on the timing of subsequent pacing events, but they are used by the tachyarrhythmia detection features.

The device provides both bipolar and unipolar sensing polarities, and sensing operates differently depending on the polarity.

4.1.1 Operation of sensing thresholds with bipolar sensing

For leads that are configured as bipolar, the device automatically adjusts the sensing thresholds after certain paced and sensed events to help reduce the oversensing of T-waves, cross-chamber events, and pacing. Each threshold adjustment depends on the type of event that precedes the adjustment. During an automatic adjustment, the sensing threshold automatically increases, but it gradually decreases toward the programmed sensitivity value, which is the minimum amplitude that can be sensed. The threshold decrease is intended to be rapid enough to allow subsequent low-amplitude signals to be sensed. Threshold adjustment corresponding to both leads configured for bipolar sensing (and nominal settings) is shown in Figure 5.

Figure 5. Adjustment of sensing thresholds with bipolar sensing

Sensing threshold
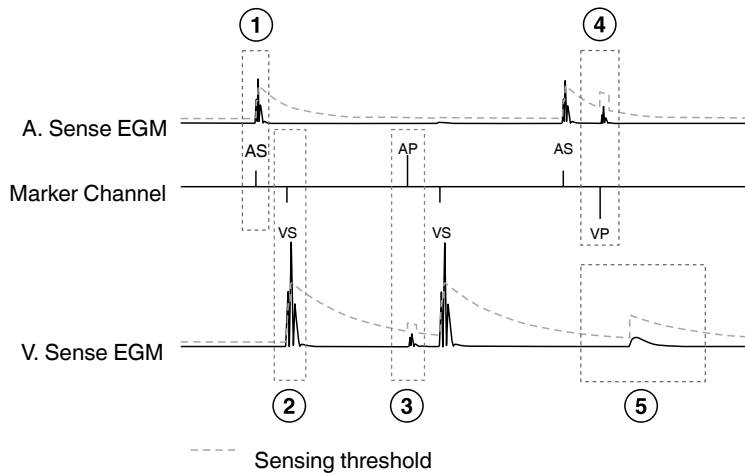
1 After an atrial sensed event, the device is temporarily less sensitive to atrial events.
2 After a ventricular sensed event, the device is temporarily less sensitive to ventricular events.
3 After an atrial paced event, the device is temporarily less sensitive to ventricular events, but the sensitivity to atrial events remains the same.
4 After a ventricular paced event, the device is temporarily less sensitive to atrial events.
5 After the post-pace blanking period, the device is temporarily less sensitive to ventricular events.

Note: When high-amplitude sensed events occur, the decrease in sensitivity is limited to prevent undersensing of subsequent intrinsic events.

4.1.2 Operation of sensing thresholds with unipolar sensing

The device does not adjust the sensing threshold for a lead that is configured for unipolar sensing. The sensing threshold remains at the level determined by the programmed sensitivity parameter. The fixed thresholds corresponding to both leads configured for unipolar sensing are shown in Figure 6.

Figure 6. Fixed sensing thresholds with unipolar sensing
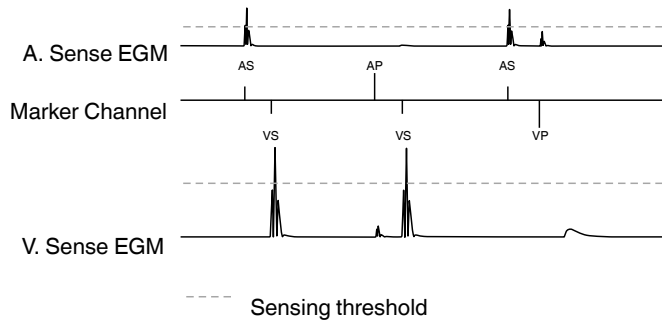
4.1.3 Operation of blanking periods

Blanking periods follow paced and sensed events. Blanking periods help to prevent the device from sensing pacing pulses, post-pacing depolarization, T-waves, and oversensing of the same event. The blanking periods after paced events are longer than or equal to those after sensed events to avoid sensing the atrial and ventricular depolarizations.

Programmable parameters determine the lengths of the blanking periods that follow sensed events and paced events.

Figure 7. Programmable blanking periods
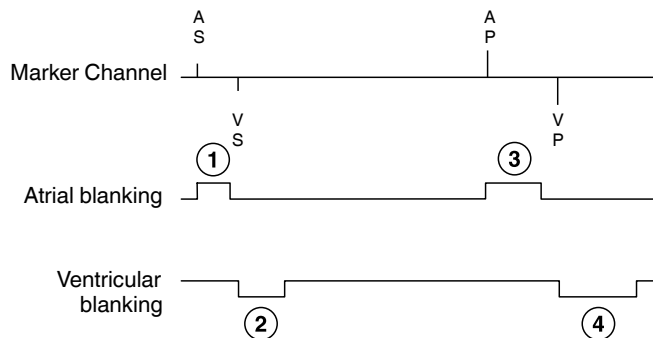
1 For the duration of this atrial blanking period, which is defined by the A. Blank Post AS parameter, atrial sensing is disabled after a sensed atrial event.

2 For the duration of this ventricular blanking period, which is defined by the V. Blank Post VS parameter, ventricular sensing is disabled after a sensed ventricular event.

3 For the duration of this atrial blanking period, which is defined by the A. Blank Post AP parameter, atrial sensing is disabled after a paced atrial event.

4 For the duration of this ventricular blanking period, which is defined by the V. Blank Post VP parameter, ventricular sensing is disabled after a paced ventricular event.

The cross-chamber blanking periods listed in Table 6 are nonprogrammable.

Table 6. Cross-chamber blanking periods

Parameter	Value
Atrial blanking after a ventricular pacing pulse (bipolar atrial sensing)	30 ms
Atrial blanking after a ventricular pacing pulse (unipolar atrial sensing)	40 ms
Ventricular blanking after an atrial pacing pulse (bipolar ventricular sensing)	30 ms[a]
Ventricular blanking after an atrial pacing pulse (unipolar ventricular sensing)	40 ms

[a] If the RV pacing amplitude is programmed at 8 V, this value is 35 ms.

4.1.4 Operation of Post-Ventricular Atrial Blanking (PVAB)

The system uses Post-Ventricular Atrial Blanking (PVAB) to eliminate the effect of far-field R-waves. Far-field R-waves are ventricular events that are sensed in the atrium. The PVAB operation is determined by 2 programmable parameters: PVAB Interval and PVAB Method. Atrial events that are sensed during the PVAB interval are used only by tachyarrhythmia detection and do not affect pacing timing. However, changing the PVAB interval determines whether or not events fall in the interval.

The 3 programmable values of PVAB Method are Partial, Partial+, and Absolute. This parameter determines whether atrial events that occur during PVAB interval are sensed by the device.

4.1.4.1 PVAB operation with bipolar atrial sensing

Partial PVAB – When the Partial PVAB method is used, atrial events sensed during the programmed PVAB interval are not used by the bradycardia pacing features but are used by the tachyarrhythmia detection features.

Partial+ PVAB – The Partial+ PVAB method may eliminate the sensing of far-field R-waves more effectively than Partial PVAB. The Partial+ PVAB method operates similarly to the Partial PVAB method. The difference is that after a ventricular event, the atrial sensing threshold is increased for the duration of the programmed PVAB interval. During this time, far-field R-waves are less likely to be sensed. After the PVAB interval, the atrial sensing threshold gradually returns to the programmed level. Extending the PVAB interval may affect

intrinsic and far-field R-wave sensing because it changes the time during which the sensing threshold is increased.

Absolute PVAB – When the Absolute PVAB method is used, no atrial events are sensed in the PVAB interval. The Absolute PVAB method is recommended only for addressing complications that are not addressed by the other PVAB methods.

Warning: Programming Absolute as the PVAB Method means that no atrial sensing occurs during the blanking interval. Absolute blanking may reduce the ability to sense AT/AF and reduce the ability to discriminate between VT and SVT. Use the Partial or Partial+ methods unless you are sure that Absolute blanking is appropriate.

Figure 8. Comparison of the PVAB methods
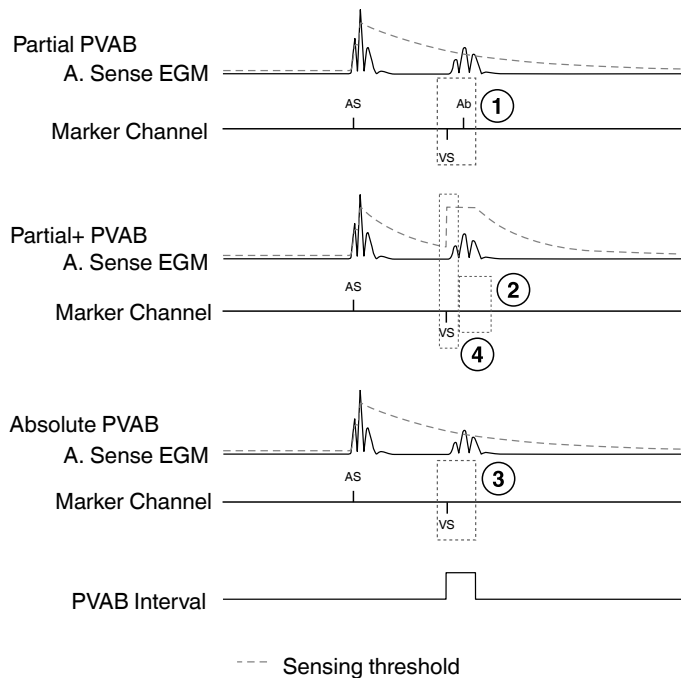
1 When the Partial PVAB method is used, if the far-field R-wave exceeds the atrial threshold, an Ab marker indicates that the event is sensed during the PVAB interval.
2 With the Partial+ PVAB method, after a ventricular sensed or paced event, the atrial sensing threshold increases, and the device is less sensitive to atrial events.

3   When the Absolute PVAB method is used, an atrial event is blanked in the PVAB interval whether or not the far-field R-wave exceeds the atrial threshold.

4   Except for the change in the atrial sensing threshold, the Partial+ PVAB and Partial PVAB methods are similar. With either method, atrial events sensed in the PVAB interval are used by the tachyarrhythmia detection features.

4.1.4.2 PVAB operation with unipolar atrial sensing

Partial PVAB and Partial+ PVAB – If the atrial lead is configured for unipolar sensing, Partial PVAB and Partial+ PVAB operate in the same way. Atrial sensed events in the PVAB interval are not used by bradycardia pacing features but are used by tachyarrhythmia detection features.

Absolute PVAB – When the Absolute PVAB method is used, no atrial events are sensed in the PVAB interval. The Absolute PVAB method is recommended only for addressing complications that are not addressed by the other PVAB methods.

Warning: Programming Absolute as the PVAB Method means that no atrial sensing occurs during the blanking interval. Absolute blanking may reduce the ability to sense AT/AF and reduce the ability to discriminate between VT and SVT. Use the Partial or Partial+ methods unless you are sure that Absolute blanking is appropriate.

Figure 9. Comparison of PVAB methods (unipolar atrial sensing)
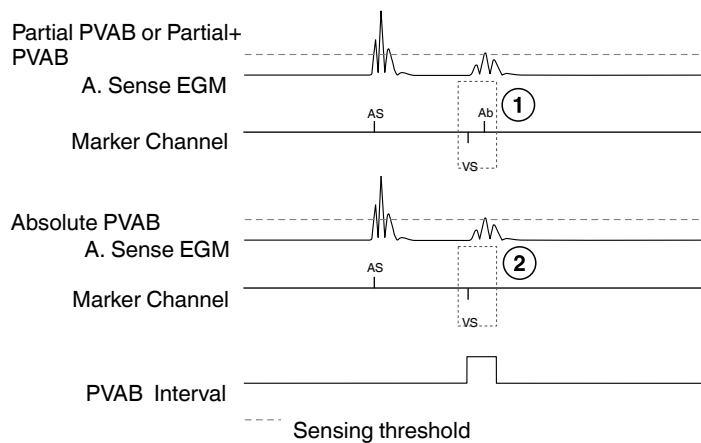
1   When the Partial PVAB method is used, if the far-field R-wave exceeds the atrial threshold, an Ab marker indicates that the event is sensed during the PVAB interval.

2   When the Absolute PVAB method is used, an atrial event is blanked in the PVAB interval whether or not the far-field R-wave exceeds the atrial threshold.

4.1.5 Operation of refractory periods

During a refractory period, the device senses normally but classifies sensed events as refractory and limits its response to these events. The pacing refractory periods prevent inappropriately sensed signals, such as far-field R-waves or electrical noise, from triggering certain pacing timing intervals. Pacing refractory periods do not affect tachyarrhythmia detection.

The availability of refractory periods depends on the programmed pacing mode. The Post Ventricular Atrial Refractory Period (PVARP) is available in dual chamber pacing modes, and the Atrial Refractory Period is available in atrial pacing modes.

4.1.5.1 Post Ventricular Atrial Refractory Period (PVARP)

The Post Ventricular Atrial Refractory Period (PVARP) follows a paced, sensed, or refractory sensed ventricular event. An atrial event that is sensed during this interval is classified as a refractory event. It does not inhibit a scheduled atrial pace or start a Sensed AV interval. The PVARP setting is only programmable for dual chamber pacing modes (except DOO mode).

- When the device is operating in the DDDR and DDD modes, the PVARP setting prevents the tracking of retrograde P-waves that could initiate a pacemaker-mediated tachycardia.

- When the device is operating in the DDIR and DDI modes, the PVARP setting prevents the inhibition of atrial pacing based on sensed retrograde P-waves. PVARP should be programmed to a value longer than the VA interval (retrograde) conduction time.

Figure 10. Timing for fixed PVARP
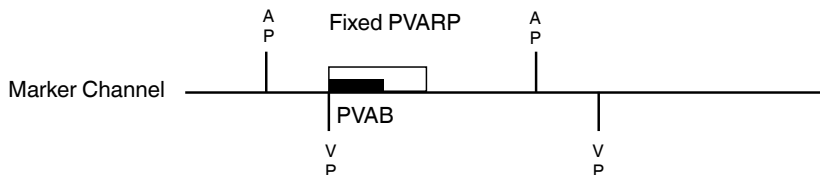
The PVARP parameter may be programmed to Auto instead of a fixed value. Auto PVARP adjusts PVARP in response to changes in the patient's intrinsic rate or pacing rate. During a Mode Switch episode, the device enables Auto PVARP. For more information, see Section 4.9, "Auto PVARP", page 89.

The PVARP setting may be extended by the PVC Response feature or the PMT Intervention feature.

4.1.5.2 Atrial Refractory Period

The Atrial Refractory Period setting is programmable only for the AAI and AAIR single chamber pacing modes. The Atrial Refractory Period prevents the inhibition of atrial pacing due to sensed far-field R-waves or noise.

4.1.6 Programming sensing

Table 7. How to navigate to sensing parameters

Parameters	Path
Atrial Sensitivity RV Sensitivity A. Refractory	Params
Atrial Sense Polarity RV Sense Polarity	Params > Sense Polarity…
PVARP	Params > PVARP…
PVAB Interval PVAB Method	Params > Blanking…
A. Blank Post AP A. Blank Post AS	
V. Blank Post VP V. Blank Post VS	

Sensing thresholds – The sensing thresholds, set by programming the sensitivity parameters, apply to all features related to sensing, including detection, bradycardia pacing, and the Sensing Test.

Bradycardia pacing and sensing – A combination of high pacing pulse width or high amplitude with a low sensing threshold may cause oversensing across chambers or in the same chamber. Programming a lower pulse width, lower amplitude, longer pace blanking, or a higher sensing threshold may eliminate this inappropriate sensing.

High ventricular sensing threshold – If the RV Sensitivity value is set too high, the device may undersense. This may result in asynchronous pacing.

Long blanking periods – If you set the blanking periods too long, the device may undersense.

Dual chamber sensing and bradycardia pacing modes – The device senses in both the atrium and the ventricle at all times, except when the programmed bradycardia pacing mode is DOO, VOO, or AOO. When the pacing mode is programmed to DOO or VOO, there is no sensing in the ventricle. When the pacing mode is programmed to DOO or AOO, there is no sensing in the atrium.

High atrial sensing threshold – If you set the Atrial Sensitivity value too high, the device may not provide reliable sensing of P-waves during AT/AF episodes and sinus rhythm.

Atrial pacing and ventricular sensing – If you program the device to an atrial pacing mode, make sure that it does not sense atrial pacing pulses as ventricular events.

Atrial lead selection – Atrial leads with narrow tip-to-ring spacing (for example, 10 mm) may reduce far-field R-wave sensing.

Repositioning the atrial lead – You may need to reposition or replace the atrial sensing lead if reprogramming the Atrial Sensitivity parameter does not provide reliable atrial sensing during AT/AF episodes and sinus rhythm.

Absolute PVAB – PVAB Method cannot be set to Absolute when the programmed pacing mode is ODO, AAI, or AAIR.

Upper rates and refractory periods – A combination of high Upper Sensor Rate, high Upper Tracking Rate, and a long refractory period may result in competitive atrial pacing. For more information, see Section 4.13, "Non-Competitive Atrial Pacing", page 99.

Low sensing threshold with bipolar sensing – If you set a sensitivity parameter to its most sensitive value, the device is more susceptible to electromagnetic interference (EMI), cross-chamber sensing, and oversensing.

Low sensing threshold with unipolar sensing – The device is more susceptible to electromagnetic interference (EMI) and oversensing.

Recommended ventricular sensing threshold with bipolar sensing – Setting RV Sensitivity to 0.9 mV is recommended to limit the possibility of oversensing and cross-chamber sensing.

Recommended ventricular sensing threshold with unipolar sensing – Setting RV Sensitivity to 2.8 mV is recommended to limit the possibility of oversensing.

Recommended atrial sensing threshold with bipolar sensing – Setting Atrial Sensitivity to 0.3 mV is recommended to optimize the effectiveness of atrial detection and pacing operations while limiting the possibility of oversensing and cross-chamber sensing.

Recommended atrial sensing threshold with unipolar sensing – Setting Atrial Sensitivity to 0.45 mV is recommended to limit the possibility of oversensing.

Testing sensitivity after reprogramming – If you change the ventricular sensing threshold or the ventricular sensing polarity, evaluate for proper sensing.

Effects of myopotential sensing in unipolar sensing configurations – In unipolar sensing configurations, the device may not distinguish myopotentials from cardiac signals. This may result in a loss of pacing due to inhibition. Also, unipolar atrial sensing in atrial tracking modes can result in elevated ventricular pacing rates. To address these situations, the device may be programmed to be less sensitive (using higher sensitivity values). However, the sensitivity level must be balanced against the potential to undersense true

cardiac signals. Typically, this balance is easily attained for ventricular sensing using sensitivity values around 2.8 mV, but it may be difficult to attain for atrial sensing because of the smaller P-wave amplitudes.

Atrial Rate Stabilization (ARS) and unipolar sensing – ARS must be Off if the atrial sensing polarity is unipolar or if Lead Monitor is set to Adaptive for the atrial lead.

AT/AF Detection and unipolar pacing or sensing – AT/AF Detection must be set to Monitor if the atrial sensing polarity is unipolar, if the atrial pacing polarity is unipolar, or if Lead Monitor is set to Adaptive for the atrial lead. Mode Switch remains available.

Atrial Capture Management (ACM) operation and unipolar sensing – If the atrial sensing polarity is unipolar and Atrial Sensitivity is less than 0.45 mV, the ACM feature does not operate.

Disabling Atrial Sensitivity – When changing the mode to VVI or VVIR, consider programming Atrial Sensitivity to Off. Disabling Atrial Sensitivity can preserve battery energy and avoid collection of irrelevant data.

Note: When Atrial Sensitivity is programmed to Off, AT/AF monitoring is disabled.

4.1.7 Evaluation of sensing

4.1.7.1 Using the Sensing Test to evaluate sensing

The Sensing Test allows you to measure P-wave and R-wave amplitudes. These measurements may be useful for assessing lead integrity and sensing performance. After the Sensing Test is complete, the test results are displayed on the test screen. You may view and print the results when desired. For more information, see the programming guide.

4.1.7.2 Viewing the Sensing Integrity Counter

To access the Sensing Integrity Counter, select the Remaining Longevity [>>] button from the Quick Look II screen, or select Data > Device/Lead Diagnostics > Battery and Lead Measurements > [Open Data].

The Sensing Integrity Counter records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate oversensing, lead fracture, or a loose setscrew. If the Sensing Integrity Counter reports more than 300 short ventricular intervals, investigate potential sensing and lead integrity issues.

Note: If the number of short intervals that are displayed exceeds 300, the programmer displays a Quick Look II observation.

4.1.7.3 Viewing P-wave and R-wave amplitude trends

To access P-wave and R-wave amplitude trends, select the [>>] button next to Wave Amplitude on the Quick Look II screen, or select Data > Device/Lead Diagnostics > P/R Wave Amplitude Trends > [Open Data].

P-wave and R-wave amplitude trend data may be useful for assessing lead integrity and sensing performance.

4.2 Basic pacing

Patients have a variety of conditions for which pacing therapy may be indicated. These conditions include cardiac asystole, chronic AT/AF, loss of atrioventricular (AV) synchrony, or poor ventricular function due to heart failure.

Dual chamber and single chamber pacing modes address different cardiac conditions. Dual chamber pacing restores AV synchrony by sensing and stimulating 2 chambers of the heart, the right atrium and right ventricle. Single chamber pacing supports patients with infrequent or no occurrences of asystole or patients with chronic AT/AF and for whom dual chamber pacing is not justified.

4.2.1 Operation of pacing and sensing

The output energy for pacing pulses in each chamber is determined by individually programmed amplitude and pulse width parameters. Although you can program these parameters manually, the Capture Management feature is available to manage pacing output energies in the atrium and right ventricle. For more information, refer to Section 4.7, "Capture Management", page 77.

The device provides sensing in both the atrium and right ventricle. Refer to Section 4.1, "Sensing", page 43 for information about sensing thresholds, sensing polarity, blanking periods, and refractory periods.

4.2.2 Operation of dual chamber pacing

In dual chamber modes, pacing and sensing occur in the atrium and ventricle. The dual chamber pacing modes include DDDR, DDD, DDIR, and DDI. In the DDD mode, pacing occurs at the programmed Lower Rate in the absence of intrinsic atrial activity. In the DDI mode, pacing occurs at the programmed Lower Rate. In the DDDR and DDIR modes, which are rate-responsive, pacing occurs at the sensor rate.

4.2.2.1 AAIR<=>DDDR and AAI<=>DDD modes

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 4.5, "Managed Ventricular Pacing (MVP)", page 66.

4.2.2.2 DDDR and DDD modes

DDDR and DDD are atrial tracking pacing modes. Atrial tracking means that when the device senses an intrinsic atrial event, it schedules a ventricular paced event in response (see Figure 11). The delay between the sensed atrial event and the corresponding ventricular paced event is the Sensed AV (SAV) interval. The delay between the paced atrial event and the corresponding ventricular paced event is the Paced AV (PAV) interval. If a pacing interval ends before the device senses an atrial event, the device paces the atrium and then schedules a ventricular paced event to occur at the end of the PAV interval. If a ventricular sensed event occurs during the SAV interval or the PAV interval, ventricular pacing is inhibited. A sensed atrial event that occurs during the Post Ventricular Atrial Refractory Period (PVARP) is classified as refractory. It does not inhibit atrial pacing, and it is not tracked. For more information, see Section 4.1.5.1, "Post Ventricular Atrial Refractory Period (PVARP)", page 49.

Figure 11. Operation of dual chamber pacing in DDDR
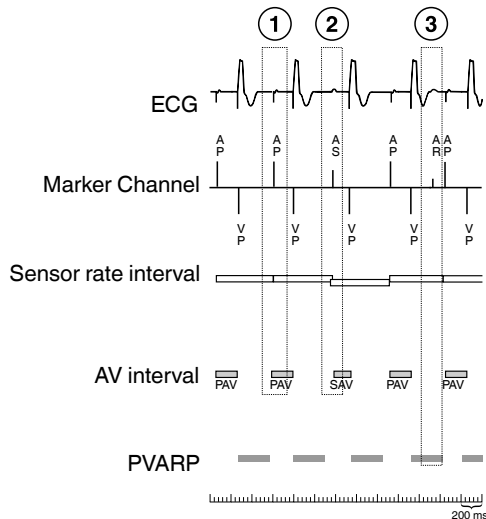
1 An atrial paced event starts a PAV interval.
2 An atrial sensed event starts an SAV interval.
3 An atrial sensed event during PVARP is not tracked.

4.2.2.3 DDIR and DDI modes

In the DDIR and DDI modes, sensed atrial events are not tracked. When an atrial event is sensed, atrial pacing is inhibited, but a SAV interval is not started (see Figure 12). Instead, ventricular pacing is delivered at the current pacing rate (for example, at the Lower Rate or sensor rate). If the current pacing interval ends before the device senses an atrial event, the device paces the atrium and then schedules a ventricular paced event to occur at the end of the PAV interval. If a ventricular sensed event occurs during the PAV interval, ventricular pacing is inhibited. A sensed atrial event that occurs during PVARP is classified as refractory and does not inhibit atrial pacing. For more information, see Section 4.1.5.1, "Post Ventricular Atrial Refractory Period (PVARP)", page 49.

Figure 12. Operation of dual chamber pacing in DDIR
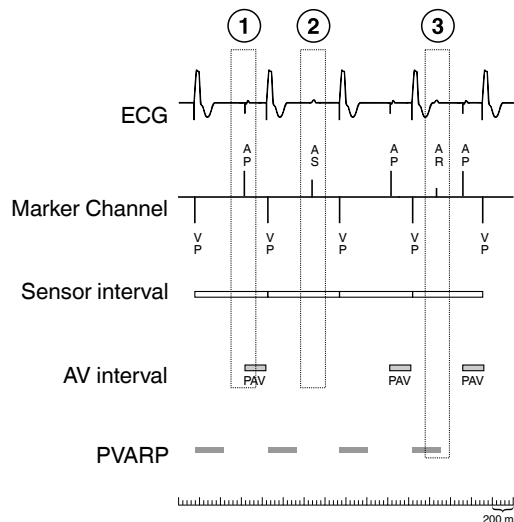
1 An atrial paced event starts a PAV interval.
2 An atrial sensed event inhibits the scheduled atrial paced event but does not start an SAV interval (is not tracked).
3 An atrial event that is sensed during PVARP does not inhibit the scheduled atrial paced event.

4.2.2.4 ODO mode (bradycardia pacing off)

The ODO mode does not deliver ventricular or atrial pacing, regardless of the intrinsic rate. The ODO mode is intended only for those situations in which bradycardia pacing is not necessary.

Dual chamber sensing, atrial detection, and ATP therapy continue to operate as programmed when pacing is programmed to the ODO mode.

Caution: The device provides no pacing support when it is programmed to ODO mode. Use ODO mode only in clinical situations where bradycardia pacing is not necessary or is detrimental to the patient.

4.2.2.5 DOO mode

The DOO mode provides AV sequential pacing at the programmed Lower Rate with no inhibition by intrinsic events.

The device provides no sensing or detection in either chamber when it is programmed to DOO mode. Use DOO mode only in situations in which asynchronous pacing is warranted. AT/AF Detection must be programmed to Monitor to program the device to the DOO mode.

4.2.3 Operation of single chamber pacing

Single chamber pacing modes are used to pace either the atrium or the ventricle.

4.2.3.1 AAIR<=>DDDR and AAI<=>DDD modes

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 4.5, "Managed Ventricular Pacing (MVP)", page 66.

4.2.3.2 VVIR and VVI modes

In the VVIR and VVI modes, the ventricle is paced if no intrinsic ventricular events are sensed. Pacing occurs at the programmed Lower Rate in the VVI mode and at the sensor rate in the VVIR mode (see Figure 13). In VVIR and VVI modes, the device continues sensing atrial events for tachyarrhythmia detection purposes.

Figure 13. Operation of single chamber ventricular pacing in VVIR
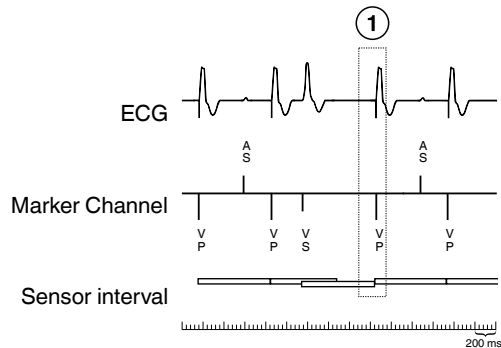
1 A ventricular paced event occurs when no intrinsic ventricular event is sensed.

4.2.3.3 AAIR and AAI modes

In the AAIR and AAI modes, the atrium is paced if no intrinsic atrial events are sensed. Pacing occurs at the programmed Lower Rate in the AAI mode and at the sensor rate in the AAIR mode (see Figure 14).

A sensed event that occurs during the Atrial Refractory Period is classified as refractory and does not inhibit atrial pacing. In AAIR and AAI modes, the device continues sensing ventricular events for tachyarrhythmia detection purposes. VT detection is available but compromised in the AAIR and AAI modes. Cross-chamber blanking can cause ventricular events to go undetected, and crosstalk can cause false detection.

Warning: Do not use the AAIR or AAI mode in patients with impaired AV nodal conduction because these modes do not provide ventricular support.

Figure 14. Operation of single chamber atrial pacing in AAIR
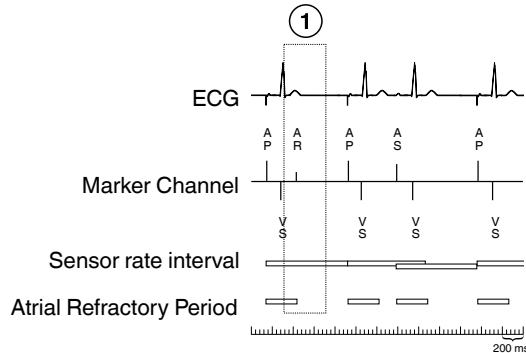
1 An atrial event during the Atrial Refractory Period does not restart the A-A pacing interval.

4.2.3.4 VOO mode

The VOO mode provides ventricular pacing at the programmed Lower Rate with no inhibition by intrinsic ventricular events.

Ventricular detection is not available in the VOO mode, although the device continues to sense in the atrium and monitor for atrial arrhythmias. AT/AF Detection must be programmed to Monitor to program the device to the VOO mode.

4.2.3.5 OVO mode (bradycardia pacing off)

The OVO mode does not deliver ventricular pacing, regardless of the intrinsic rate. The OVO mode is available only in the single-chamber devices. It is intended only for those situations in which bradycardia pacing is not necessary.

Caution: The device provides no pacing support when it is programmed to OVO mode. Use OVO mode only in clinical situations where bradycardia pacing is not necessary or is detrimental to the patient.

4.2.3.6 AOO mode

The AOO mode provides atrial pacing at the programmed Lower Rate with no inhibition by intrinsic atrial events.

When the device is programmed to the AOO mode, it provides no atrial detection although it offers ventricular sensing and monitoring. AT/AF Detection must be programmed to Monitor to program the device to the AOO mode.

4.2.4 Programming pacing therapies

Table 8. How to navigate to basic pacing parameters

Parameters	Path
Mode	Params
Lower Rate Upper Track	
Atrial Amplitude RV Amplitude	Params > Amplitude…
Atrial Pulse Width RV Pulse Width	Params > Pulse Width…
Paced AV	Params > Paced AV…
Sensed AV	Params > Sensed AV…

TherapyGuide – It is suggested that you use the TherapyGuide feature to determine the pacing mode for a particular patient. For more information, refer to the programming guide.

SAV and PAV intervals – The SAV interval is usually programmed 30 ms to 50 ms shorter than the PAV interval. This is done to compensate for the inherent delay between the actual cardiac event in the atrium and when it is detected by the device.

Upper Tracking Rate – When programming higher upper tracking rates, SAV and PVARP should be programmed to appropriate values to assure 1:1 tracking. See Section 4.2.6.

Upper rates and refractory periods – A combination of a high Upper Sensor Rate and a long refractory period may result in competitive atrial pacing. See Section 4.2.6. Consider programming Non-Competitive Atrial Pacing (NCAP) to On.

Pacing safety margins – Pacing pulses must be delivered at an adequate safety margin above the stimulation thresholds.

High pacing output levels – The pulse width and amplitude settings affect the longevity of the device, particularly if the patient requires bradycardia pacing therapy most of the time.

Cross-chamber sensing – Pulse width and amplitude settings can affect cross-chamber sensing. If you set the pulse width and amplitude values too high, pacing pulses in one chamber may be sensed in the other chamber, which could cause inappropriate inhibition of pacing.

4.2.5 Evaluation of pacing therapies

To verify that the device is pacing appropriately, review the Percentage of Time (% of Time) data on the Quick Look II screen. Select Data > Quick Look II.

Percentage of Time (% of Time) – For single chamber modes, the % of Time section reports the patient's pacing (VP) and sensing (VS) as the percentage of the total time during

the reporting period. For dual chamber modes, the % of Time section reports the percentage of ventricular pacing (VP) and atrial pacing (AP).

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, "Quick Look II summary data", page 19.

4.2.6 Tracking rapid atrial rates

When the device is operating in the DDDR or DDD mode, the device can track atrial rhythms only up to a certain rate. Limitations on atrial tracking include the 2:1 block rate and the programmed Upper Tracking Rate as described in Section 4.2.6.1.

4.2.6.1 2:1 block

2:1 block occurs when the intrinsic atrial interval is so short that every other atrial sensed event occurs during PVARP (see Figure 15). These atrial events do not start an SAV interval and therefore do not result in ventricular paced events. Because only every other atrial sensed event is tracked, the ventricular pacing rate becomes one-half of the atrial rate. 2:1 block can be a desirable means to prevent rapid ventricular pacing rates at the onset of AT/AF. However, 2:1 block during exertion or exercise is normally undesirable because the ventricular pacing rate can suddenly drop to one-half of the atrial rate. The sudden reduction in cardiac output can result in patient symptoms.

Figure 15. Example of pacing at the 2:1 block rate
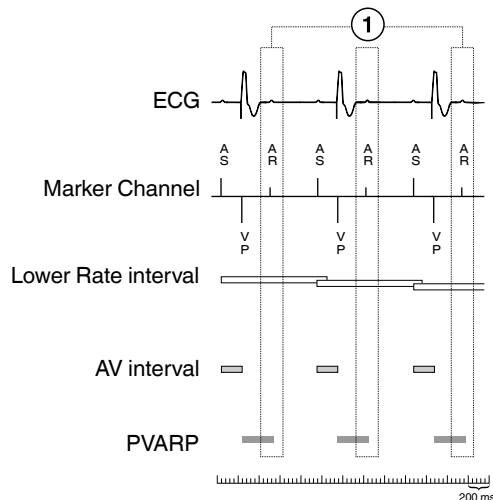
1 One of every 2 atrial sensed events occurs during PVARP and is not tracked.

In some cases, the amount of rate drop is less severe because of pacing at the sensor rate (in the DDDR mode) or because of various rate stabilization, smoothing, or overdrive pacing features.

A common method to prevent 2:1 block at elevated exercise rates (for example, above 150 bpm) is to program shorter than nominal values for SAV and PVARP. Use of the Rate Adaptive AV and Auto PVARP features dynamically shortens the operating SAV and PVARP values during exercise. For more information, see Section 4.9, "Auto PVARP", page 89. These features can prevent symptomatic 2:1 block during exercise while allowing nominal or longer SAV and PVARP values at resting rates to help prevent rapid ventricular pacing rates during the onset of AT/AF.

When programming the SAV or PVARP parameters, the programmer calculates and displays the 2:1 block rate. When the 2:1 block rate is dynamic due to the Rate Adaptive AV or Auto PVARP features, the programmer displays 2:1 block rates at both rest and exercise.

4.2.6.2 Upper Tracking Rate

The programmable Upper Tracking Rate also places a limit on the fastest ventricular pacing rate during atrial tracking. Typically, the Upper Tracking Rate is programmed to a rate that is below the exercise 2:1 block rate. If not, the 2:1 block rate becomes the absolute limit and the Upper Tracking Rate cannot be achieved.

1:1 atrial tracking can occur for sinus rates at or below the programmed Upper Tracking Rate. As the sinus rate increases beyond the Upper Tracking Rate, the ventricular pacing rate remains at the Upper Tracking Rate, and the observed SAV interval (AS-VP interval) lengthens with each subsequent pacing cycle. Eventually, after several pacing cycles, an atrial sensed event occurs during PVARP and is not tracked, resulting in a dropped beat. This pattern repeats itself as long as the sinus rate remains above the programmed Upper Tracking Rate. The dropped beat occurs less often when the sinus rate is only slightly above the Upper Tracking Rate (for example, every 7 or 8 beats) and more often as the sinus rate exceeds the Upper Tracking Rate by larger amounts (for example, every 3 or 4 beats).

This Upper Tracking Rate behavior is known as pacemaker Wenckebach (see Figure 16). Wenckebach behavior can be further defined by how often the dropped beat occurs, typically as a ratio of the number of atrial sensed events compared to ventricular paced events (for example, 8:7, 7:6, 6:5, or 3:2). Further increases in the atrial rate may eventually reach the 2:1 block rate where the ratio becomes 2:1.

Figure 16. Example of Wenckebach pacing
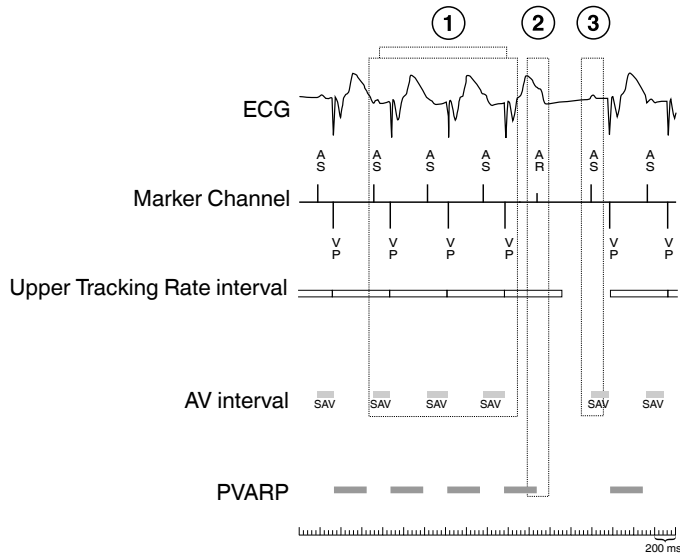
1 SAV intervals extend so that ventricular paced events do not violate the Upper Tracking Rate.
2 An atrial event occurs during PVARP and is not tracked.
3 Tracking resumes on subsequent atrial events.

To provide proper tachyarrhythmia detection, the programmer forces the various tachyarrhythmia detection rates to be programmed above the programmed Upper Tracking Rate and prevents long blanking periods from being programmed along with high Upper Tracking Rate values.

4.3 Implant Detection

Implant Detection is a 30 min period, beginning when the device is placed in the surgical pocket. During this period, the device verifies lead connection and automatically configures the pacing and sensing lead polarities. When the Implant Detection period is completed, various automatic features and diagnostics are activated.

4.3.1 Operation of Implant Detection

Figure 17. Implant Detection process
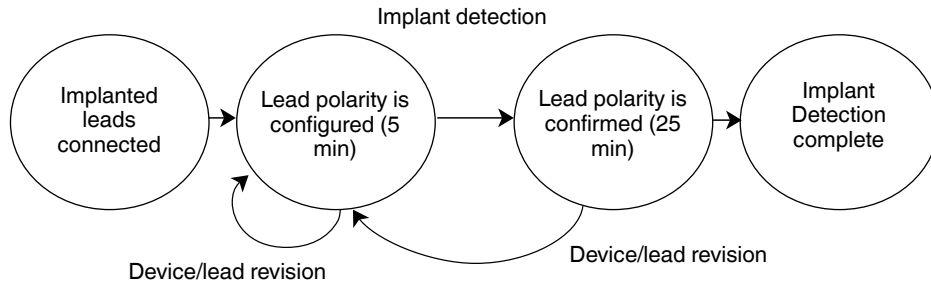
When Implant Detection is started, the device performs lead impedance measurements to verify that the leads have been connected to the device. After the first 5 min of the Implant Detection process, the device automatically configures the sensing and pacing polarities. The atrial and RV leads are configured independently. If the device detects high impedance paces that are out of range, it assumes the lead is not connected due to a lead or device revision, and it restarts the 30 min Implant Detection process. When lead configuration is complete, the device configuration is set to bipolar for bipolar leads and to unipolar for unipolar leads. When Implant Detection is complete, the device activates the following features:

- MVP feature
- Atrial Preference Pacing
- Rate Response
- Capture Management feature
- diagnostic data collection

Lead polarity can also be set manually at any time during the automatic configuration process.

Note: If unipolar leads are being implanted, consider manual completion of Implant Detection.

4.3.2 Programming Implant Detection and lead polarity

Table 9. How to navigate to Implant Detection and lead polarity parameters

Parameters	Path
Implant Detection	Params > Additional Features…
Atrial Pace Polarity RV Pace Polarity	Params > Pace Polarity…
Atrial Sense Polarity RV Sense Polarity	Params > Sense Polarity…

MRI SureScan mode and lead polarity – The MRI SureScan parameter cannot be programmed to On unless Atrial Pace Polarity and RV Pace Polarity are set to Bipolar.

Implant Detection – If you program Implant Detection to Off/Complete before the 30 min automatic polarity configuration period is completed, you must program sensing and pacing polarities manually.

AT/AF Detection – AT/AF Detection must be set to Monitor if the Atrial Pace or Sense Polarity is set to Unipolar. This prevents the device from delivering atrial ATP therapies in the unipolar configuration.

Polarity override – Do not override the polarity verification prompt with bipolar polarity when a unipolar lead is connected. Overriding the polarity verification prompt results in no pacing output.

4.4 Lead Monitor

The Lead Monitor feature measures lead impedances over the long-term operation of the device and enables the device to switch bipolar pacing and sensing to unipolar when bipolar lead integrity is in doubt.

4.4.1 Operation of Lead Monitor

Throughout the life of the device, Lead Monitor measures the impedance of each pacing pulse to determine whether it falls within the programmed impedance range for a stable lead. If you program Lead Monitor to Adaptive, the device switches bipolar pacing and sensing polarity to unipolar when lead integrity is in doubt due to a prevalence of high or low impedance paces. If you program Lead Monitor to Monitor Only, the device monitors impedance values to determine whether they are out of range, but it does not switch polarity when an out-of-range lead impedance is detected.

When a lead polarity switch occurs, the sensitivity value is changed to the nominal unipolar sensitivity value if the previous value was more sensitive.

Caution: If the Lead Monitor detects out-of-range lead impedance, the device records a Quick Look II Observation. In addition, a lead warning message is displayed as a window on the programmer screen the next time the device is interrogated by a programmer. Investigate possible lead system failures. Lead system failures can prevent adequate sensing or full pacing support.

4.4.2 Programming Lead Monitor

Table 10. How to navigate to Lead Monitor parameters

Parameters	Path
Atrial Lead Monitor RV Lead Monitor Atrial Min Limit RV Min Limit Atrial Max Limit RV Max Limit	Params > Pace Polarity…

MRI SureScan mode and lead polarity – When Lead Monitor switches the polarity to unipolar, the MRI SureScan parameter cannot be programmed to On.

AT/AF Detection – When the Atrial Lead Monitor is set to Adaptive, AT/AF Detection must be set to Monitor because there is potential for the device to switch to a unipolar configuration.

4.4.3 Evaluation of Lead Monitor

If Lead Monitor detects a possible lead system failure, the device records a Quick Look II Observation. In addition, a lead warning message is displayed as a window on the programmer screen the next time the device is interrogated by a programmer. Also, the lead impedance trend data displays a Lead Warning annotation. To access the lead impedance trend data, select the Impedance [>>] button on the Quick Look II screen.

4.5 Managed Ventricular Pacing (MVP)

Unnecessary right ventricular pacing may be associated with an increased risk of atrial fibrillation, left ventricular dysfunction, and congestive heart failure, especially in patients with intact or intermittent AV conduction.[3,4,5]

The MVP (Managed Ventricular Pacing) feature is an atrial-based pacing mode that is designed to switch to a dual chamber pacing mode in the presence of AV block. Specifically, the MVP feature provides the following functions:

- AAI(R) mode pacing when AV conduction is intact

- the ability to switch to DDD(R) pacing during AV block

- periodic conduction checks while operating in DDD(R) mode, with the ability to switch back to AAI(R) mode when AV conduction resumes

- backup ventricular support for transient loss of AV conduction

4.5.1 Operation of MVP mode

Figure 18. Overview of MVP mode
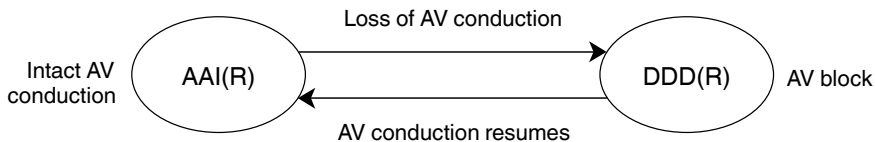
4.5.1.1 Intact AV conduction

The MVP modes, AAIR<=>DDDR and AAI<=>DDD, provide AAIR or AAI mode pacing while monitoring AV conduction. If AV conduction is intact, the device remains in AAIR or AAI mode. While operating in AAI or AAIR mode, the parameters associated with single chamber atrial pacing are applicable.

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[3] Sweeney M, Hellkamp A, Ellenbogen K, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. *Circulation*. 2003;107:2932-2937.

[4] Nielsen J, Kristensen L, Andersen H, et al. A randomized comparison of atrial and dual-chamber pacing in 177 consecutive patients with sick sinus syndrome: echocardiographic and clinical outcome. *J Am Coll Cardiol*. 2003;42:614-623.

[5] Andersen H, Nielsen J, Thomsen P, et al. Long-term follow-up of patients from a randomised trial of atrial versus ventricular pacing for sick-sinus syndrome. *Lancet*. 1997;350:1210-1216.

4.5.1.2 Loss of AV conduction

If 2 of the 4 most recent A-A intervals are missing a ventricular event, the device identifies a loss of AV conduction and switches to the DDDR or DDD mode. The device provides backup ventricular pacing in response to dropped ventricular events until the loss of AV conduction is identified.

Figure 19. Switching from AAIR mode to DDDR mode
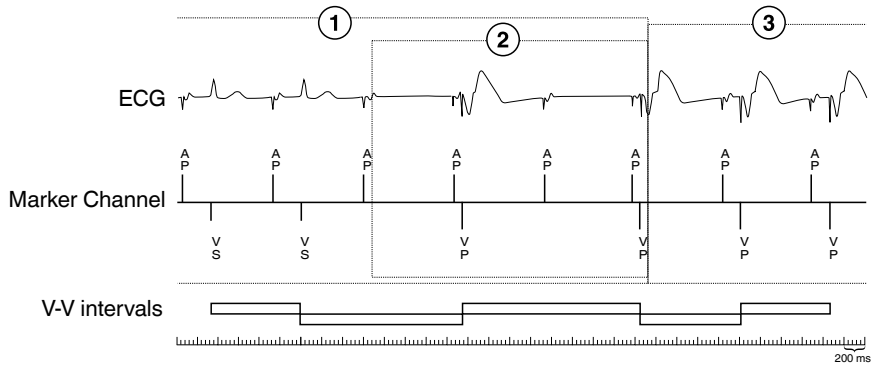
1 The device operates in AAIR mode.
2 At the onset of AV block, the device supplies ventricular backup pacing pulses.
3 The device switches to DDDR mode.

4.5.1.3 AV conduction resumes

After switching to DDDR or DDD mode, the device periodically checks AV conduction for an opportunity to return to AAIR or AAI mode. The first AV conduction check occurs 1 min after switching to DDDR or DDD mode. During the conduction check, the device switches to AAIR or AAI pacing mode for one cycle.

- If the next A-A interval includes a sensed ventricular beat, the conduction check succeeds. The device remains in AAIR or AAI pacing mode.

- If the next A-A interval does not include a sensed ventricular beat, the conduction check fails and the device switches back to the DDDR or DDD mode. The time between conduction checks doubles (2, 4, 8 … min, up to a maximum of 16 hours) with each failed conduction check.

Figure 20. Switching from DDDR mode to AAIR mode after AV conduction resumes
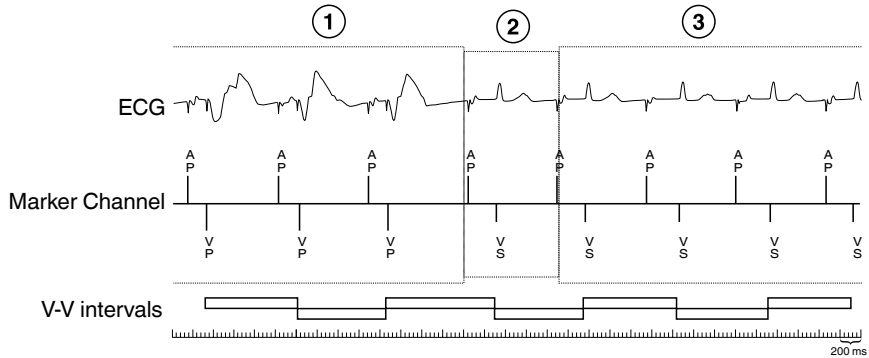
1 The device operates in DDDR mode.
2 The device performs an AV conduction check. AV conduction is detected.
3 The device operates in AAIR mode.

4.5.1.4 Complete AV block

For patients with complete AV block, the device operates in DDDR or DDD mode persistently. Every 16 hours, the device checks for AV conduction, which results in a single dropped ventricular beat.

Figure 21. Remaining in DDDR mode after an AV conduction check
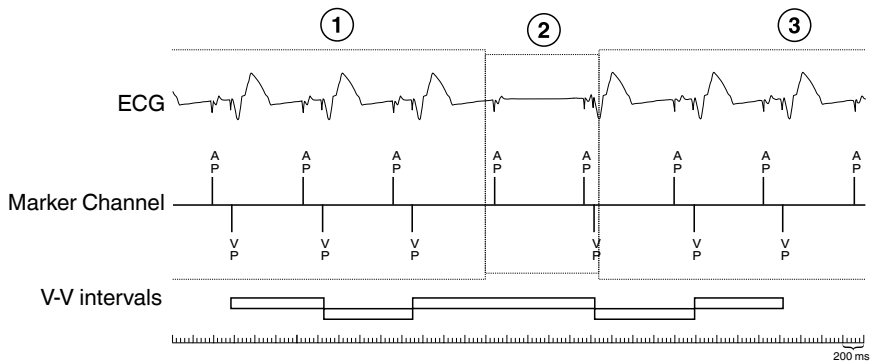
1 The device operates in DDDR mode.
2 The device checks for AV conduction, but conduction is not detected.
3 The device continues to operate in DDDR mode.

4.5.1.5 Transient loss of conduction

For transient loss of AV conduction, the device remains in the AAIR or AAI mode and provides a backup ventricular pacing pulse in response to an A-A interval that is missing a ventricular sense.

4.5.1.6 Interactions with MVP mode

Mode Switch – Mode Switch and the MVP modes operate together to adjust the pacing mode according to the patient's atrial rhythm and AV conduction status.

Figure 22. Operation of MVP mode and Mode Switch
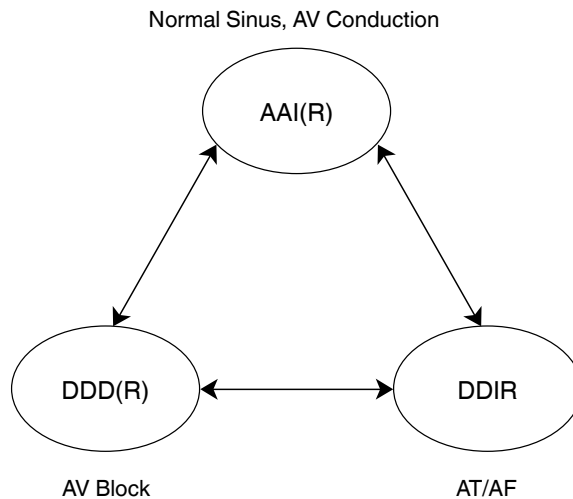
Atrial Refractory Period – When the MVP feature is operating in AAIR or AAI mode, the Atrial Refractory Period is not programmable. Instead, it is automatically adjusted according to the current heart rate: 600 ms for rates below 75 bpm and 75% of the ventricular interval for rates at or above 75 bpm.

PVCs and ventricular tachyarrhythmias – When the MVP feature is operating in AAIR or AAI mode, the device inhibits atrial pacing in response to PVCs, PVC runs, and ventricular tachyarrhythmia episodes. This behavior is intended to prevent unnecessary atrial pacing when the ventricular rate is faster than the pacing rate. It also allows tachyarrhythmia detection features to operate without disruption from blanking periods caused by atrial pacing.

4.5.2 Programming MVP mode

Table 11. How to navigate to MVP parameters

Parameters	Path
Mode	Params
Maximum AV Interval Limit	Params > Paced AV…

V-V interval variations – Depending on the patient's intrinsic rhythm and conduction, the MVP mode allows V-V interval variations and occasional pauses of up to twice the lower rate interval.

Paced AV and Sensed AV – For MVP modes, it is not necessary to program longer Paced AV and Sensed AV intervals to promote intrinsic AV conduction. Paced AV and Sensed AV intervals apply only when loss of AV conduction is detected.

Lower rate programming – Upon abrupt loss of AV conduction, prior to switching to DDDR or DDD mode, ventricular pacing support can be as low as one-half the programmed Lower Rate for 2 consecutive intervals. For patients with sinus bradycardia or frequent loss of AV conduction, program the Lower Rate to 50 bpm or higher.

Complete heart block – For patients with complete heart block, the device drops 1 beat every 16 hours (AV conduction check). See Section 4.5.1.4. If this is undesirable, permanent DDDR or DDD modes may be more appropriate.

Long PR intervals – For patients with long PR intervals, the device remains in the AAIR or AAI mode. Permanent DDDR or DDD modes may be more appropriate for patients with symptomatic first-degree AV block. Alternatively, you can program the Maximum AV Interval Limit parameter, which causes the device to switch to DDDR or DDD mode if the patient's PR interval exceeds the programmed limit.

Operation immediately after implant – The device is shipped in the MVP mode, initially operating in DDD mode. Approximately 30 min after implant, the device checks for AV conduction and switches to AAIR or AAI mode if the next A-A interval includes a sensed ventricular beat. See Section 4.5.1.3 for more information.

4.5.3 Evaluation of MVP mode

The following features can help to assess atrial and ventricular pacing and MVP performance:

- the pacing mode indicator near the top of the programmer screen
- the Quick Look II screen
- the Rate Histograms diagnostic and report

- the Cardiac Compass Trends diagnostic and report
- the MVP Mode Switches diagnostic and MVP Mode Switches List report

4.5.3.1 Pacing mode indicator

When the device is programmed to an MVP mode, the pacing mode indicator near the top of the screen displays the mode in which the device is currently operating. (When the device is operating in an atrial mode, the pacing mode indicator displays AAI+ or AAIR+.)

4.5.3.2 Quick Look II screen

To access the Quick Look II screen, select Data > Quick Look II.

The Quick Look II screen shows the percentages of atrial and ventricular pacing since the last session. The Quick Look II screen also indicates whether the device is programmed to an MVP mode. If the present programmed pacing mode is AAIR<=>DDDR or AAI<=>DDD, the message "MVP On" appears on the Quick Look II screen. Otherwise, the screen displays "MVP Off."

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, "Quick Look II summary data", page 19.

4.5.3.3 Cardiac Compass Trends

To access Cardiac Compass Trends, select the Cardiac Compass [>>] button on the Quick Look II screen, or select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data].

The % Pacing/day trend in Cardiac Compass Trends provides a view of pacing over time that can help you identify pacing changes and trends. The graph displays the percentage of all events occurring during each day that are atrial paces and ventricular paces. This information can help determine the effect of MVP mode on ventricular pacing.

4.5.3.4 MVP Mode Switches diagnostic

To access the MVP Mode Switches diagnostic, select Data > Clinical Diagnostics > MVP Mode Switches > [Open Data].

The MVP Mode Switches diagnostic lists up to 10 of the most recent MVP mode switches to DDD(R). For more information, see Section 3.8, "MVP Mode Switches data", page 35

4.6 Rate Response

Some patients exhibit heart rates that do not adapt to changes in their physical activity. Their symptoms might be shortness of breath, fatigue, or dizziness. This includes patients with chronotropic incompetence and patients with chronic or paroxysmal AF.

Rate-responsive pacing adapts the pacing rate to changes in patients' physical activity. This device uses an activity sensor to measure the patient's movement and to determine the appropriate pacing rate. It provides dual-slope rate response that may be either automatic or manual.

4.6.1 Operation of Rate Response

Figure 23. Overview of Rate Response
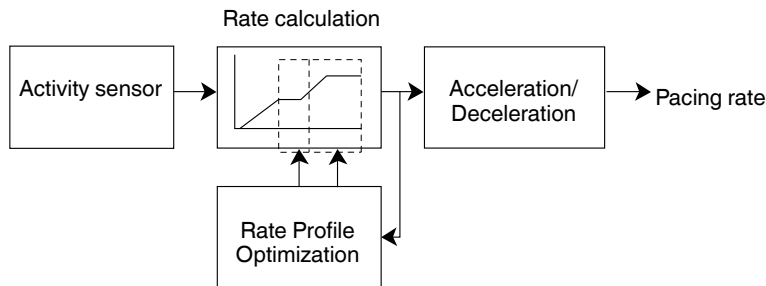
The Rate Response system includes an activity sensor to measure patient movement, rate calculation to convert the patient's level of physical activity to a pacing rate, Rate Profile Optimization to automatically adjust rate response settings over time, and acceleration and deceleration to smooth the pacing rate. This pacing rate is also described as the sensor rate.

4.6.1.1 Activity sensing

The activity sensor is an accelerometer in the device that detects the patient's body movements. Because activity detection varies from patient to patient, the sensitivity to motion can be adjusted by reprogramming the Activity Threshold parameter. If the Activity Threshold is lowered, smaller body movements influence the pacing rate. If the Activity Threshold is raised, body movements must be larger to influence the pacing rate. The activity count used to calculate the sensor rate is weighted based on the frequency and amplitude of the accelerometer signal.

The pacing rate is determined by the patient's level of physical activity and the rate response parameters. In the absence of activity, such as when the patient is sitting, the pacing rate is close to the programmed Lower Rate setting. During increased activity, such as when the patient is walking, the pacing rate is higher.

4.6.1.2 Rate calculation

The rate curve shows how the device calculates the pacing rate as the patient's activity level changes.

Figure 24. Rate curve

Increasing activity ➔
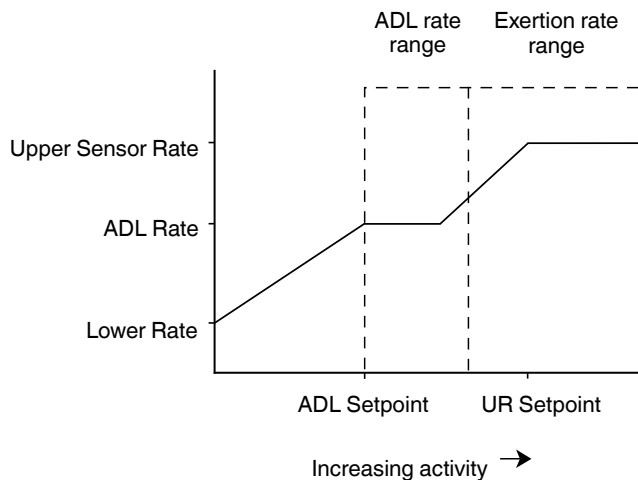
Programmable rates – The Lower Rate is the slowest rate at which pacing occurs in the absence of physical activity. The Activities of Daily Living Rate (ADL Rate) is the approximate pacing rate during moderate exercise and provides a plateau which helps maintain a stable pacing rate during changes in moderate activity. The Upper Sensor Rate is the upper limit for the pacing rate during vigorous exercise.

Rate Response setpoints – The setpoints define the 2 slopes characteristic of dual-slope Rate Response. The ADL Setpoint determines the weighted activity counts that cause the pacing rate to reach the ADL Rate. The UR Setpoint determines the weighted activity counts that cause the pacing rate to reach the Upper Sensor Rate. A lower setpoint means fewer activity counts are required to reach upper rates.

Automatic Rate Response – With automatic Rate Response, Rate Profile Optimization continues to adjust the rate curve by varying these setpoints. The rate curve is adjusted based on how the ADL Response and Exertion Response parameters are programmed. The

ADL Response controls the first slope, which determines how aggressively the pacing rate increases from the Lower Rate to the ADL Rate. The Exertion Response controls the second slope, which determines how aggressively the pacing rate approaches the Upper Sensor Rate.

Manual Rate Response (Rate Profile Optimization programmed to Off) – With manual Rate Response, the rate curve is established during a patient session when the rates and setpoints are programmed. The rate curve remains constant until the parameters are reprogrammed.

4.6.1.3 Rate Profile Optimization

Rate Profile Optimization automatically adjusts the patient's rate response between office visits. The goal of Rate Profile Optimization is to ensure that the rate response remains appropriate for the full range of patient activities. Each day, the device collects and stores daily and long-term averages of the percentage of time that the patient sensor-indicated rate is at different pacing rates. The device then uses the ADL Response and Exertion Response parameters to define the percentage of time that the pacing rate stays in the ADL rate range and exertion rate range, respectively. Based on daily comparisons, the device adjusts the ADL Setpoint, the UR Setpoint, or both setpoints.

By programming new settings for rates or Rate Profile Optimization, you are affecting the comparisons. Immediate changes occur. These changes project how rate response should change in the future based on stored sensor rate information and the selected Rate Profile Optimization settings. The device continues to adjust the rate response over time.

The device adapts Rate Response more rapidly for the first 10 days after Rate Profile Optimization is first activated post-implant or after certain Rate Response parameters are manually reprogrammed (Lower Rate, ADL Rate, Upper Sensor Rate, ADL Response, or Exertion Response). The intent is to quickly match Rate Response to the operation prescribed by the parameter changes.

Note: Because the device is automatically changing the setpoint values, if you manually program the setpoint values, Rate Profile Optimization is disabled.

4.6.1.4 Activity Acceleration and Activity Deceleration

The Activity Acceleration and Activity Deceleration parameters are used to smooth the pacing rate. Activity Acceleration controls how rapidly the pacing rate increases. Activity Deceleration controls how rapidly the pacing rate decreases and has both fixed values and the Exercise option. The Exercise setting adjusts the deceleration dynamically based on the intensity and duration of exercise, and it can extend the deceleration up to 20 min.

As shown in Figure 25, changing the values of the Activity Acceleration and Activity Deceleration parameters affects the pacing rate during and after exertion.

Figure 25. Activity Acceleration and Deceleration curves for rate response
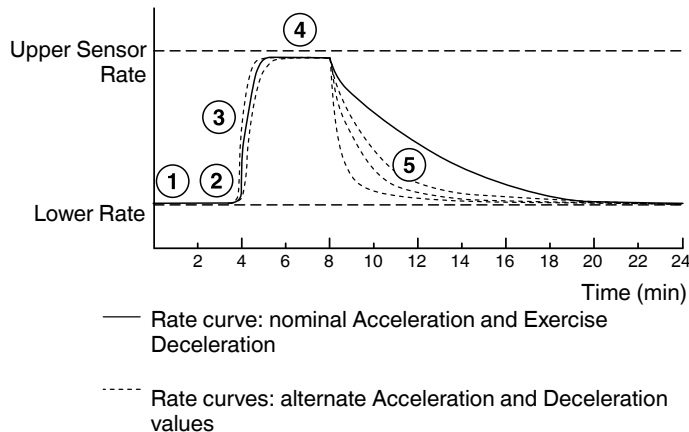
1 Pacing occurs with the patient at rest.
2 Activity increases and Activity Acceleration begins.
3 Activity Acceleration continues toward a higher pacing rate.
4 Pacing occurs at a higher rate during exertion.
5 Exertion ends and the pacing rate decelerates.

4.6.1.5 Rate Response during implant

Rate Response does not operate during an implant procedure to avoid increased pacing caused by handling. Rate Response and Rate Profile Optimization begin operating when Implant Detection is complete. For more information, see Section 4.3, "Implant Detection", page 62

4.6.1.6 Rate Response parameters screen

The parameters screen for Rate Response shows the rate curve corresponding to the interrogated parameter values. If you select pending values for the parameters, the screen also shows a pending curve. The pending curve reflects the immediate changes that will occur after reprogramming.

4.6.2 Programming Rate Response

Table 12. How to navigate to Rate Response parameters

Parameters	Path
Lower Rate ADL Rate Upper Sensor Rate Profile Optimization ADL Response Exertion Response	Params > Rate Response…
Activity Threshold Activity Acceleration Activity Deceleration ADL Setpoint UR Setpoint	Params > Rate Response… > Additional Parameters…

TherapyGuide – The TherapyGuide feature suggests parameter values based on information entered about the patient's clinical conditions. Parameter values for Rate Response are included. For more information about the TherapyGuide feature, refer to the programming guide.

Rate-responsive pacing and DDD or AAI<=>DDD mode – When the programmed pacing mode is DDD or AAI<=>DDD (an MVP mode) and Mode Switch is enabled, the Rate Response parameters are programmable. However, these parameters apply only during Mode Switch episodes when the operating mode is DDIR.

Adjusting the Activity Threshold – For many patients there is no need to reprogram the Activity Threshold parameter. However, if a patient has minimal rate response during exercise, the Activity Threshold may need to be programmed to a lower (more sensitive) setting. The most sensitive setting is "Low". Conversely, if a patient has an elevated pacing rate at rest, the Activity Threshold may need to be programmed to a higher (less sensitive) setting. The least sensitive setting is "High".

Adjusting Rate Profile Optimization – Before programming other Rate Response parameters, first verify that the settings for Lower Rate, ADL Rate, and Upper Sensor Rate are appropriate for the patient.

It may be necessary to reprogram the ADL Response and Exertion Response parameters if reprogramming the rates does not have the desired effect on Rate Profile Optimization. By reprogramming the ADL Response and Exertion Response parameters, you can prescribe a rate profile that matches the patient's lifestyle or activity levels in each rate range.

Adjust the ADL Response to prescribe how quickly the patient reaches the ADL Rate and the Exertion Response to prescribe how quickly the patient reaches the Upper Sensor Rate. In both cases, a lower value decreases the rate responsiveness and a higher value increases the rate responsiveness.

Note: If increasing the Exertion Response setting does not make Rate Response aggressive enough, increase the ADL Response setting.

Adjusting the setpoints manually – You can program Rate Profile Optimization to Off and program the setpoints manually. In this case, the ADL Setpoint and UR Setpoint determine the pacing rate curve, and rate response calculations continue to operate as programmed.

4.6.3 Evaluation of Rate Response

4.6.3.1 Rate Histograms

To access Rate Histograms, select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

Rate Histograms provide information about how Rate Response has been performing since the previous patient session. For example, if Rate Response was programmed to be more aggressive, the histograms will likely show that the percentage of atrial pacing has shifted from lower rates to higher rates.

4.6.3.2 Flashback Memory

Flashback Memory provides a rate trend based on the initial interrogation.

To access Flashback Memory data, select Data > Clinical Diagnostics.

Set the plot display to Rate to see how Rate Response was operating before the patient session.

Note: To evaluate new Rate Response settings, instruct the patient to complete a hall walk and then reinterrogate the device.

4.7 Capture Management

Maintaining adequate safety margins for pacing output energies and optimizing device longevity are critical to patient care. As the patient's condition changes, pacing thresholds may change, requiring pacing outputs to be monitored regularly and modified, if necessary, to capture the myocardium.

The Capture Management feature automatically manages pacing thresholds in the right atrium and right ventricle. It monitors whether pacing pulses capture the myocardium and, optionally, adjusts their amplitude to changing patient conditions.

4.7.1 Operation of the Capture Management feature

The Capture Management feature is a programmable feature that is available for the right atrium (ACM) and right ventricle (RVCM). In Capture Management operation, the device prepares for a pacing threshold search, conducts the pacing threshold search, and determines the pacing threshold. Over time, the threshold measurements are collected to create threshold trends. If the Capture Management feature is programmed to Adaptive, the device may automatically adjust the pacing outputs. If the Capture Management feature is programmed to Monitor, no adjustments occur.

4.7.1.1 Manual adjustment of pacing outputs

You have the option to program pacing outputs manually instead of using the automatic Capture Management feature. The pacing safety margins should be checked if the Capture Management feature is programmed to Monitor. Threshold data that is collected during pacing threshold searches can make it easier for you to select values for pacing output parameters. For more information, see Section 4.2, "Basic pacing", page 53.

4.7.1.2 Pacing thresholds and safety margins

The amplitude and pulse width parameters control the output energy of pacing pulses in each chamber. The pacing output energy determines whether pacing pulses capture the myocardium. It is necessary for pacing output settings to exceed the pacing threshold by a safety margin. Pacing threshold variations may be caused by exercise, eating, sleeping, drug therapy, or changes in other cardiac conditions.

4.7.2 Operation of the Atrial Capture Management feature

The Atrial Capture Management (ACM) feature is available when the pacing mode is programmed to DDDR, DDD, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD), and it functions when the device is operating in one of these modes. If ACM is programmed to Monitor or Adaptive, the device conducts a pacing threshold search to determine the atrial pacing threshold. If ACM is programmed to Adaptive, the device uses the atrial pacing threshold to define a target amplitude and adjusts the pacing amplitude toward the target amplitude. The target amplitude is based on the programmed settings for the Atrial Amplitude Safety Margin and the Atrial Minimum Adapted Amplitude parameters.

Note: In the event of partial or complete lead dislodgment, ACM may not prevent loss of capture.

4.7.2.1 Preparing for an atrial pacing threshold search

Every day at 01:00, the device schedules Capture Management operations in the available chambers. ACM is scheduled when no other pending features have a higher priority. ACM starts with a device check to determine if any parameter settings would prevent a search. For example, the permanent programmed values of Atrial Amplitude or Atrial Pulse Width cannot exceed limits of 5 V or 1 ms. If the device check is unsuccessful, no atrial pacing threshold searches are scheduled until the following day.

The device also evaluates whether the patient's current rhythm is stable enough to support a pacing threshold search. If the stability check is successful, the pacing threshold search is initiated. If stability checks are unsuccessful, the device automatically continues to schedule searches at 30 min intervals until the end of the day. If the device is unable to complete a stability check successfully during one day, the process is repeated on the following day.

If the programmed pacing mode is an MVP mode and the stability check is successful, the device switches to a temporary mode for the duration of the pacing threshold search. It switches from AAIR<=>DDDR mode to DDDR mode or from AAI<=>DDD mode to DDD mode.

### 4.7.2.2 Searching for and determining the atrial pacing threshold

The device conducts a pacing threshold search to determine the atrial pacing amplitude threshold at a fixed pulse width of 0.4 ms. ACM varies the amplitude of test paces to find the lowest amplitude that consistently captures the atrial myocardium.

If the right atrium responds to a test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test paces at the same test amplitude. If there are too many inconclusive results, the device stops the pacing threshold search and retries it at the next scheduled period. See Section 4.7.2.4.

A pacing threshold search begins at a test amplitude that is 0.125 V lower than the last measured threshold. If there was no previous search, a new search begins at 0.75 V. The device continues to decrease the test amplitude in steps of 0.125 V until a test amplitude is classified as being below the pacing threshold. The device then increases the test amplitude in steps of 0.125 V until the same test amplitude is classified as being above the pacing threshold 3 times in succession. This test amplitude is the atrial pacing threshold.

At the beginning of a pacing threshold search, the device selects a method for evaluating atrial capture based on the patient's current sinus rhythm. The Atrial Chamber Reset (ACR) method is used when the patient has a stable sinus rhythm (a sensed atrial rate that is not faster than 87 bpm). The AV Conduction (AVC) method is used when stable 1:1 AV conduction is observed with atrial pacing. These methods evaluate capture differently, but threshold determination is the same.

Atrial Chamber Reset (ACR) method – In the ACR method, each test pace is preceded by 3 support cycles and followed by 2 extra support cycles. The 3 support cycles monitor AS-AS intervals to ensure that the patient's rhythm is stable before the test pace is delivered. The 2 extra support cycles provide time after the test pace for the atrial rhythm to stabilize. ACR evaluates capture based on the response of the intrinsic rhythm to the atrial test pace. "Loss of capture" is characterized by an atrial event that follows the test pace but occurs within the atrial refractory period. As shown in Figure 26, this event is indicated by an AR marker.

Figure 26. Atrial Chamber Reset test method
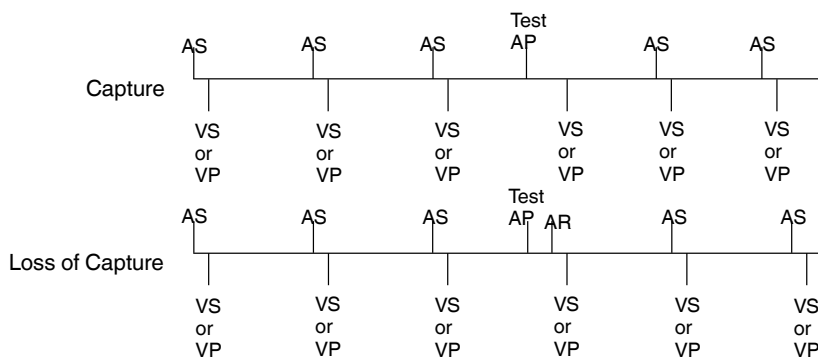
AV Conduction (AVC) method – In the AVC method, each test pace is preceded by 3 support cycles and followed by a backup pace. During this pacing sequence, overdrive pacing is accomplished with a faster atrial pacing rate and a lengthened AV interval. These changes result in a stable AP-VS rhythm with a shorter AP-AP interval. The AP-AP interval before the test pace is even shorter than the intervals that precede it. The backup pace has the programmed amplitude and a 1.0 ms pulse width.

The AVC method evaluates capture by observing the conducted ventricular response to an atrial test pace. The intervals containing the test pace and the support cycle preceding it are shown in Figure 27. If the test pace captures the atrium, the next VS event results from AV conduction of the test pace. If no capture occurs, the next VS event results from AV conduction of the backup pace, which is delivered 70 ms after the test pace.

Figure 27. AV Conduction test method
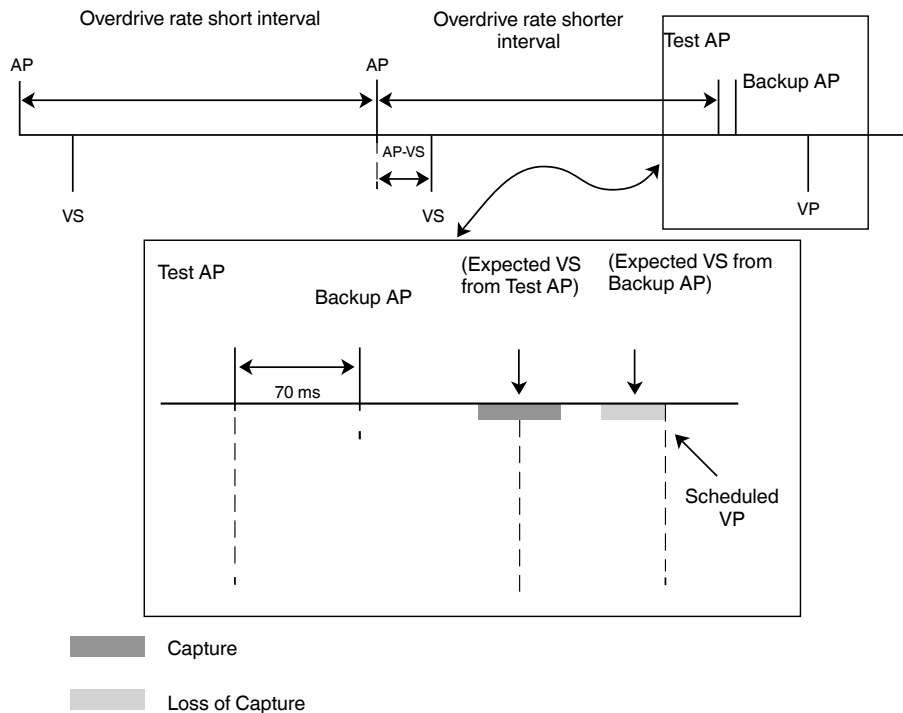
4.7.2.3 Adjusting atrial pacing outputs

If ACM is programmed to Adaptive, the device automatically adjusts the Atrial Amplitude based on the pacing threshold search results. After a successful pacing threshold search, the device calculates a target amplitude by multiplying the programmed Atrial Amplitude Safety Margin by the amplitude threshold measured at a pulse width of 0.4 ms. The device calculation for the target amplitude is rounded up to the next programmable amplitude setting. For information about target amplitudes and safety margins, see Section 4.7.1.2.

Adjustments during the acute phase – The programmable acute phase corresponds to the lead maturation period. During this time, adequate pacing output is ensured by restricting output adjustments. The acute phase begins when implant detection is complete. The nominal length of the acute phase is 120 days, but the Acute Phase Remaining parameter can be reprogrammed to change the length of the acute phase.

During the acute phase, the lower limit for Atrial Amplitude is the last user-programmed amplitude setting or 3.5 V, whichever value is higher. The Atrial Pulse Width is maintained at the last highest setting programmed by the user or 0.4 ms, whichever value is higher.

Adjustments after the acute phase – The device applies the programmed Atrial Amplitude Safety Margin to the target amplitude measured at a 0.4 ms pulse width to determine the new amplitude setting. The device then adjusts the current Atrial Amplitude toward this target. The device reduces the amplitude by 0.25 V every other day until it reaches the target amplitude. If the operating amplitude is below the target, the device adjusts it to the target immediately. The lower limit is set by the programmed Atrial Minimum Adapted Amplitude. If the operating pulse width has a value different from 0.4 ms, the device adjusts it to that value.

Upper limit for adjustments – The device adjusts the Atrial Amplitude to 5.0 V and the Atrial Pulse Width to 1.0 ms if the amplitude threshold is greater than 2.5 V or the target amplitude is greater than 5.0 V.

4.7.2.4 Stopping an atrial pacing threshold search in progress

The device stops a pacing threshold search immediately if there are sudden changes in the patient's heart rate or if other device features take precedence over the search.

When a pacing threshold search cannot be completed, the device automatically schedules another search within 30 min. If 5 more search attempts are stopped during a day, the pacing threshold test is suspended until the following day. Whenever this happens, a device check occurs again, and the process is repeated. The reasons for stopping a pacing threshold search are noted in the Capture Threshold trends diagnostic. See Section 4.7.5.

4.7.3 Operation of the Right Ventricular Capture Management feature

The Right Ventricular Capture Management (RVCM) feature is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, VVIR, VVI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD), and it functions when the device is operating in one of these modes. If RVCM is programmed to Monitor or Adaptive, the device conducts a pacing threshold search to determine the RV pacing threshold. If RVCM is programmed to Adaptive, the device uses the RV pacing threshold to define a target amplitude and adjusts the pacing amplitude toward the target amplitude. The target amplitude is based on the programmed settings for the RV Amplitude Safety Margin and the RV Minimum Adapted Amplitude parameters.

Note: In the event of partial or complete lead dislodgment, RVCM may not prevent loss of capture.

Note: If the battery reaches the Elective Replacement Indicator (ERI), the device aborts RVCM. No additional RV pacing threshold searches are conducted.

4.7.3.1 Preparing for an RV pacing threshold search

Every day at 01:00, the device schedules Capture Management operations in the available chambers. RVCM is scheduled when no other pending features have a higher priority. RVCM starts with a device check to determine if any parameter settings would prevent a search. For example, the permanent programmed values of RV Amplitude or RV Pulse Width cannot exceed limits of 5 V or 1 ms. If the device check is unsuccessful, no RV pacing threshold searches are scheduled until the following day.

The device also evaluates whether the patient's current rhythm is stable enough to support a pacing threshold search. If the stability check is successful, the pacing threshold search is initiated. If stability checks are unsuccessful, the device automatically continues to schedule searches at 30 min intervals until the end of the day. If the device is unable to complete a stability check successfully during one day, the process is repeated on the following day.

If the programmed pacing mode is an MVP mode and the stability check is successful, the device switches to a temporary mode for the duration of the pacing threshold search. It switches from AAIR<=>DDDR mode to DDDR mode or from AAI<=>DDD mode to DDD mode.

4.7.3.2 Searching for and determining the RV pacing threshold

The device conducts a pacing threshold search to determine the RV pacing amplitude threshold at a fixed pulse width of 0.4 ms. RVCM varies the amplitude of test paces to find the lowest amplitude that consistently captures the right ventricular myocardium. The device evaluates capture by detecting the evoked response signal following each test pace.

If the right ventricle responds to a test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test paces at the same test amplitude. If there are too many inconclusive results, the device stops the pacing threshold search and retries it at the next scheduled period. See Section 4.7.3.4.

A pacing threshold search begins at a test amplitude that is 0.125 V lower than the last measured threshold. If there was no previous search, a new search begins at 0.75 V. The device continues to decrease the test amplitude in steps of 0.125 V until a test amplitude is classified as being below the pacing threshold. The device then increases the test amplitude in steps of 0.125 V until the same test amplitude is classified as being above the pacing threshold 3 times in succession. This test amplitude is the RV pacing threshold.

In each threshold measurement, the test pace is part of a test sequence (see Figure 28). In each test sequence, 3 support cycles precede the test pace, and an automatic backup pace follows the test pace. The support cycles provide pacing at the programmed amplitude and pulse width. The support cycles may or may not include ventricular paced events. During testing, the backup pace maintains rhythm stability, and it provides pacing support to the patient when the test pace does not capture the myocardium. The backup pace is delivered 100 ms after the test pace at the programmed amplitude and a 1.0 ms pulse width.

Figure 28. RVCM test sequence

S = Support cycle

T = Test pace

B = Backup pace
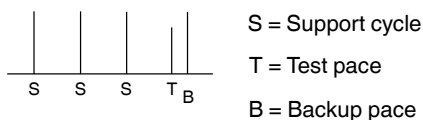
During a pacing threshold search, the device promotes ventricular pacing, which may affect the normal pacing operation. To ensure ventricular pacing, the device may adapt timing in both tracking and nontracking modes.

4.7.3.3 Adjusting the RV pacing outputs

If RVCM is programmed to Adaptive, the device automatically adjusts the RV Amplitude based on the pacing threshold search results. After a successful pacing threshold search, the device calculates a target amplitude by multiplying the programmed RV Amplitude Safety Margin by the amplitude threshold measured at a pulse width of 0.4 ms. The device calculation for the target amplitude is rounded up to the next programmable amplitude setting. See Section 4.7.1.2.

Adjustments during the acute phase – The programmable acute phase corresponds to the lead maturation period. During this time, adequate pacing output is ensured by allowing only increasing adjustments of the RV Amplitude. The acute phase begins when implant detection is complete. The nominal length of the acute phase is 120 days, but the Acute Phase Remaining parameter can be reprogrammed to change the length of the acute phase.

During the acute phase, the lower limit for RV Amplitude is the last user-programmed amplitude setting or 3.5 V, whichever value is higher. The RV Pulse Width is maintained at the last highest setting programmed by the user or 0.4 ms, whichever value is higher.

Adjustments after the acute phase – The device applies the programmed RV Amplitude Safety Margin to the target amplitude measured at a 0.4 ms pulse width to determine the new amplitude setting. The device then adjusts the current RV Amplitude toward this target. The device reduces the amplitude by 0.25 V every other day until it reaches the target amplitude. If the operating amplitude is below the target, the device adjusts it to the target immediately.

The lower limit is set by the programmed RV Minimum Adapted Amplitude. If the operating pulse width has a value different from 0.4 ms, the device adjusts it to that value.

Upper limit for adjustments – The device adjusts the RV Amplitude to 5.0 V and the RV Pulse Width to 1.0 ms if the amplitude threshold is greater than 2.5 V or the target amplitude is greater than 5.0 V.

4.7.3.4 Stopping an RV pacing threshold search in progress

The device stops a pacing threshold search immediately if there are sudden changes in the patient's heart rate or if other device features take precedence over the search.

When a pacing threshold search cannot be completed, the device automatically schedules another search within 30 min. If 5 more search attempts are stopped during a day, the pacing threshold test is suspended until the following day. Whenever this happens, a device check occurs again, and the process is repeated. The reasons for stopping a pacing threshold search are noted in the Capture Threshold trends diagnostic. See Section 4.7.5.

4.7.4 Programming the Capture Management feature

Warning: The Capture Management feature does not program right ventricular or atrial outputs above 5.0 V or 1.0 ms. If the patient needs a pacing output higher than 5.0 V or 1.0 ms, you must program Amplitude and Pulse Width manually.

Caution: Epicardial leads have not been determined appropriate for use with RVCM operation. Program this feature to Off if implanting an epicardial lead.

For information about programming amplitude and pulse width parameters manually, see Section 4.2, "Basic pacing", page 53.

Note: An Adaptive symbol next to the value of an Amplitude or Pulse Width parameter indicates that the programmed value can be adapted by the device. The symbol does not necessarily indicate that the parameter value has been adapted.

Table 13. How to navigate to Capture Management parameters

Parameters	Path
Atrial Capture Management Atrial Amplitude Atrial Amplitude Safety Margin Atrial Minimum Adapted Amplitude Atrial Pulse Width RV Capture Management RV Amplitude RV Amplitude Safety Margin RV Minimum Adapted Amplitude RV Pulse Width	Params > Amplitude…
Atrial Acute Phase Remaining RV Acute Phase Remaining	Params > Amplitude… > Additional Parameters…

Conditions that may influence threshold measurements – In a small percentage of patients, the following conditions may influence thresholds measured by RVCM:

- With poor lead fixation, modulations in pacing timing and rate could influence thresholds.

- In rare instances, combinations of morphology and rhythm may result in a low threshold measurement. This may occur if the pacing threshold search is unable to differentiate between myocardial contractions caused by the pacing pulse and those caused by physiologic means.

High threshold measurements with RVCM – In rare instances, the device may not detect the waveform created by the contracting myocardium immediately following a pacing pulse. In such instances, a high threshold measurement may result.

Rate Drop Response – The device disables Rate Drop Response during a pacing threshold search.

4.7.5 Evaluation of the Capture Management feature

4.7.5.1 Quick Look II

To access capture threshold trends and Quick Look II Observations, select Data > Quick Look II.

Threshold trends – The Quick Look II screen shows trends of average capture thresholds. The threshold data is collected by the automatic daily threshold tests performed by the Capture Management feature. Select the Threshold [>>] button to view the Lead Trends and Capture Threshold diagnostic screens.

For more information about Capture Threshold trends data, see Section 3.10.4, "Capture threshold measurements", page 40

Quick Look II Observations – If there are significant observations about Capture Management operation, they are shown in the Quick Look II Observations window.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 3.1, "Quick Look II summary data", page 19.

4.8 Rate Adaptive AV

A fixed AV interval makes it difficult to select the optimal AV interval value that meets all of the patient's needs. A short AV interval is desirable at higher rates to avoid symptomatic 2:1 block during exercise and to avoid asynchronous pacing. A long AV interval is desirable at lower rates to promote intrinsic AV conduction and to potentially improve hemodynamics.

Rate Adaptive AV shortens AV intervals at elevated rates to maintain 1:1 tracking and AV synchrony.

4.8.1 Operation of Rate Adaptive AV

Rate Adaptive AV is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). Rate Adaptive AV functions when the device is operating in the DDDR, DDD, DDIR, or DDI mode.

The way in which Rate Adaptive AV adjusts the operating AV intervals in a linear manner as the heart rate changes in bpm is shown in Figure 29.

Figure 29. Operation of Rate Adaptive AV in DDDR mode
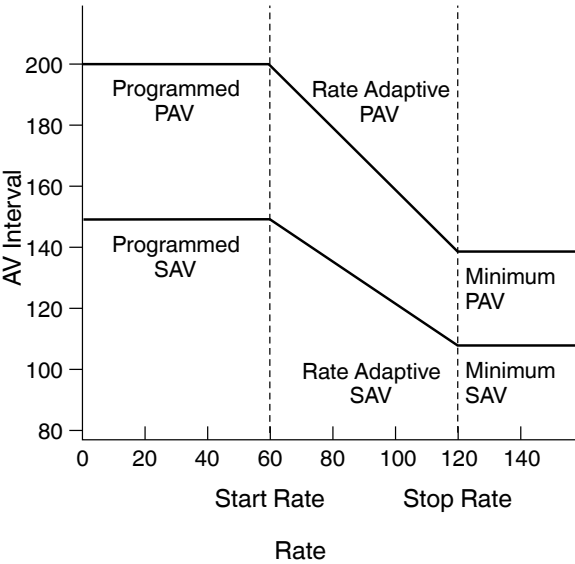
The Start Rate determines the heart rate at which the AV intervals begin to shorten. The Stop Rate determines the heart rate at which the Minimum PAV intervals and Minimum SAV intervals are applied.

4.8.2 Programming Rate Adaptive AV

Table 14. How to navigate to Rate Adaptive AV parameters

Parameters	Path
Rate Adaptive AV Start Rate Stop Rate Minimum Paced AV Minimum Sensed AV	Params > Paced AV…

TherapyGuide – The TherapyGuide feature suggests parameter values based on information entered about the patient's clinical conditions. Parameter values for Rate Adaptive AV are included. For more information about the TherapyGuide feature, refer to the programming guide.

2:1 block rate programmer message – The programmer calculates the dynamic 2:1 block rate based on the selected pacing parameters. You can view the calculated dynamic 2:1

block rate by selecting the information icon. If you select a new value for a parameter that affects dynamic 2:1 block rate (for example, Sensed AV or PVARP), return to the Parameters screen and select the information icon to see the recalculated rate.

4.9 Auto PVARP

A fixed value for the Post Ventricular Atrial Refractory Period (PVARP) may not provide the optimal PVARP setting to meet the changing needs of the patient. At low heart rates, PVARP should be long enough to prevent pacemaker-mediated tachycardia (PMT). At elevated heart rates, PVARP should be short enough to avoid 2:1 block and promote AV synchrony.

For more information, see Section 4.1, "Sensing", page 43 and Section 4.2, "Basic pacing", page 53.

Auto PVARP adjusts PVARP in response to changes in the patient's heart rate or pacing rate.

4.9.1 Operation of Auto PVARP

Auto PVARP is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, or an MVP mode (AAIR<=>DDDR, or AAI<=>DDD). Auto PVARP functions when the device is operating in the DDDR, DDD, DDIR, or DDI mode.

In a tracking mode (DDDR or DDD), the Auto PVARP feature adjusts PVARP based on the current heart rate of the patient. When the heart rate is low, PVARP is longer to prevent PMT. As the heart rate increases, PVARP shortens to maintain 1:1 tracking. Auto PVARP allows 1:1 tracking of atrial events up to 30 bpm above the heart rate or 100 bpm, whichever is greater.

The programmable Minimum PVARP parameter value sets a limit on the shortest PVARP that is allowed. If the programmed Minimum PVARP value is reached and the Rate Adaptive AV (RAAV) parameter is programmed to On, the Sensed AV (SAV) interval is shortened to help maintain 1:1 tracking.

For more information, see Section 4.8, "Rate Adaptive AV", page 87.

Figure 30. Operation of Auto PVARP in the DDDR or DDD mode
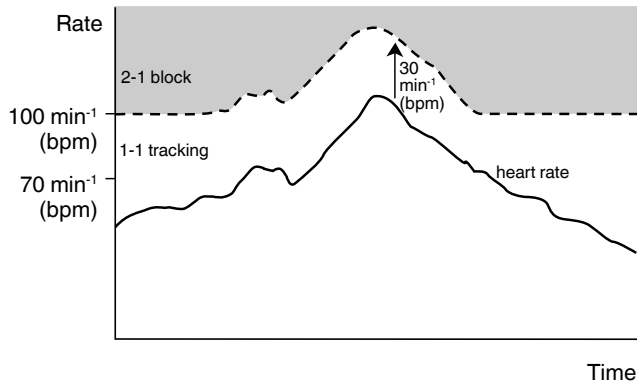
In a nontracking mode (DDIR or DDI), PVARP varies with the current pacing rate to be long enough to promote AV synchrony at a low pacing rate and short enough to prevent atrial competitive pacing at a high pacing rate.

The device calculates PVARP to attempt to maintain a 300 ms window of time between the end of PVARP and the next atrial pace. PVARP is limited to be no shorter than the programmed interval for the Post-Ventricular Atrial Blanking (PVAB) parameter.

Figure 31. Operation of Auto PVARP in the DDIR or DDI mode
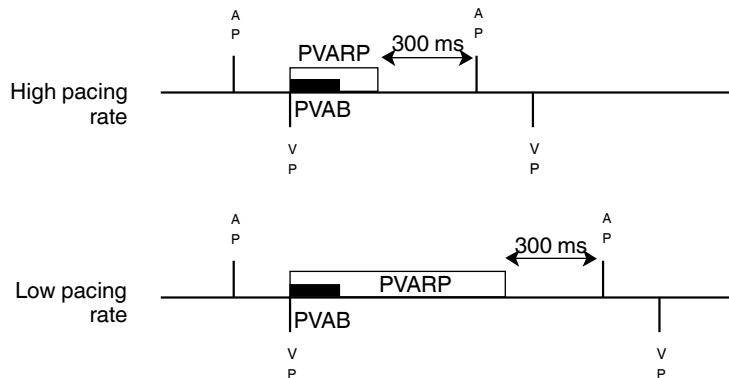
4.9.2 Programming Auto PVARP

Table 15. How to navigate to Auto PVARP parameters

Parameters	Path
PVARP Minimum PVARP	Params > PVARP…

Minimum PVARP value selection – When programming a higher value for the Upper Tracking Rate, you may have to program a lower Minimum PVARP value to achieve 1:1 tracking up to the higher rate. An alternative is to use the Rate Adaptive AV feature, or a combination of Rate Adaptive AV and a lower Minimum PVARP value. For more information, see Section 4.8, "Rate Adaptive AV", page 87.

When you select a new value for Minimum PVARP or Rate Adaptive AV, the programmer recalculates the dynamic 2:1 block rate at exercise. The device achieves 1:1 tracking up to the Upper Tracking Rate when the recalculated dynamic 2:1 block rate is above the Upper Tracking Rate. You can view the programmer message about the dynamic 2:1 block rate by selecting the information icon on the programmer screen.

Note: The Minimum PVARP parameter only applies when the device is operating in a tracking mode (DDDR or DDD).

Fixed PVARP with DDI and DDIR modes – If the device is programmed to permanent DDI mode or DDIR mode, a fixed PVARP may be more appropriate. The purpose of Auto PVARP in nontracking modes is to support the DDIR portion of Mode Switch operation during AT/AF.

4.10 Rate Drop Response

Patients with carotid sinus syndrome or vasovagal syncope may lose consciousness or experience related symptoms after significant drops in heart rate. When syncope is caused primarily by cardioinhibition and when permanent AF is not present, pacing at an elevated rate may prevent syncope and related symptoms from occurring.

Rate Drop Response monitors the heart for significant drops in heart rate and responds by pacing the heart at an elevated rate.

4.10.1 Operation of Rate Drop Response

Figure 32. Overview of Rate Drop Response
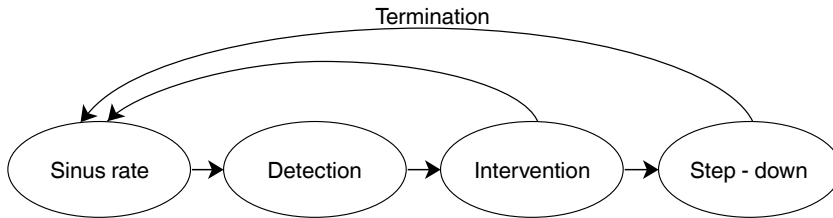
Rate Drop Response operates in phases. During the detection phase, the device monitors the heart for rate drops that conform to programmed criteria. During the intervention phase, the device paces the heart at a programmed elevated rate for a programmed duration. During the step-down phase, the device gradually slows pacing to the sinus rate or the Lower Rate.

Figure 33. Rate Drop Response Rate and Time
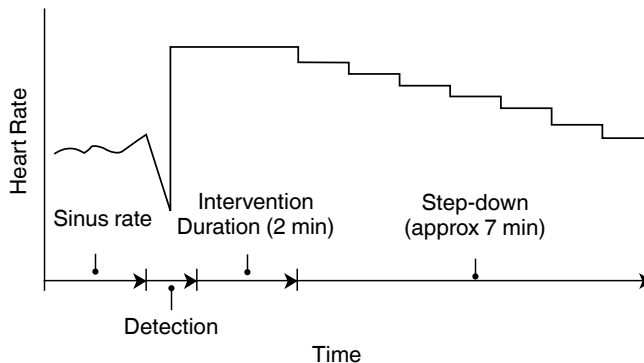
As shown in Figure 33, Rate Drop Response typically operates over several minutes, and most of this time involves the step-down phase.

Rate Drop Response is available when the pacing mode is programmed to DDD, DDI, or AAI<=>DDD (MVP mode). Rate Drop Response functions when the device is operating in the DDD or DDI mode. For the MVP mode, the device operates in DDD mode during Rate Drop Response interventions. Rate Drop Response does not operate during tachyarrhythmias, Mode Switch episodes, and Capture Management pacing threshold searches.

4.10.1.1 Detection

Rate Drop Response provides 2 methods for detecting significant rate drops:

- Drop Detection
- Low Rate Detection

Figure 34. Drop Detection
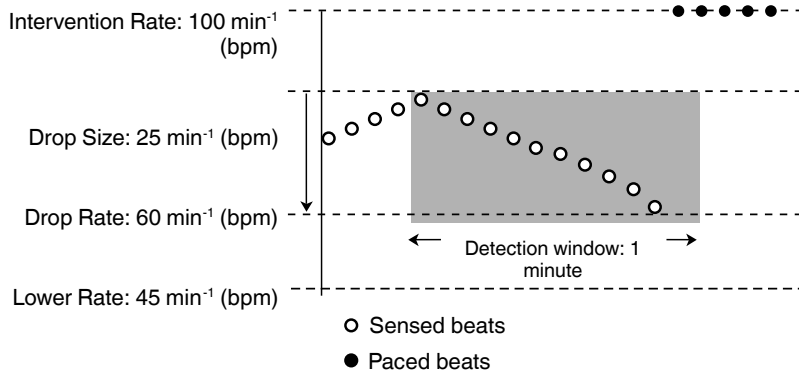
With Drop Detection, the device intervenes when the ventricular rate drops by a specified number of beats per minute to below a specified heart rate within a specified period of time. These conditions are established by programming the Drop Size, Drop Rate, and Detection Window parameters, respectively.

Figure 35. Low Rate Detection
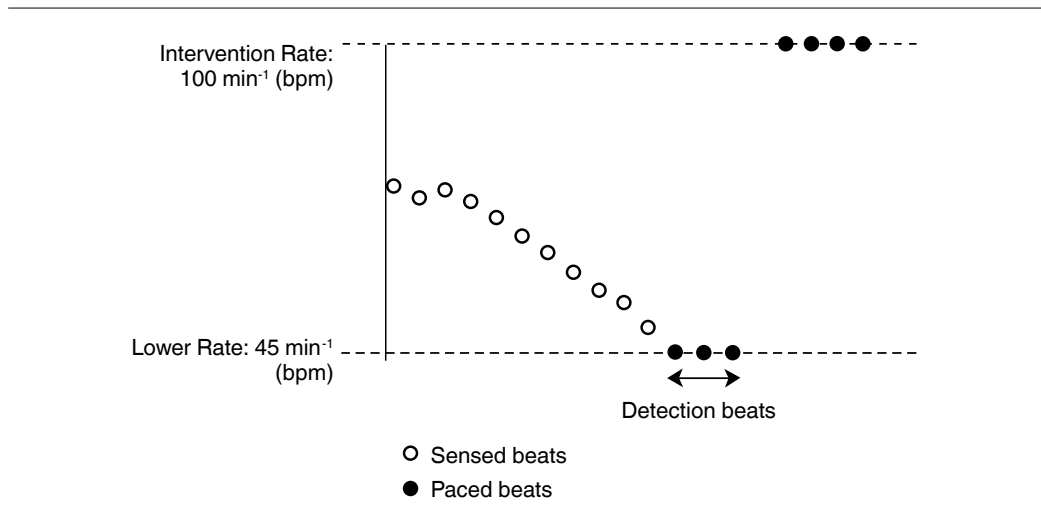
With Low Rate Detection, the device intervenes when the atrium is paced at the Lower Rate for the number of consecutive beats specified by the Detection Beats parameter.

Note: In DDI mode, Low Rate Detection occurs when the atrium or the ventricle is paced at the Lower Rate for the programmed number of beats.

When both detection methods are programmed, the device intervenes when either Drop Detection or Low Rate Detection criteria are met. For example, if the heart rate drops too slowly to meet programmed Drop Detection criteria and continues to drop, the heart is eventually paced at the Lower Rate. If this continues for the programmed number of detection beats, the device intervenes.

4.10.1.2 Intervention and step-down

When a rate drop is detected, the device paces the heart at the programmed Intervention Rate for the programmed Intervention Duration. After the Intervention Duration is complete, the device reduces the pacing rate by 5 bpm steps per minute. This step-down process continues until the sinus rate or the Lower Rate is reached.

Intervention pacing and step-down pacing are immediately ended when the device senses 3 consecutive nonrefractory atrial events.

Note: If the Lower Rate is reached at the conclusion of the step-down phase and Low Rate Detection is programmed, the device does not detect another rate drop until it senses evidence of a sinus rate that is above the programmed Lower Rate.

See Figure 36 for an example of the device detecting a rate drop and starting to pace the heart at the programmed Intervention Rate.

Figure 36. Example of detection and intervention

1 Normal sinus rhythm   3 Intervention pacing started
2 Rate drop detected
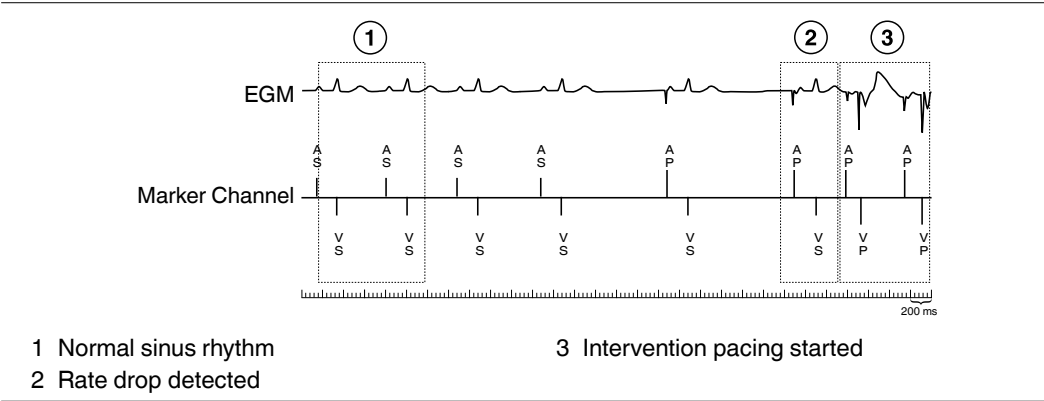
4.10.2 Programming Rate Drop Response

Table 16. How to navigate to Rate Drop Response parameters

Parameters	Path
Rate Drop Response Detection Type Drop Size Drop Rate Detection Window Detection Beats Intervention Rate Intervention Duration	Params > Additional Features… > Rate Drop Response…

TherapyGuide – The TherapyGuide feature suggests parameter values based on information entered about the patient's clinical conditions. Parameter values for Rate Drop Response are included. For more information about the TherapyGuide feature, refer to the programming guide.

Symptoms during sleep – During sleep, a patient's sinus rate may fall below the programmed Lower Rate, thereby triggering intervention pacing at an inappropriate time. There are two ways to address this problem. First, you can turn off Low Rate Detection. Second, you can turn on the Sleep feature. The Sleep feature replaces the programmed Lower Rate with a slower pacing rate during the time of day the patient normally sleeps. For more information, see Section 4.12, "Sleep feature", page 97.

Features that adjust pacing rate – Features that adjust the pacing rate, such as the Atrial Rate Stabilization feature and the Ventricular Rate Stabilization feature, are unavailable when Rate Drop Response is programmed to On.

4.10.3 Evaluation of Rate Drop Response

The Rate Drop Response Episodes screen provides beat-to-beat data that is useful for analyzing Rate Drop Response episodes and the events that lead up to them. It also provides information that may help you select appropriate Rate Drop Response detection parameters.

To access Rate Drop Response episode data, select Data > Clinical Diagnostics > Rate Drop Response Episodes > [Open Data].

4.11 Rate Hysteresis

The patient's intrinsic heart rate is preferable to pacing during extended periods of patient inactivity, such as when the patient is sleeping.

Rate Hysteresis allows intrinsic rhythms to occur below the programmed Lower Rate.

4.11.1 Operation of Rate Hysteresis

Rate Hysteresis is available when the pacing mode is programmed to VVI or AAI, and it functions when the device is operating in one of these modes.

Rate Hysteresis allows a slower lower rate when the intrinsic rate is below the programmed Lower Rate. After each sensed event, the programmed hysteresis rate is applied. After each paced event, the programmed Lower Rate is applied.

Figure 37. Operation of Rate Hysteresis in VVI mode
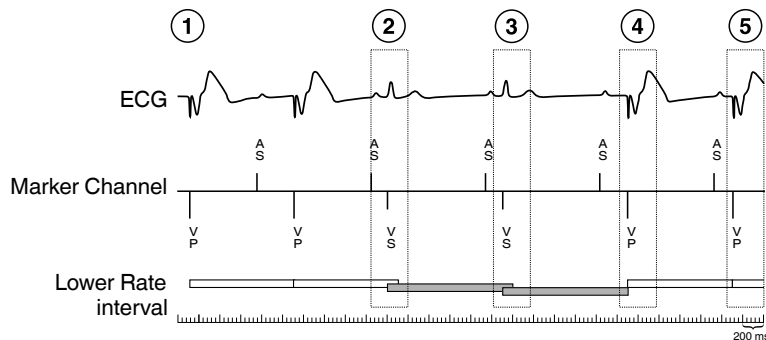
1 The device paces in VVI mode at the programmed Lower Rate.
2 After a ventricular sensed event, the device applies the hysteresis interval (shaded bar).
3 A sensed event occurs before the hysteresis interval expires, so hysteresis operation continues.
4 The hysteresis interval expires, and the device paces the ventricle and reapplies the Lower Rate interval.
5 The ventricle is paced at the Lower Rate.

4.11.2 Programming Rate Hysteresis

To access Rate Hysteresis, select Params > Additional Features… > Rate Hysteresis.

Verifying adequate cardiac support – The programmed hysteresis rate determines the slowest heart rate that can occur before pacing starts. Ensure that the selected hysteresis rate is adequate to support the patient's cardiac condition.

Programming the hysteresis rate – To avoid large, sudden changes in heart rate, you would normally select a hysteresis rate that is no more than 30 bpm below the programmed Lower Rate.

Lower Rate – You cannot program the hysteresis rate to a value equal to or above the Lower Rate.

Compatibility – Rate Hysteresis cannot be enabled at the same time as Ventricular Rate Stabilization, Atrial Rate Stabilization, or Atrial Preference Pacing.

4.11.3 Evaluation of Rate Hysteresis

The Ventricular Rate Histogram indicates when the device has allowed the patient's intrinsic heart rhythm to prevail at rates lower than the Lower Rate.

To view the Ventricular Rate Histogram, Select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

4.12 Sleep feature

Some patients have difficulty sleeping when they are paced at a rate that is intended for times when they are normally awake.

The Sleep feature replaces the programmed Lower Rate with a slower pacing rate during the time of day that the patient normally sleeps.

4.12.1 Operation of the Sleep feature

Figure 38. Overview of the Sleep feature
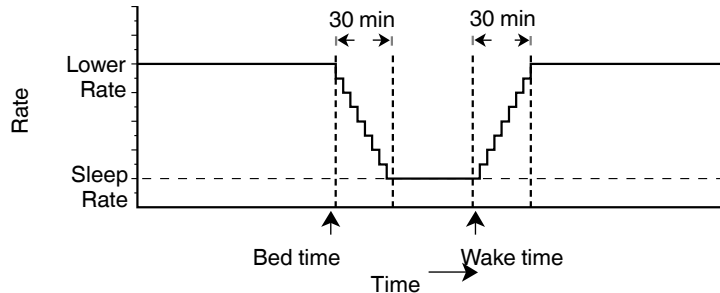
The Sleep feature is controlled by 3 programmable parameters: Sleep Rate, Bed Time, and Wake Time. During the 30 min following the programmed Bed Time, the device gradually reduces its slowest pacing rate from the Lower Rate to the Sleep Rate. The Sleep Rate remains in effect until the programmed Wake Time. During the 30 min following the programmed Wake Time, the device gradually increases its slowest pacing rate from the Sleep Rate to the Lower Rate.

In rate response modes, when patients awake and become active during programmed sleep times, the device provides rate-responsive pacing as needed. However, the rate profile starts from the slower Sleep Rate and increases to the Activities of Daily Living Rate (ADL Rate). The rate profile above the ADL Rate remains the same.

Programming any bradycardia pacing parameter during the Sleep period cancels the Sleep operation for that day.

If the patient experiences an AT/AF episode and the Mode Switch feature is operating during the Sleep period, the device does not pace below the Lower Rate until the AT/AF episode has ended. For more information, see Section 4.17, "Mode Switch", page 106.

4.12.2 Programming the Sleep feature

Table 17. How to navigate to Sleep feature parameters

Parameters	Path
Sleep Sleep Rate Bed Time Wake Time	Params > Additional Features… > Sleep…
Time Zone	Params > Data Collection Setup… > Device Date/Time…

When you set Bed Time and Wake Time, consider time zone changes resulting from travel, daylight savings time, and variations in the patient's sleep patterns, such as variable work shifts.

4.12.3 Evaluation of the Sleep feature

The Ventricular Rate Histogram shows heart rates below the Lower Rate but above the Sleep Rate for the percentage of time that correlates to the Sleep period. For more information, see Section 3.9, "Rate Histograms", page 36.

Cardiac Compass Trends shows the average ventricular rate during the day and night, which should indicate that the device is allowing a slower heart rate at night. For more information, see Section 3.3, "Cardiac Compass Trends", page 24.

4.13 Non-Competitive Atrial Pacing

An atrial tachycardia may be initiated if an atrial paced event occurs within the vulnerable period of the atrium. This situation can happen when the device is pacing at a high rate if a premature atrial contraction occurs during an atrial refractory period and is quickly followed by an atrial pace.

The Non-Competitive Atrial Pacing (NCAP) feature prevents pacing the atrium too soon after a refractory atrial sense by delaying the scheduled atrial pace.

4.13.1 Operation of NCAP

NCAP is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI or an MVP mode (AAIR<=>DDDR or AAI<=>DDD), and it functions when the device is operating in one of these modes.

Whenever an atrial refractory sense occurs, the device starts a programmable NCAP interval. If an atrial pace is scheduled to occur during the NCAP interval, the atrial pace is delayed until the NCAP interval expires. When an atrial pace is delayed by the NCAP feature, the AP-VP interval decreases (but not to less than 30 ms). After NCAP decreases the AP-VP interval, some variation in the VP-VP interval may occur. These variations only affect the current and next ventricular interval.

The NCAP interval is 400 ms for 1 pacing cycle whenever a PVC Response or a PMT Intervention occurs.

Figure 39. Operation of NCAP
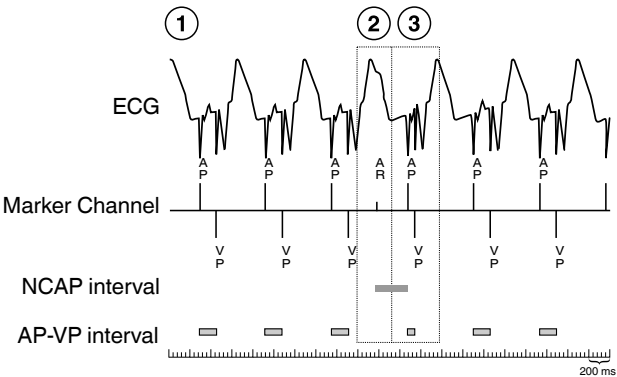
1   The device is pacing at an elevated rate.
2   An atrial refractory sense occurs, starting an NCAP interval (300 ms in this case).
3   After the NCAP interval, the device paces the atrium and then paces the ventricle after a shortened AP-VP interval.

4.13.2 Programming NCAP

Table 18. How to navigate to NCAP parameters

Parameters	Path
Non-Comp Atrial Pacing NCAP Interval	Params > Additional Features…

4.13.3 Evaluation of NCAP

When evaluating an ECG strip, you will notice that the AP-VP interval has been shortened and the NCAP interval can be seen as the time between the AR and AP events (see Figure 39).

4.14 PMT Intervention

In tracking modes (DDDR and DDD), retrograde conduction can result in a pacemaker-mediated tachycardia (PMT). A PMT is a repetitive sequence in which the device responds to each retrograde P-wave by pacing the ventricle at an elevated rate, which, in turn, generates a retrograde P-wave.

The PMT Intervention feature extends the PVARP after detecting a PMT. This interrupts the PMT by causing the subsequent atrial-sensed event to fall within the refractory period.

4.14.1 Operation of PMT Intervention

PMT Intervention is available when the pacing mode is programmed to DDDR, DDD, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). PMT Intervention functions when the device is operating in the DDDR or DDD mode.

The device identifies a PMT by evaluating VP-AS intervals in 2 phases:

- Detection phase: When 8 consecutive VP-AS intervals occur at less than 400 ms, a PMT is suspected.

- Confirmation phase: Following the detection phase, the device adjusts the timing of the ventricular paced events and evaluates the timing of the subsequent atrial sensed events. If the timing of the ventricular pacing affects the timing of the atrial sensing for 3 consecutive groups of VP-AS intervals, a PMT is confirmed. Otherwise, the device determines that a PMT is not occurring.

When the device confirms the occurrence of a PMT, the PMT Intervention feature forces a 400 ms PVARP immediately after the last interval of the confirmation phase. This causes the next atrial sense to fall within the refractory period. Because this refractory event is not tracked to the ventricle for 1 cycle, the PMT is interrupted.

After the confirmation phase ends, PMT Intervention is suspended for 85 s in order to prevent unnecessary intervention in the presence of fast intrinsic atrial rates.

PVC Response can also prevent PMT. If the PVC Response and PMT Intervention features are programmed to On and PMTs are observed, evaluate the atrial and ventricular lead performance or positions or consider drug therapy to reduce retrograde conduction.

Figure 40. Operation of PMT Intervention
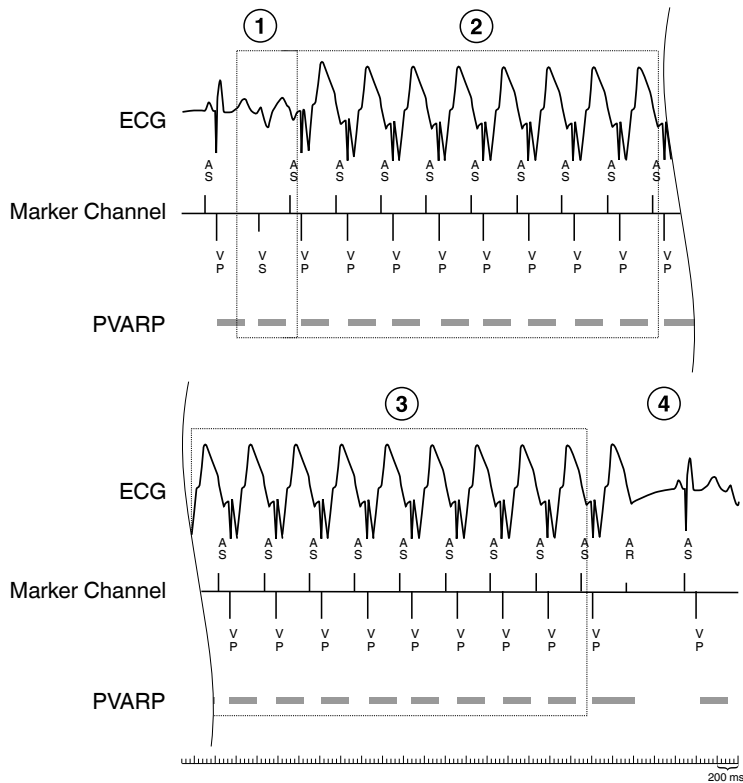
1 Retrograde conduction following a PVC is detected as an atrial sensed event.
2 A PMT begins. The rhythm is suspected to be PMT at the end of the 8-interval detection phase.
3 The confirmation phase continues for 9 VP-AS intervals.
4 The PMT is confirmed, and the PVARP lengthens to terminate the PMT.

4.14.2 Programming PMT Intervention

To access PMT Intervention, select Params > Additional Features… > PMT Intervention.

4.15 PVC Response

Retrograde conduction following a PVC can disrupt AV synchrony and affect pacing mode timing. For tracking modes (DDDR and DDD), retrograde conduction following a PVC can initiate a pacemaker-mediated tachycardia (PMT), a repetitive sequence in which the device responds to each retrograde P-wave by pacing the ventricle at an elevated rate and each ventricular pace, in turn, generates a retrograde P-wave. For nontracking modes (DDIR and DDI), retrograde conduction following a PVC can cause a loss of AV synchrony by causing a repetitive sequence of atrial inhibition followed by a ventricular pace.

PVC Response extends the PVARP following a PVC to avoid tracking a retrograde P-wave and to prevent retrograde conduction from inhibiting an atrial pace.

4.15.1 Operation of PVC Response

PVC Response is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). PVC Response functions when the device is operating in the DDDR, DDD, DDIR or DDI mode.

The system defines a PVC as any ventricular sensed event that follows another ventricular event without an intervening atrial event. When the device senses a PVC, the device forces the PVARP to be at least 400 ms. (No action is taken if the current PVARP is already 400 ms or longer.) Because retrograde conduction normally occurs within 400 ms of a PVC, the retrograde P-wave will be within the PVARP, will not be tracked, and will not inhibit atrial pacing. This prevents initiating a PMT (DDDR and DDD modes) and preserves AV synchrony (DDIR and DDI modes).

If PVC Response is programmed to On and PMTs are observed, consider programming PMT Intervention, evaluate the atrial and ventricular lead performance or positions, or consider drug therapy to reduce retrograde conduction.

Figure 41. PVC Response starts an extended PVARP
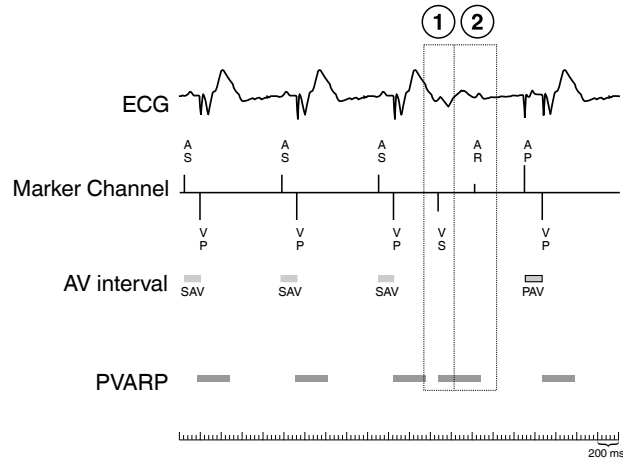
1 A PVC occurs.
2 The device extends the PVARP to 400 ms, and the subsequent atrial event is classified as refractory.

4.15.2 Programming PVC Response

To access PVC Response, select Params > Additional Features… > PVC Response.

4.16 Ventricular Safety Pacing

In a dual chamber pacing system with atrial and ventricular pacing and ventricular sensing, the device may sense an atrial pacing pulse on the ventricular channel and inhibit ventricular pacing (crosstalk). When inhibition of ventricular pacing occurs, the device may not provide full ventricular support.

Ventricular Safety Pacing (VSP) detects crosstalk by monitoring for nonphysiologic ventricular sensed events and responds by pacing the ventricle.

4.16.1 Operation of VSP

VSP is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). VSP functions when the device is operating in the DDDR, DDD, DDIR or DDI mode.

The device uses a 110 ms VSP window to monitor for ventricular senses that occur too soon after an atrial pacing pulse. Ventricular senses in the VSP window are classified as nonphysiologic and are likely due to crosstalk. If a ventricular sensed event occurs within the VSP window, the device delivers a VSP pulse at the end of the VSP window.

If the sensed event is a result of crosstalk, the backup pacing pulse provides ventricular support. If the sensed event is a ventricular depolarization, the backup pacing pulse occurs soon enough to fall in the absolute refractory period of the ventricle to avoid pacing on the T-wave.

Figure 42. VSP pulse delivered at the end of the VSP window (110 ms)
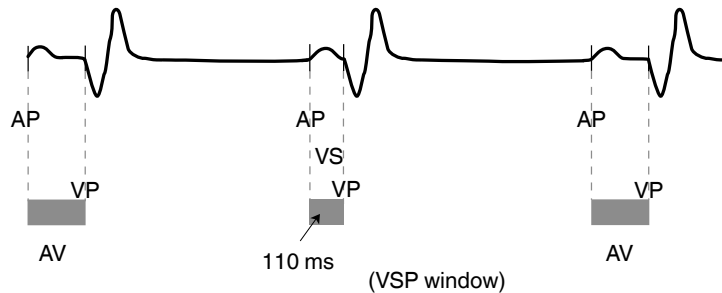
When the operating Paced AV interval is shorter than the VSP window, the ventricular pace is delivered at the end of the Paced AV interval. The VSP window switches from 110 ms during low pacing rates to 70 ms during elevated pacing rates. This shortening of the VSP window to 70 ms helps support ventricular tachycardia detection.

Although crosstalk is rare, there are other situations when the device may deliver VSP, including atrial undersensing and occurrences of PVCs during the VSP window.

4.16.2 Programming VSP

To access V. Safety Pacing, select Params > Additional Features… > V. Safety Pacing.

Caution: Do not program VSP to Off if the patient is pacemaker-dependent because ventricular support may not be provided during crosstalk.

4.16.3 Evaluation of VSP

Figure 43. Recognizing VSP on an ECG strip
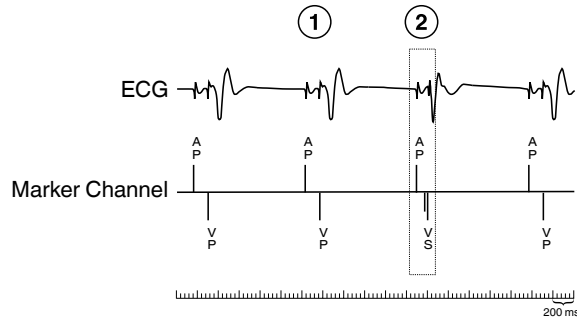
1 Normal AV intervals
2 VSP pulse shortly after a ventricular sense

When evaluating an ECG strip, you will notice that the VSP pulse appears shortly after a ventricular sense and usually has a shorter AV interval. The "VP" annotation in the Marker Channel area usually does not appear on a printed real-time ECG strip due to the limited space after the "VS" annotation. Both the "VP" and the "VS" annotations appear in the Live Rhythm Monitor, on frozen strips, and on printed frozen strips.

4.17 Mode Switch

An atrial tachyarrhythmia may result in a rapid ventricular pacing rate when the device is operating in the DDDR or DDD mode. The implanted device should be capable of withholding atrial tracking during periods of atrial tachyarrhythmia while tracking the normal sinus rate.

The Mode Switch feature switches the device pacing mode to a nontracking mode upon detection of an atrial tachyarrhythmia and restores the programmed pacing mode when the atrial tachyarrhythmia ends. By operating in a nontracking mode, the device prevents rapid ventricular pacing that may result from a high atrial rate.

4.17.1 Operation of Mode Switch

Figure 44. Overview of Mode Switch operation

Mode Switch is available when the pacing mode is programmed to DDDR, DDD, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). Mode Switch functions when the device is operating in the DDDR or DDD mode.

Mode Switch operation starts when the device detects the onset of an atrial tachyarrhythmia episode. The detection of AT/AF onset is based on the programmed AT/AF Interval and the accumulation of additional evidence of atrial tachyarrhythmia based on the number and timing of atrial events within the ventricular intervals. For more information, see Section 5.1, "AT/AF detection", page 124.

After the device detects the onset of an atrial tachyarrhythmia, Mode Switch changes the pacing mode from the programmed mode to a nontracking mode (DDIR). The ventricular pacing rate gradually changes from the tracking rate to the sensor rate. This change prevents an abrupt drop in the ventricular rate.

When the atrial tachyarrhythmia ends and the atrial rate decreases below the programmed Upper Tracking Rate, Mode Switch changes the pacing mode back to the programmed tracking mode. The ventricular pacing rate gradually changes from the sensor rate to the tracking rate.

Figure 45. Example of a Mode Switch episode
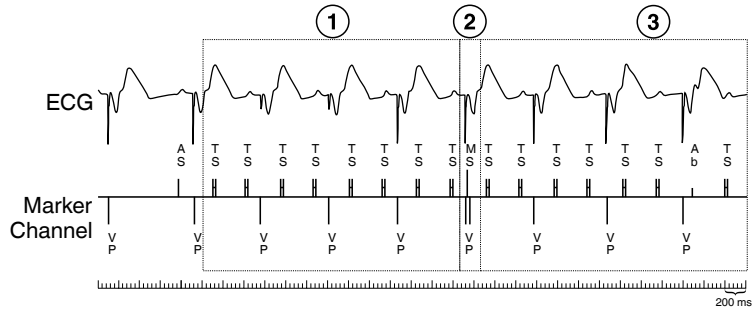
1 An atrial tachyarrhythmia episode starts, causing faster ventricular pacing in response.
2 When the device detects an atrial tachyarrhythmia, Mode Switch (MS) changes the programmed pacing mode to DDIR.
3 The device gradually changes the faster ventricular pacing rate to the sensor rate.

4.17.1.1 Interactions with other device operations

Antitachycardia pacing (ATP) therapies – A Mode Switch operation cannot start during an ATP therapy. If a Mode Switch episode starts before the ATP therapy begins, the device suspends Mode Switch operation during the therapy and resumes it after the therapy delivery.

Mode Switch and MVP modes – Mode Switch and MVP modes (AAIR<=>DDDR or AAI<=>DDD) interact to adjust the pacing mode according to the patient's atrial rhythm and AV conduction status. For more information, see Section 4.5, "Managed Ventricular Pacing (MVP)", page 66.

4.17.2 Programming Mode Switch

To access Mode Switch, select Params > Mode Switch.

MVP modes – Mode Switch is automatically set to On when the pacing mode is set to an MVP mode (AAIR<=>DDDR or AAI<=>DDD).

Post Mode Switch Overdrive Pacing – You can program Post Mode Switch Overdrive Pacing (PMOP) to extend pacing in the DDIR mode when the atrial tachyarrhythmia ends. For more information, see Section 4.21, "Post-Mode Switch Overdrive Pacing", page 118.

4.17.3 Evaluation of Mode Switch performance

4.17.3.1 EGM strip

Select an AT/AF episode from the Arrhythmia Episodes log. To access Arrhythmia Episodes data, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

Check the A/V bpm column to evaluate the average atrial and ventricular rates during the episode. Check the EGM column for an indication that an EGM strip is available for this episode. If EGM is available, select the EGM option. You can evaluate atrial and ventricular events in the stored EGM strip to see if the device was operating in a nontracking pacing mode during the episode.

4.17.3.2 Mode Switch transitions

The Marker Channel area includes an "MS" marker for each Mode Switch transition, either to a nontracking mode or back to a tracking mode.

The current operating mode is displayed in the upper left-hand corner of the screen. During a Mode Switch episode, DDIR is displayed.

4.18 Conducted AF Response

When AT/AF occurs in patients with intact AV conduction, the fast atrial rhythm may be conducted irregularly to the ventricles, often resulting in patient symptoms.

The Conducted AF Response feature helps promote a regular ventricular rate during conducted AT/AF episodes.

4.18.1 Operation of Conducted AF Response

To promote a regular ventricular rate during AT/AF episodes, you can program the device to increase the pacing rate in concert with the patient's intrinsic ventricular response to a conducted atrial tachyarrhythmia. The Conducted AF Response feature adjusts the pacing rate to be faster when ventricular sensed events occur and slower when ventricular pacing pulses occur. Depending on the programmed Response Level value, the device adds up to 3 bpm in response to a sensed event and subtracts 1 bpm in response to a pacing pulse. The result is ventricular pacing at an average rate that closely matches the patient's intrinsic ventricular response to the AT/AF episode.

In dual chamber devices, Conducted AF Response is available when the pacing mode is programmed to DDDR, DDD, DDIR, VVIR, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). Conducted AF Response operates only in nontracking modes (DDIR and VVIR). It is typically applied during a mode switch brought about by the onset of an atrial tachyarrhythmia.

In single chamber devices, Conducted AF Response operates only in VVIR mode.

Figure 46. Operation of Conducted AF Response
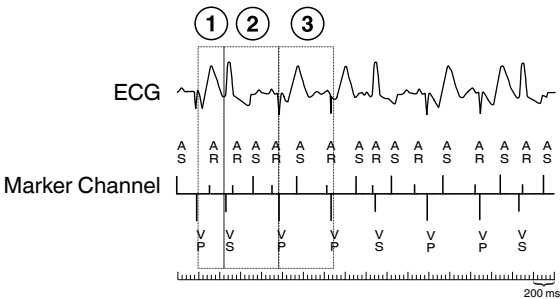
1 VP-AR-VS sequence causes the pacing rate to increase by 1 bpm if Response Level is programmed to Low or Medium.
2 VS-VP sequence causes the pacing rate to remain unchanged.
3 VP-VP sequence causes the pacing rate to decrease by 1 bpm.

Note: Conducted AF Response operation is suspended during automatic tachyarrhythmia therapies, system tests, EP study inductions, and manual therapies. Conducted AF Response operation is not suspended during an impedance test.

4.18.2 Programming Conducted AF Response

Table 19. How to navigate to Conducted AF Response parameters

Parameters	Path
Conducted AF Response	Params > Arrhythmia Interventions…
Conducted AF Response Level Conducted AF Response Maximum Rate	Params > Arrhythmia Interventions… > Additional V Settings…

Maximum Rate – Increases to the pacing rate caused by Conducted AF Response are limited by the programmed Maximum Rate.

Response Level value – A higher Response Level value results in a higher percentage of ventricular pacing and faster alignment with the patient's own ventricular response rate.

DDD or DDDR mode – Conducted AF Response operates only in nontracking modes. Therefore, when the device is programmed to DDD or DDDR mode, Conducted AF Response operates only during a mode switch to DDIR mode. Mode Switch must be programmed to On to program Conducted AF Response to On.

Conducted AF Response and VRS – In DDIR and VVIR modes, Conducted AF Response and VRS cannot be programmed to On at the same time.

4.18.3 Evaluation of Conducted AF Response

4.18.3.1 Rate Histograms

Select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

The Ventricular Rate During AT/AF Histogram shows the distribution of ventricular rates during AT/AF episodes. For more information, see Section 3.9, "Rate Histograms", page 36.

4.18.3.2 Cardiac Compass Trends

To access Cardiac Compass Trends, select Data > Quick Look II > Cardiac Compass [>>] button, or select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data].

The Cardiac Compass Trends data shows the ventricular rate during AT/AF episodes, providing maximum and average rates for each episode. For more information, see Section 3.3, "Cardiac Compass Trends", page 24.

4.19 Atrial Rate Stabilization

The management of patients with atrial tachyarrhythmias is made more challenging by the different types of mechanisms known to initiate atrial tachyarrhythmias. It is also made more challenging by the high incidence of tachyarrhythmia recurrences following both therapeutic and spontaneous terminations. Potential causes of atrial tachyarrhythmias include premature atrial contractions (PACs) that result in long sinus pauses and ectopic beats that originate from multiple atrial activation sites. In addition, the vulnerable phase in atrial electrophysiologic properties following the restoration of sinus rhythm may contribute to early recurrences of atrial tachyarrhythmias.

The system provides overdrive pacing techniques that are designed to counteract potential atrial tachyarrhythmia initiating mechanisms.

Atrial Rate Stabilization (ARS) adapts the pacing rate in response to a PAC to avoid long sinus pauses following short atrial intervals (short-long-short sequences that may cause the onset of some atrial tachycardias).

4.19.1 Operation of ARS

Atrial Rate Stabilization (ARS) is available when the pacing mode is programmed to DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode, and it functions when the device is operating in one of these modes.

Figure 47. Atrial Rate Stabilization (ARS)

- ● Atrial Rate Stabilization pacing
- □ Paced beats
- △ Intrinsic beats
- ⊟ Scheduled pace
- − Atrial rate
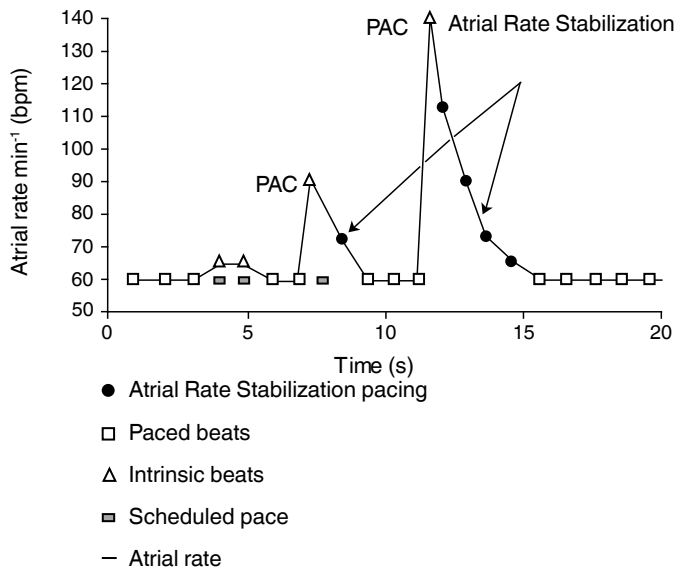
ARS is a programmable feature designed to prevent the long sinus pause that typically follows a PAC. ARS responds to a PAC by instantly elevating the atrial pacing rate and then smoothly slowing the rate back to the intrinsic rate or the programmed pacing rate (whichever is faster). When activated by a PAC, the device delivers a pacing pulse at the premature interval increased by a percentage of that interval (defined by a programmed Interval Percentage Increment parameter). For each subsequent atrial paced or atrial sensed event, the device continues to increase each pacing interval by the programmed percentage of the previous interval. In this way, ARS prevents the "short-long-short" sequences of atrial intervals that may precede the onset of some atrial tachyarrhythmias. The Maximum Rate parameter sets an upper rate limit for ARS.

Atrial pacing pulses delivered for ARS are annotated on the Marker Channel area with PP (proactive pace).

Figure 48. Example of ARS operation
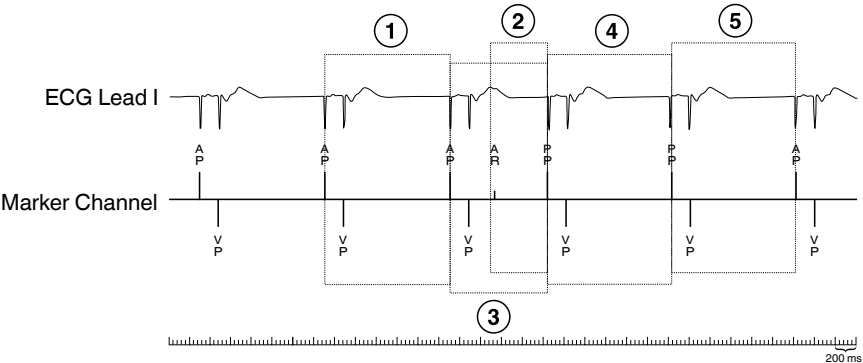
1 Pacing occurs at the programmed pacing rate.
2 A premature beat occurs followed by an ARS pacing pulse (indicated by the PP marker). The pacing pulse is delivered at the AP-AR interval plus the programmed Interval Percentage Increment value (25% in this example).
3 The device uses the AP-PP interval to calculate the subsequent ARS pacing interval.
4 Based on the programmed Interval Percentage Increment value, the ARS pacing interval is 25% longer than the preceding one.
5 ARS pacing ends when the sensor rate or lower rate is reached.

Interactions with other device operations – ARS is suspended during mode switching (including PMOP) and detected tachyarrhythmia episodes.

Note: Generally, when multiple device features attempt to control the pacing rate, the feature with the fastest rate takes precedence.

4.19.2 Programming ARS

Table 20. How to navigate to ARS parameters

Parameters	Path
A. Rate Stabilization	Params > Arrhythmia Interventions…
ARS Maximum Rate ARS Interval Percentage Increment	Params > Arrhythmia interventions… > Additional A Settings…

Non-Competitive Atrial Pacing (NCAP) – The NCAP feature may delay an atrial pacing pulse that results from Atrial Rate Stabilization.

Programming constraints – To ensure reliable tachyarrhythmia detection, the system regulates the values that you can select for the Maximum Rate, Upper Rate, AT/AF Detection Interval, and VT Monitor Interval.

4.19.3 Evaluation of ARS

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.5, "Episode and therapy counters", page 32.

The % of Time Atrial Intervention line in the AT/AF Summary section of the Counters screen displays the total percentage of time that the patient received atrial intervention pacing. The displayed percentage reflects the combined total of pacing resulting from ARS and APP.

Note: If APP is enabled, atrial intervention pacing is more likely to have resulted from APP than ARS.

4.20 Atrial Preference Pacing

The management of patients with atrial tachyarrhythmias is made more challenging by the different types of mechanisms known to initiate atrial tachyarrhythmias. It is also made more challenging by the high incidence of tachyarrhythmia recurrences following both therapeutic and spontaneous terminations. Potential causes of atrial tachyarrhythmias include premature atrial contractions (PACs) that result in long sinus pauses and ectopic beats that originate from multiple atrial activation sites. In addition, the vulnerable phase in atrial electrophysiologic properties following the restoration of sinus rhythm may contribute to early recurrences of atrial tachyarrhythmias.

The system provides overdrive pacing techniques that are designed to counteract potential atrial tachyarrhythmia initiating mechanisms.

Atrial Preference Pacing (APP) is designed to maintain a consistent activation sequence by providing continuous pacing that is closely matched to the intrinsic sinus rate.

4.20.1 Operation of APP

Atrial Preference Pacing (APP) is available when the pacing mode is programmed to DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode, and it functions when the device is operating in one of these modes.

Figure 49. Atrial Preference Pacing (APP)
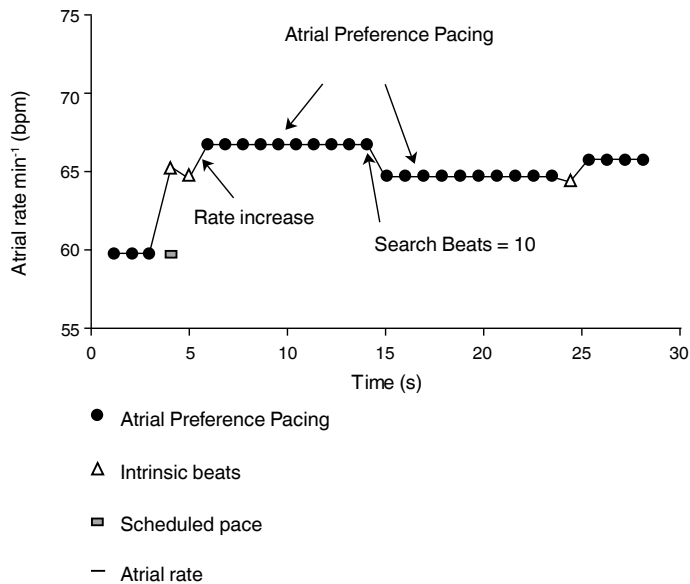
APP is a programmable feature that is designed to maximize atrial overdrive pacing when the patient is not experiencing an atrial tachyarrhythmia. The device responds to changes in the atrial rate by accelerating the pacing rate until reaching a paced rhythm that is slightly faster than the intrinsic rate.

After each nonrefractory atrial sensed event, the device decreases the atrial pacing interval by the programmed Interval Decrement value. This progression continues until the pacing rate exceeds the intrinsic rate, resulting in an atrial paced rhythm. It sustains this increased rate for the number of beats programmed for a Search Beats parameter and then decreases the pacing rate slightly (by 20 ms) to search for the next intrinsic beat. This results in a dynamic, controlled, stair-step increase or decrease in the pacing interval resulting in a pacing rate slightly above the intrinsic rate. The Maximum Rate parameter sets an upper rate limit for APP.

Atrial pacing pulses delivered for APP are annotated on the Marker Channel area with PP (proactive pace).

Figure 50. Example of APP operation
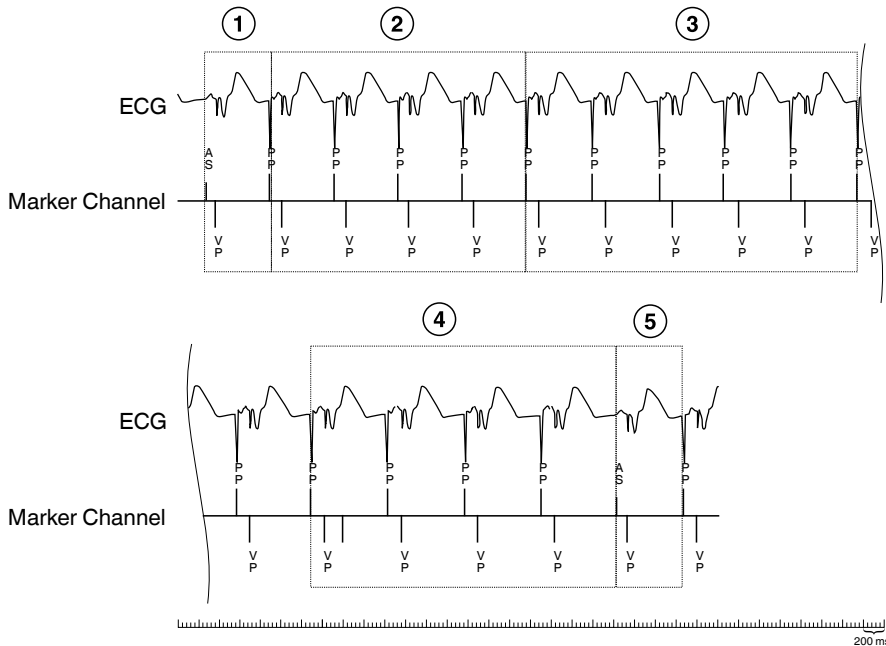
1 A nonrefractory atrial sensed event occurs, causing an increase in the atrial pacing rate (as defined by the Interval Decrement parameter).
2 The rate is maintained for the number of search beats defined by the Search Beats parameter.
3 The rate decreases slightly (by 20 ms) for another set of search beats.
4 This cycle continues until the intrinsic rate is reached.
5 Another nonrefractory atrial sensed event occurs, again causing an increase in the atrial pacing rate.

Notes:

• APP is suspended during mode switching (including PMOP operation) and during detected tachyarrhythmia episodes.

• Generally, when multiple device features attempt to control the pacing rate, the feature with the fastest rate takes precedence.

4.20.2 Programming APP

Table 21. How to navigate to APP parameters

Parameters	Path
A. Preference Pacing	Params > Arrhythmia Interventions…
APP Maximum Rate APP Interval Decrement APP Search Beats	Params > Arrhythmia Interventions… > Additional A Settings…

Device longevity – When APP is programmed to On, the device tends to provide a higher ratio of paced to sensed events, which may decrease device longevity.

Interval Decrement parameter – When choosing a value for the Interval Decrement parameter, be aware that a larger value (for example, 100 ms) provides a more aggressive response to a sinus rate increase. This results in APP pacing occurring more often, more quickly, and for a longer duration than with a smaller Interval Decrement value. A smaller value for the Interval Decrement parameter decreases the response to isolated PACs and sinus variability near the lower or sensor rate.

Non-Competitive Atrial Pacing (NCAP) – The NCAP feature may delay an atrial pacing pulse that results from APP.

Programming constraints – To ensure reliable tachyarrhythmia detection, the system regulates the values that you can select for the Maximum Rate, Upper Rate, AT/AF Detection Interval, and VT Monitor Interval.

4.20.3 Evaluation of APP

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.5, "Episode and therapy counters", page 32.

The % of Time Atrial Intervention line in the AT/AF Summary section of the Counters screen displays the total percentage of time that the patient received atrial intervention pacing. The displayed percentage reflects the combined total of pacing resulting from ARS and APP.

Note: If APP is enabled, atrial intervention pacing is more likely to have resulted from APP than ARS.

4.21 Post-Mode Switch Overdrive Pacing

The management of patients with atrial tachyarrhythmias is made more challenging by the different types of mechanisms known to initiate atrial tachyarrhythmias. It is also made more challenging by the high incidence of tachyarrhythmia recurrences following both therapeutic and spontaneous terminations. Potential causes of atrial tachyarrhythmias include premature atrial contractions (PACs) that result in long sinus pauses and ectopic beats that originate from multiple atrial activation sites. In addition, the vulnerable phase in atrial electrophysiologic properties following the restoration of sinus rhythm may contribute to early recurrences of atrial tachyarrhythmias.

The system provides overdrive pacing techniques that are designed to counteract potential atrial tachyarrhythmia initiating mechanisms.

Post Mode Switch Overdrive Pacing (PMOP) works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

4.21.1 Operation of PMOP

Post-Mode Switch Overdrive Pacing (PMOP) is available when the pacing mode is programmed to DDDR, DDD, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode, and it functions when the device is operating in one of these modes.

Figure 51. Post-Mode Switch Overdrive Pacing (PMOP)
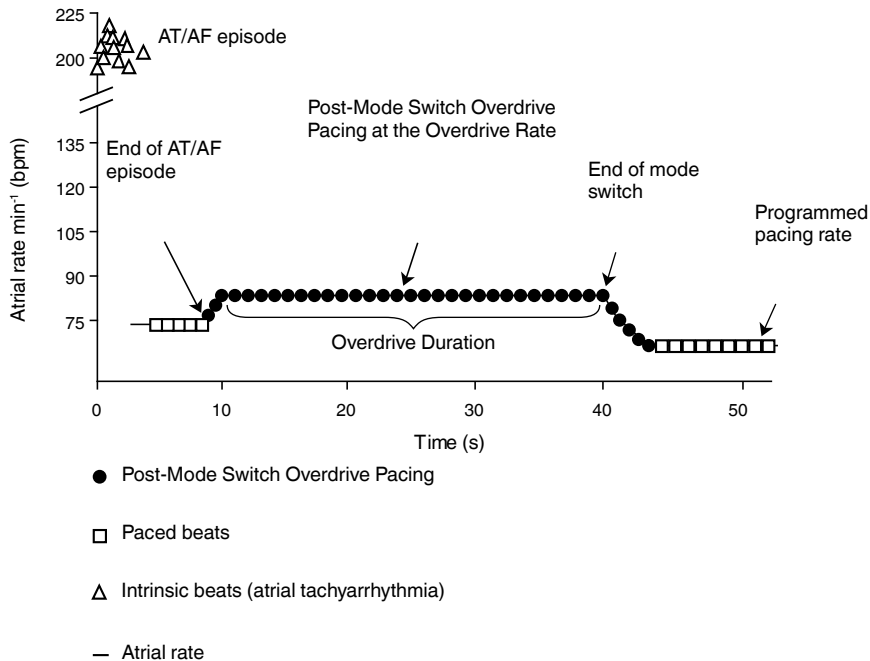
PMOP is a programmable feature that provides overdrive atrial pacing following the end of a mode switch. After a mode switch, the device increases the pacing rate beat-by-beat (decreasing the pacing interval by 70 ms per pulse) until it reaches the programmed Overdrive Rate. It continues DDIR pacing at the overdrive rate for the duration of the programmed Overdrive Duration. It then smooths the return to the programmed atrial tracking mode by gradually slowing the rate (increasing the pacing interval by 70 ms per pulse) until reaching the programmed pacing rate.

Figure 52. Example of PMOP operation
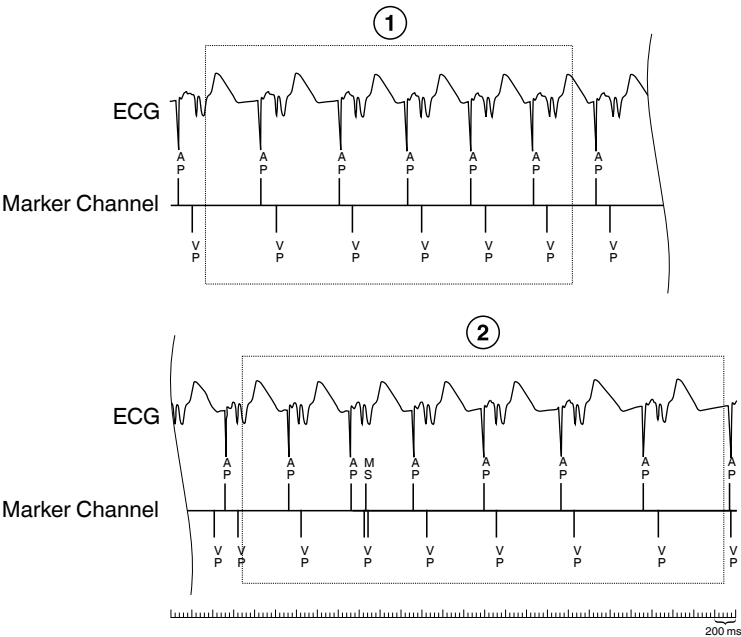
1 Following a mode switch, the device gradually increases the pacing rate to the programmed Overdrive Rate.

2 After pacing for the programmed Overdrive Duration, the device indicates the end of the mode switch and gradually slows the pacing rate to the programmed rate.

For more information, see Section 4.17, "Mode Switch", page 106.

4.21.2 Programming PMOP

Table 22. How to navigate to PMOP parameters

Parameters	Path
Post Mode Switch Post Mode Switch Overdrive Rate Post Mode Switch Overdrive Duration	Params > Arrhythmia Interventions…

Potential right ventricular pacing increase – Since the device remains in DDIR mode during PMOP operation, programming PMOP on may lead to increased right ventricular pacing in patients who experience frequent paroxysmal AT or AF episodes.

Mode Switch – PMOP can be programmed to On only if the Mode Switch feature is on.

4.21.3 Evaluation of PMOP

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 3.5, "Episode and therapy counters", page 32.

4.22 Ventricular Rate Stabilization

When a patient experiences a PVC, it is often followed by a long pause in the cardiac cycle.

The Ventricular Rate Stabilization (VRS) feature is designed to eliminate the long pause that commonly follows a PVC. VRS responds to a PVC by increasing the pacing rate and then gradually slowing it back to the programmed pacing rate or intrinsic rate.

4.22.1 Operation of VRS

VRS operates as a constant rate-smoothing function by adjusting the ventricular intervals that may follow a PVC. The following programmable parameters control the pacing rate determined by VRS:

- Maximum Rate sets a limit on the minimum pacing interval.
- Interval Increment increases the pacing interval length with each successive ventricular sense or ventricular pace.

Following each successive ventricular sense or ventricular pace event, the device calculates a new pacing interval by adding the programmed interval increment value to the previous pacing interval. The calculated interval lengthens, from beat to beat, until the device returns to the intrinsic rate or the programmed pacing rate, whichever occurs first. The pacing rate increase determined by VRS, however, does not exceed the maximum rate programmed for this feature.

VRS is available when the pacing mode is programmed to DDDR, DDD, DDIR, DDI, VVIR, VVI, or an MVP mode (AAIR<=>DDDR or AAI<=>DDD). VRS functions when the device is operating in the DDDR, DDD, DDIR, DDI, VVIR or VVI mode.

Figure 53. Operation of VRS
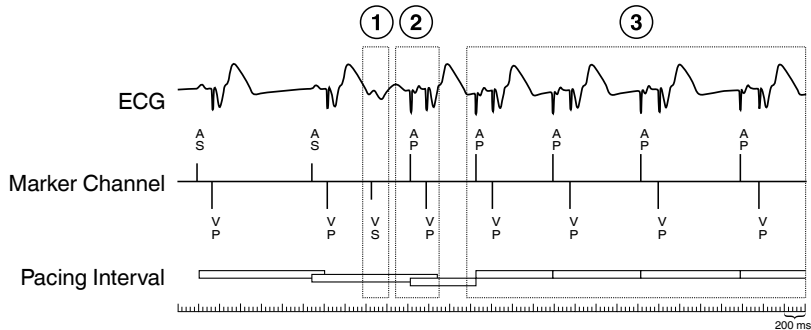
1   A PVC occurs, causing a short pacing interval.
2   The device paces the ventricle at the previous pacing interval plus the programmed interval increment. VRS schedules the atrial pace early to maintain AV synchrony.
3   With each successive pace, VRS increases the pacing interval by the programmed interval increment until it reaches the programmed pacing rate or the intrinsic rate.

Notes:

• An upper limit is placed on the operation of VRS because it is intended as a response to a premature ventricular beat. VRS does not respond to sustained high heart rates.

• In dual chamber pacing modes, VRS automatically shortens the atrial pacing interval so that the ventricular pacing pulse is delivered at the required pacing interval.

• Generally, when multiple device features attempt to control the pacing rate, the feature with the fastest rate takes precedence.

4.22.2 Programming VRS

Table 23. How to navigate to VRS parameters

Parameters	Path
V. Rate Stabilization	Params > Arrhythmia Interventions…
VRS Maximum Rate VRS Interval Increment	Params > Arrhythmia Interventions… > Additional V Settings…

Auto PVARP and VRS – In the DDIR or DDI mode, when VRS increases the pacing rate, Auto PVARP reduces the likelihood of competitive atrial pacing.

Mode Switch and VRS – VRS does not operate during Mode Switch episodes.

Conducted AF Response and VRS – In DDIR and VVIR modes, Conducted AF Response and VRS cannot be programmed to On at the same time.

4.22.3 Evaluation of VRS performance

The device collects and stores counter data that includes information about the frequency of PVCs and VRS operation. To access counter data, select Data > Clinical Diagnostics > Counters > [Open Data] > VT/VF Episodes. You can view the stored data on the programmer screen and print the data.

For more information, see Section 3.5, "Episode and therapy counters", page 32

5 Tachyarrhythmia detection features

5.1 AT/AF detection

Atrial tachyarrhythmias are generally characterized by atrial rates that are faster than the ventricular rates. Atrial tachyarrhythmia can cause patient symptoms. When the device is in an atrial tracking mode, atrial tachyarrhythmia can also cause inappropriately fast ventricular pacing.

Atrial tachyarrhythmia detection is an ongoing process by which the device analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. The accurate detection of an atrial tachyarrhythmia enables the device to respond with appropriate antitachycardia therapies and to collect diagnostic information that may help manage patients with atrial tachyarrhythmias. You can program the device to respond to an atrial tachyarrhythmia by switching to nontracking DDIR mode to avoid high-rate ventricular pacing. When programmed to Monitor, the device switches to DDIR mode, if necessary, and collects atrial tachyarrhythmia episode data but does not deliver therapies.

5.1.1 Operation of AT/AF detection

Figure 54. Overview of AT/AF detection
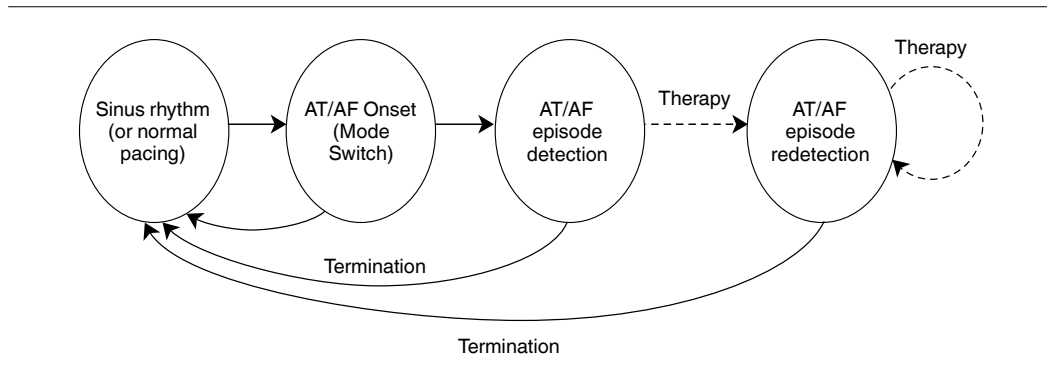
The device detects an atrial tachyarrhythmia episode when it determines both that the atrial rate has increased and that additional evidence of atrial tachyarrhythmia has accumulated based on the number and timing of atrial events within the ventricular intervals. Following the initial episode detection, the device continues to monitor the episode until it terminates. Depending on device programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

5.1.1.1 Identifying atrial tachyarrhythmia onset

The device identifies the onset of an atrial tachyarrhythmia when both of the following conditions are met:

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 3 ventricular intervals must have passed since the beginning of the episode).

- The median of the 12 most recent atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

AT/AF onset is marked in the episode record. If Mode Switch is programmed to On, the device switches to a nontracking mode (DDIR) at AT/AF onset.

Note: The system begins to calculate the percentage of time the patient spends in AT/AF when the conditions for AT/AF onset are met. This information is used in Cardiac Compass Trends.

5.1.1.2 Detecting an atrial tachyarrhythmia episode

The device accumulates evidence of an atrial tachyarrhythmia based on the number and timing of atrial events during ventricular intervals. The device confirms initial AT/AF episode detection when both of the following conditions are met:

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 32 ventricular intervals must have passed since the beginning of the episode).

- The median of the 12 most recent sensed atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

Episode record storage occurs when the conditions for AT/AF detection are met. In the episode record, AT/AF detection is marked with the annotation, AT/AF Detection. For more information, see Section 5.1.3.

Figure 55. AT/AF onset and AT/AF detection
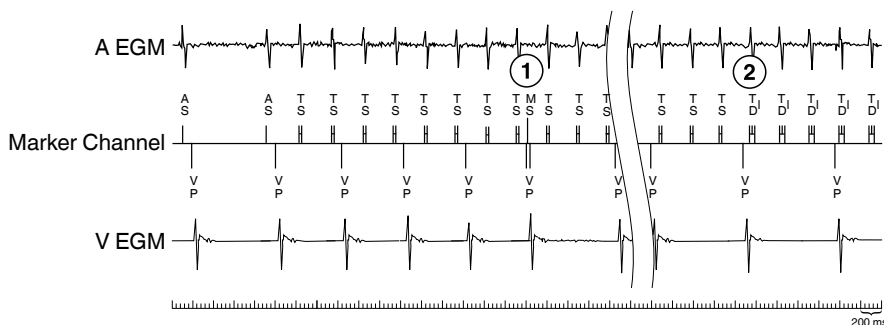
1 The MS marker indicates that Mode Switch has taken place. This marker appears only if Mode Switch has been programmed to On.

2 The TD marker indicates that AT/AF episode detection has taken place.

Notes:

- When AT/AF detection occurs, the system creates an episode record marking the AT/AF onset and detection points. If onset is reached but detection never occurs, no episode record is stored for that instance of AT/AF.

- When there are at least 2 atrial events in a ventricular interval, the device analyzes A:V pattern information to determine if one of the atrial events is actually a far-field R-wave. Far-field R-waves are not counted toward AT/AF detection.

- VT monitor takes priority over AT/AF detection. When a VT Monitor episode is detected, any ongoing AT/AF detection process is postponed until after the VT Monitor episode terminates.

- AT/AF detection does not take place when MRI SureScan mode is on.

5.1.1.3 Classifying atrial tachyarrhythmia episodes for treatment

The system uses programmable "detection zones" to classify atrial tachyarrhythmias for treatment. You can program 1 detection zone (AT/AF) or 2 detection zones (AT/AF and Fast AT/AF). Use 1 zone if the patient exhibits one clinical atrial tachyarrhythmia. Use 2 zones if the patient exhibits 2 distinct clinical atrial tachyarrhythmias and you want to treat each tachyarrhythmia with a unique set of therapies.

To program the AT/AF detection zone, select an AT/AF interval, labeled as A. Interval (Rate) on the programmer screen. If you program the Zones field to 2, you can also select an AT/AF interval for Fast AT/AF.

5.1.1.4 Redetecting an atrial tachyarrhythmia

After a therapy sequence is delivered, the device must redetect the atrial tachyarrhythmia before applying another therapy sequence. The device applies a subsequent therapy sequence only when both of the following conditions are met:

- There are at least 2 atrial sensed events per ventricular interval for a sufficient number of ventricular intervals (at least 32 ventricular intervals must have passed since therapy delivery).

- The median of the 12 most recent sensed atrial intervals is shorter than the programmed AT/AF (or Fast AT/AF) interval.

5.1.1.5 Identifying atrial tachyarrhythmia termination

The device determines that an atrial tachyarrhythmia episode has terminated when the device identifies normal sinus rhythm (or a normal paced rhythm) for 5 consecutive ventricular intervals.

Figure 56. AT/AF termination
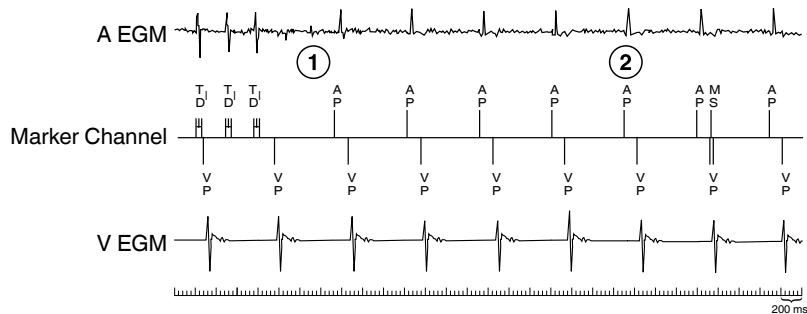
1 Atrial EGM shows that fast atrial rhythm has stopped.
2 There have been 5 consecutive intervals of 1:1 atrioventricular rhythm, all longer than the programmed AT/AF interval. The episode is terminated. The MS marker shows the mode switch back to an atrial tracking mode.

Note: When the atrial tachyarrhythmia detection process has run uninterrupted for 3 min without either the detection or termination criteria being met, the episode is terminated.

5.1.1.6 Monitoring an atrial tachyarrhythmia without delivering therapy

When atrial tachyarrhythmia detection is programmed to Monitor, the device does not deliver AT/AF therapies, and there is no redetection. All other operations, including Mode Switch, remain unchanged.

5.1.2 Programming AT/AF detection

Warning: Do not program AT/AF Detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the device could inappropriately detect AT/AF, deliver atrial ATP to the ventricle, and possibly induce a life-threatening ventricular tachyarrhythmia.

Table 24. How to navigate to AT/AF detection parameters

Parameters	Path
AT/AF Detection AT/AF Interval (Rate)	Params
Zones Fast AT/AF A. Interval (Rate)	Params > (select the rightmost field in the AT/AF row)

Asynchronous pacing mode – AT/AF Detection cannot be programmed to On when the programmed pacing mode is DOO, VOO, or AOO.

Atrial polarity – Atrial sense and pace polarity must be bipolar to program AT/AF Detection to On.

5.1.3 Evaluation of AT/AF detection

5.1.3.1 Quick Look II screen

To access Quick Look II AT/AF detection information, select Data > Quick Look II.

The Quick Look II screen shows the total percentage of time that the patient has spent in AT/AF and the number of monitored or treated AT/AF episodes since the last session.

5.1.3.2 Arrhythmia Episodes screen

To access arrhythmia episode data, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

The Arrhythmia Episodes screen displays recorded tachyarrhythmia episodes and triggered therapies. The Plot option displays a diagram of the episode and shows the times of onset, detection, therapy delivery, and termination. The EGM option displays the episode information in the context of an EGM strip. The Text option provides details about the episode, including type, time, duration, and information about relevant heart rates, delivered therapies, and programmed settings.

The most recent AT/AF episode record provides Flashback Memory data, which includes up to a total of 2000 A-A and V-V intervals and stored marker data for the episode.

5.1.3.3 Cardiac Compass Trends

To access Cardiac Compass Trends, select Data > Quick Look II > Cardiac Compass [>>] button, or select Data > Clinical Diagnostics > Cardiac Compass Trends > [Open Data].

Cardiac Compass Trends provides information about AT/AF episodes and ventricular rhythms and how much time the patient has spent in AT/AF. The V. rate during AT/AF trend displays information about ventricular response during atrial tachyarrhythmias. The AT/AF total hours/day trend provides information about the amount of time the patient has spent in AT/AF.

5.1.3.4 Rate Histograms

To access Rate Histograms, select Data > Clinical Diagnostics > Rate Histograms > [Open Data].

The Ventricular Rate During AT/AF Histogram displays information about the patient's ventricular response during AT/AF.

5.1.3.5 AT/AF episode counters

To access AT/AF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Episodes.

The AT/AF episode counters provide a summary of AT/AF activity, including the percentage of time spent in AT/AF, and the number of AT/AF episodes since the last session. For more information, see Section 3.5, "Episode and therapy counters", page 32.

5.2 VT Monitor

Information about sustained and non-sustained VT episodes is an important input for clinicians in making patient care decisions.

The system provides a VT Monitor feature that allows you to monitor episodes with ventricular rates that are within a programmable VT Monitor rate zone. The device stores Arrhythmia Episode records for these episodes.

5.2.1 Operation of VT Monitor

The device detects a ventricular tachyarrhythmia episode when 16 (for the dual chamber devices) or 20 (for the single chamber devices) consecutive sensed ventricular intervals are shorter than the programmed VT Monitor detection interval. The detected episode is classified as a VT Monitor episode if the ventricular rate is faster than the atrial rate.

Figure 57. Device detects a VT Monitor episode
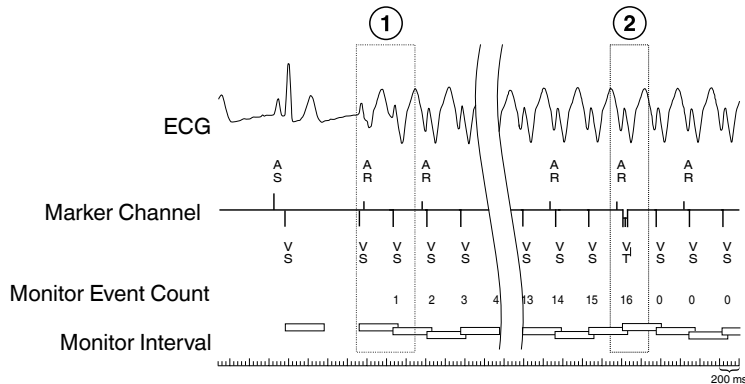
1 Sensed ventricular beats fall in the VT Monitor zone.
2 The fixed VT Monitor Initial Beats to Detect value of 16 (in this dual chamber device example) is reached. Because the ventricular rate is faster than the atrial rate, a VT Monitor episode is detected and marked VT with a vertical bar to the right. For the single chamber device, the fixed VT Monitor Initial Beats to Detect value is 20.

The device then monitors the episode until termination or until detection is suspended. The device determines that an episode has terminated if one of the following conditions occurs:

- 8 consecutive ventricular intervals are longer than or equal to the programmed VT Monitor interval.

- 20 s elapse without the median of the last 12 ventricular intervals being shorter than the programmed VT Monitor Interval.

5.2.1.1 Discriminating VT Monitor episodes from SVT episodes

Only episodes in which the ventricular rate is faster than the atrial rate are classified as VT Monitor episodes. The device discriminates VT from SVT using the following episode classifications:

Fast A&V – If the ventricular rate is in the programmed VT monitor zone, and the atrial rate is faster than or equal to the ventricular rate (for example, due to rapidly conducted atrial fibrillation or flutter), the episode is classified as Fast A&V. Fast A&V detection is marked AV with a vertical bar to the right.

SVT – If the ventricular rate is in the programmed VT monitor zone, and the device detects sinus tachycardia, the episode is classified as SVT. If the ventricular rate is in the programmed VT monitor zone, and the device detects atrial fibrillation or flutter, the episode is classified as SVT-AF. The annotation appears in the episode text but not in the episode

EGM. SVT records can be selected from the Episode Log when the device has been interrogated.

VT-NS – If at least 5 but fewer than 16 (for the dual chamber devices) or 20 (for the single chamber devices) consecutive events are in the programmed VT monitor zone, the episode is classified as a non-sustained VT (VT-NS). Non-sustained episode records can be selected from the Episode Log when the device has been interrogated.

5.2.2 Programming VT Monitor

Table 25. How to navigate to VT Monitor parameters

Parameters	Path
VT Detection VT Interval (Rate)	Params

5.2.3 Evaluation of VT Monitor

5.2.3.1 Quick Look II observations

To access Quick Look II VT Monitor information, select Data > Quick Look II.

The Quick Look II screen shows the number of monitored VT episodes since the last session.

5.2.3.2 Arrhythmia Episodes screen

To access arrhythmia episode data, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data].

The Arrhythmia Episodes screen displays recorded tachyarrhythmia episodes. The Plot option displays a diagram of the episode and shows the times of detection and termination. The EGM option displays the episode information in the context of an EGM strip. The Text option provides details about the episode, including type, time, duration, and information about relevant heart rates and programmed settings.

The most recent VT episode and Fast A&V episode provide Flashback Memory data, which includes up to a total of 2000 A-A and V-V intervals and stored marker data for each episode.

5.2.3.3 VT/VF episode counter

To access VT/VF episode data, select Data > Clinical Diagnostics > Counters > [Open Data] > VT/VF Episodes.

The VT/VF episode counter provides a summary of VT/VF activity for last session and prior session, including the number of VT, non-sustained VT, and Fast A&V episodes.

5.3 Suspending and resuming tachyarrhythmia detection

It may be necessary to turn off tachyarrhythmia detection in some situations. For example, during emergency therapies and some EP study tests, therapies are delivered manually, and detection and episode storage are not needed. Also, certain types of surgery, including electrocautery surgery, RF ablation, and lithotripsy, can cause the device to detect tachyarrhythmias inappropriately and possibly deliver inappropriate therapy.

When detection is suspended, the device temporarily stops the process of classifying intervals for tachyarrhythmia detection. Sensing and bradycardia pacing remain active, and the programmed detection settings are not modified. When the device resumes detection, it does so at the previously programmed detection settings.

Note: If MRI SureScan is programmed to On, tachyarrhythmia detection is suspended.

5.3.1 Considerations for suspending detection

If you suspend detection during a tachyarrhythmia detection process but before detection has occurred, the initial detection never occurs. When you resume, detection starts over.

If you suspend detection after a tachyarrhythmia detection has occurred and resume detection before the tachyarrhythmia episode terminates, redetection works differently for each type of episode, as follows:

AT/AF episodes – If you suspend detection during a detected AT/AF episode and then resume detection before the episode terminates, detection starts over for the same episode.

Note: Suspending tachyarrhythmia detection does not affect Mode Switch. A Mode Switch may occur whether or not tachyarrhythmia detection has been suspended.

VT Monitor episodes – If you suspend detection during a detected VT Monitor episode and then resume detection before the episode terminates, there will be episode data storage for 2 episodes, with the first episode terminated while the rate is still fast.

5.3.2 How to suspend or resume detection with the programmer

The [Suspend] and [Resume] buttons can be used whenever there is telemetry with the device and the device software is running.

1. To suspend detection, select [Suspend]. The programmer displays the word SUSPENDED.

2. To resume detection, select [Resume].

5.3.3 How to suspend or resume detection with a magnet

1. To suspend detection, place the magnet (such as the Model 9466 Tachy Patient Magnet) over the device.

2. To resume detection, remove the magnet from over the device.

Notes:

- Placing a magnet over the device also initiates magnet mode. For more information about magnet application, see the device manual for the specific device.

- A magnet can be used to suspend detection and initiate magnet mode only when there is no telemetry between the device and the programmer.

6 Tachyarrhythmia therapy features

6.1 Atrial therapy scheduling

An AT/AF episode is detected when a sustained atrial tachyarrhythmia occurs. Treatments for these episodes are intended to interrupt the atrial tachyarrhythmia and restore the patient's normal sinus rhythm. During an episode there may be changes in the atrial rhythm or in the underlying substrate. These changes might make it possible to terminate the episode with a therapy that had been unsuccessful.

Atrial therapies are scheduled for delivery throughout the duration of an AT/AF episode. You have the flexibility to determine how the device delivers the therapies by programming the atrial therapy parameters related to scheduling. Each time that an AT/AF therapy is required, the device schedules one of the available therapies in accordance with your programming.

See the following sections for information about atrial detection and therapies:

- Section 5.1, "AT/AF detection", page 124
- Section 6.2, "Atrial ATP therapies", page 139

6.1.1 Operation of atrial therapy scheduling

The device schedules the delivery of automatic antitachycardia pacing (ATP) therapies throughout a sustained AT/AF episode. The Reactive ATP feature is a programmable option that allows the device to reschedule ATP therapies that had been unsuccessful earlier in the episode.

6.1.1.1 Episode duration

The system allows you to define when atrial ATP therapies can be scheduled over the duration of the episode. In terms of therapy scheduling, the episode duration is defined as the time elapsed since the initial detection of an AT/AF episode. The following parameters allow you to program when the therapies are available:

- The programmed ATP value of the Episode Duration Before Rx Delivery parameter determines when atrial ATP sequences become available.
- If a time limit is programmed for Duration to Stop, no atrial therapies are scheduled after the episode duration reaches the Duration to Stop value.

6.1.1.2 Requirements for scheduling an automatic atrial therapy

At initial detection and at each subsequent redetection, an atrial ATP sequence is scheduled, provided that the following conditions exist:

- The last 5 atrial events were all atrial sensed events.

- The previous ventricular interval contained 3 or more atrial sensed events, or it contained 2 atrial sensed events with intervals less than the AT/AF Interval.

- The therapy is available at this point in the episode duration.

6.1.1.3 Using the Fast AT/AF detection zone

Atrial tachyarrhythmia detection can be programmed for 2 detection zones: AT/AF and Fast AT/AF. Each zone has a unique set of programmed therapies. The device schedules each therapy from the appropriate set for that zone. The availability of individual therapies may depend on the median atrial interval in effect each time that detection occurs.

6.1.1.4 Reactive ATP

In some cases, the programmed set of atrial ATP therapies may not initially terminate an atrial tachyarrhythmia. Additional attempts at termination with the same set of atrial ATP therapies may be successful, particularly if the atrial rhythm changes. The Reactive ATP feature makes it possible for the device to repeat programmed sets of atrial ATP therapies in 2 different situations. Rhythm Change, one type of Reactive ATP operation, subdivides the AT/AF detection zone into smaller regions. The ATP therapies programmed for the AT/AF zone apply to each of the smaller regions in that zone. Time Interval, the other type, makes all ATP therapies available at specific durations during an episode.

Rhythm Change – For Rhythm Change, the device detects changes in the regularity and cycle length of atrial rhythms. The AT/AF detection zone is subdivided into a series of narrower regions. The ATP therapies programmed for the AT/AF zone apply to each of the smaller regions in that zone. One series of subdivided regions is identified for regular atrial rhythms. Another series of regions is identified for irregular atrial rhythms. An atrial rhythm is classified as being regular or irregular based on the atrial cycle lengths in recent V-V intervals. If the rhythm shifts into a different region because of a change in cycle length or regularity, the device delivers therapies from those available for the new region.

The shift from a regular rhythm to an irregular rhythm introduces an additional 10 min scheduling delay to permit spontaneous termination of the irregular rhythm or a shift back to a regular rhythm.

For 1 atrial detection zone, the number of regions depends on the programmed AT/AF detection interval. Refer to Figure 58.

Figure 58. AT/AF zone subdivided for Rhythm Change (AT/AF only)

AT/AF zone (100 - 450 ms)

100 ms	150	200	250	300	350	400	450	

Regular rhythms

Irregular rhythms
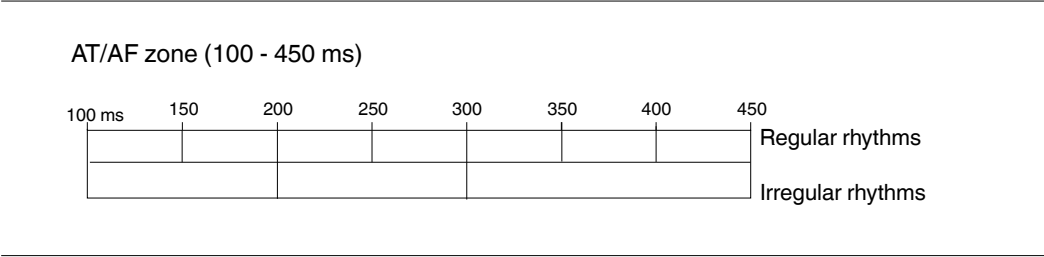
For 2 atrial detection zones, the number of regions in the AT/AF zone depends on the programmed values for the AT/AF detection interval and the Fast AT/AF detection interval. Refer to Figure 59. The Fast AT/AF zone is not subdivided, and Fast AT/AF ATP therapies are not affected by this type of Reactive ATP operation.

Figure 59. AT/AF zone subdivided for Rhythm Change (AT/AF and Fast AT/AF)

Fast AT/AF zone
(100 - 200 ms)   AT/AF zone (200 - 450 ms)

100 ms	150	200	250	300	350	400	450	

Regular rhythms

Irregular rhythms
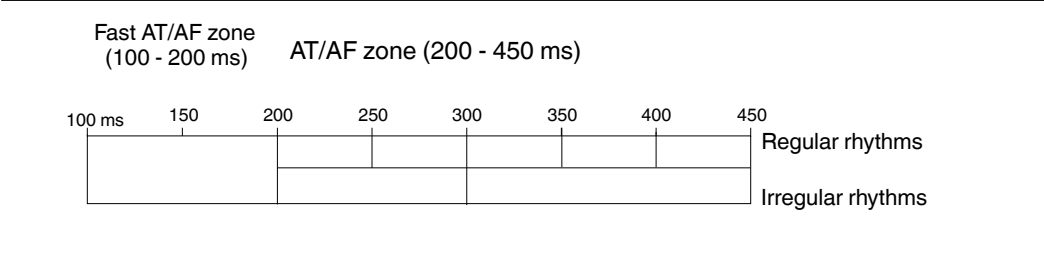
Note: To view the number of atrial ATP therapies that were delivered for each region, view the Arrhythmia Episodes diagnostic. See Section 6.1.3.

Time Interval – Time Interval allows the device to schedule additional ATP therapies regardless of rhythm changes.

All ATP sequences become available when the episode duration value reaches a multiple of the programmed Time Interval. This applies to ATP therapies for both the AT/AF zone and the Fast AT/AF zone. This function is available only within the first 48 hours of an atrial episode.

6.1.1.5 Automatically disabling atrial therapies

In some situations the device may automatically disable or suspend an ATP therapy.

VT Monitor episode after an AT/AF therapy delivery – Atrial therapies are disabled if a VT Monitor episode is detected immediately after an atrial ATP therapy sequence is delivered. It does not deliver the remaining sequences of the programmed atrial therapy. In this case, atrial therapies remain disabled until you reprogram them.

VT Monitor episode unrelated to AT/AF therapy delivery – If the device detects a VT Monitor episode during an AT/AF episode, but the detection is not related to therapy delivery, it temporarily suspends atrial therapies. Atrial therapies automatically resume when the VT Monitor episode ends.

6.1.1.6 Programmable options for disabling atrial therapies

The system also provides the following programmable options that disable atrial therapies under certain situations:

- Disable Atrial ATP if it accelerates V. rate?
- Disable all atrial therapies if atrial lead position is suspect?

Ventricular rate acceleration during an atrial ATP therapy delivery – If the ventricular rate accelerates during the delivery of an atrial ATP therapy, the device immediately disables all atrial ATP therapies. The atrial ATP therapies remain disabled until the therapies are reprogrammed. You can program this option using the "Disable atrial ATP if it accelerates V. Rate" parameter.

Atrial lead position suspect – The device checks atrial lead position every 24 hours. The Atrial Lead Position Check occurs only if the pacing mode includes atrial pacing. The check is disabled during mode switching, telemetry sessions, and any tachyarrhythmia episodes. The check paces the atrium with a series of high-output pulses. It determines the number of AP-VS intervals in the series that are shorter than 80 ms. A large number of short intervals indicates that the lead may no longer be positioned in the atrium. If the lead check fails, all atrial therapies are disabled until they are reprogrammed. You can program this option using the "Disable all atrial therapies if atrial lead position is suspect" parameter.

6.1.2 Programming atrial therapy scheduling

Note: At least one atrial therapy must be set to On before you can select values for atrial therapy scheduling.

Table 26. How to navigate to parameters for atrial therapy scheduling

Parameters	Path
Reactive ATP parameters: Rhythm Change Time Interval	Params > (select the rightmost field in the AT/AF row)
Duration parameters: Duration to Stop Episode Duration Before Rx Delivery	
Stop Atrial Rx - Atrial Therapy or Lead Suspect parameters: Disable Atrial ATP if it accelerates V. rate? Disable all atrial therapies if atrial lead position is suspect?	Params > (select the rightmost field in the AT/AF row) > Rx/Lead Suspect…

Atrial therapies and the MRI SureScan feature – If the MRI SureScan feature is programmed to On, the device does not detect atrial and ventricular tachyarrhythmias, and, therefore, does not deliver tachyarrhythmia therapies. Refer to the MRI technical manual for additional information.

Atrial therapies and AT/AF Detection – If all atrial therapies are programmed to Off and you change the AT/AF Detection parameter value from Monitor to On, the programmer automatically sets the first 2 AT/AF therapies to the nominal or previously programmed settings.

Atrial Lead Position Check – To ensure that the lead position check occurs, verify that the pacing mode includes atrial pacing. The lead position check does not occur if the programmed pacing mode is VVIR, VVI, VOO, DOO, or ODO.

Atrial Lead Position Check and Ventricular Safety Pacing – The lead position check cannot be enabled unless Ventricular Safety Pacing is enabled.

6.1.3 Evaluation of atrial therapy scheduling

You can use Arrhythmia Episodes text data to evaluate atrial therapy scheduling. To view Arrhythmia Episodes text, select Data > Clinical Diagnostics > Arrhythmia Episodes > [Open Data] >Text.

For AT/AF episodes, the Arrhythmia Episode text screen lists the following types of information:

- an episode summary

- an event sequence

- the number of atrial ATP sequences that were delivered in each Reactive ATP region

- the programmed values for AT/AF Detection, Duration to Stop, Reactive ATP, and the EGM and Sensitivity settings

6.2 Atrial ATP therapies

The device detects sustained atrial tachycardia as an AT/AF episode. Treatments for such episodes are intended to interrupt the atrial tachycardia and restore the patient's normal sinus rhythm. Pacing therapy can be an option for terminating an atrial tachycardia episode.

The device can respond to an AT/AF episode by delivering atrial antitachycardia pacing (ATP) therapies to the patient's heart. Atrial ATP therapies deliver pacing pulses designed to interrupt the AT/AF reentrant activation pattern and restore the patient's normal sinus rhythm.

For information about AT/AF detection, refer to Section 5.1, "AT/AF detection", page 124 .

6.2.1 Operation of atrial ATP therapies

The device can deliver up to 3 ATP therapies to treat an AT/AF or a Fast AT/AF episode. Atrial ATP therapy options are Burst+ and Ramp, each with a programmable number of sequences. All atrial ATP therapies are delivered in the AOO mode.

The device schedules the delivery of atrial therapies throughout a sustained AT/AF episode, based on the programmed settings. An ATP therapy may be aborted if no atrial event occurs within 500 ms after the therapy is scheduled.

When an AT/AF or Fast AT/AF episode is detected, the device delivers the first sequence of the ATP therapy. After the first ATP sequence, it continues to monitor for the presence of the atrial tachycardia episode. If it redetects the atrial tachycardia episode, the device delivers the next ATP sequence and repeats this cycle until the episode is terminated or all sequences in the therapy are exhausted.

If all sequences in an ATP therapy are unsuccessful, the device starts delivering the next scheduled ATP therapy. If the device detects that the current AT/AF episode has accelerated and become a Fast AT/AF episode, it skips the remaining sequences of the ATP therapy and starts the next scheduled ATP therapy for the episode. The device, however, delays therapy for a Fast AT/AF episode detected after the delivery of an AT/AF pacing therapy. A Fast AT/AF therapy is delayed for at least 10 min to allow an accelerated rhythm to terminate spontaneously or revert to the previous AT/AF rhythm.

Note: Atrial detection is suspended during the delivery of an atrial ATP therapy sequence.

Figure 60. Overview of atrial ATP therapy delivery
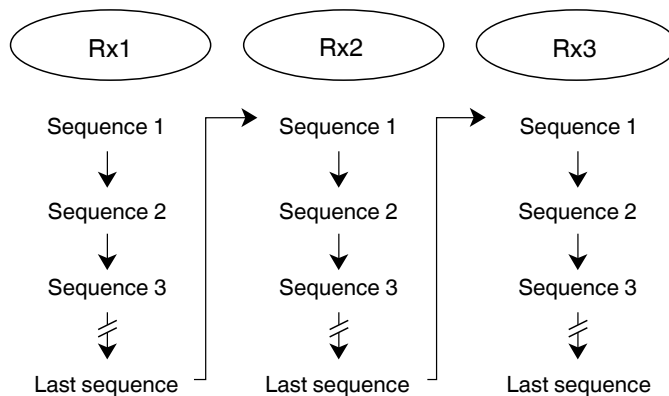
For an overview of atrial ATP sequence delivery, see Figure 61.

Note: VVI backup pacing is available during an atrial ATP therapy delivery. For more information, refer to Section 6.2.1.5.

6.2.1.1 Atrial ATP therapy scheduling

The device prepares to deliver an atrial ATP therapy if the following conditions are met:

- An atrial episode is in progress at the time of the scheduled delivery.
- Atrial ATP therapy sequencing indicates that ATP therapies are enabled for the given rhythm classification (AT/AF or Fast AT/AF).
- There is an unused atrial ATP therapy remaining for that classification.

For details about atrial ATP therapy scheduling, including parameters that disable or suspend ATP therapies, see Section 6.1, "Atrial therapy scheduling", page 134.

Figure 61. Overview of atrial ATP sequence delivery
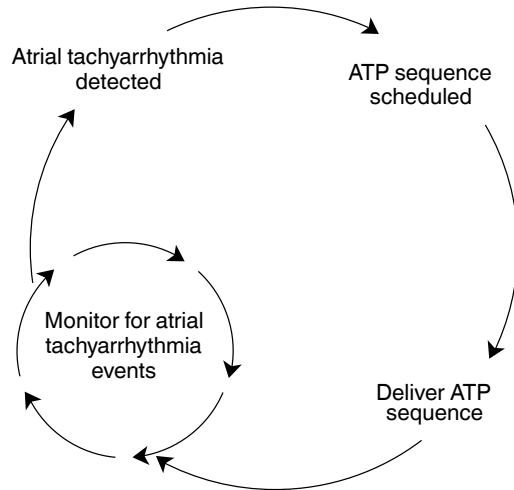
6.2.1.2 Atrial ATP therapy pacing rate and output

Minimum limit for atrial ATP pacing interval – The Burst+ and Ramp pacing intervals are based on programmed percentages of the atrial tachycardia cycle length, which is calculated as the median of the last 12 atrial intervals prior to therapy delivery. The median atrial tachycardia cycle length can vary from one sequence in a therapy to the next, and the ATP pacing intervals vary accordingly.

The programmable A-A Minimum ATP Interval parameter limits the pacing intervals at which the Burst+ and Ramp pacing pulses are delivered. If some calculated intervals are shorter than the programmed A-A Minimum ATP Interval, the pulses are delivered at the A-A Minimum ATP Interval.

If the median of the last 12 A-A intervals is shorter than the programmed A-A Minimum ATP Interval, the device does not deliver Burst+ or Ramp therapies until the atrial rate slows.

Pacing output for ATP therapies – The A. Pacing Amplitude and A. Pacing Pulse Width parameter values are the same for all atrial ATP therapies, but they are programmed separately from the pacing amplitude and pulse width for bradycardia pacing pulses.

6.2.1.3 Operation of Burst+ pacing

The programmable parameter Initial #S1 Pulses sets the number of Initial #S1 Pulses in each Burst+ therapy sequence. A-S1 Interval (%AA), S1-S2 (%AA), and S2-S3 Decrement are programmable parameters that determine the pacing intervals in a Burst+ sequence.

Each Burst+ sequence consists of the programmed number of Initial #S1 Pulses, followed by up to 2 additional pulses, if the parameters for these pulses are programmed to On. The pacing intervals for the first Burst+ sequence and additional pulses are determined as percentages of the atrial tachycardia cycle length. In the first Burst+ sequence, all Initial #S1 Pulses are delivered at the same pacing interval, which is determined by the A-S1 Interval (%AA) percentage. The first additional pulse is delivered at an interval determined by the S1-S2 (%AA) percentage. The pacing interval for the subsequent pulse is calculated by subtracting the S2-S3 Decrement value from the previous interval. This pulse is delivered only if the S1-S2 (%AA) parameter is programmed to On.

If the atrial tachycardia is redetected after an unsuccessful sequence, the device delivers another Burst+ sequence with shorter pacing intervals. For this sequence, the device calculates the pacing intervals by subtracting the programmed Interval Decrement value from each pacing interval in the previous sequence.

VVI ventricular backup pacing is available during Burst+ pacing.

Figure 62. Example of Burst+ pacing operation
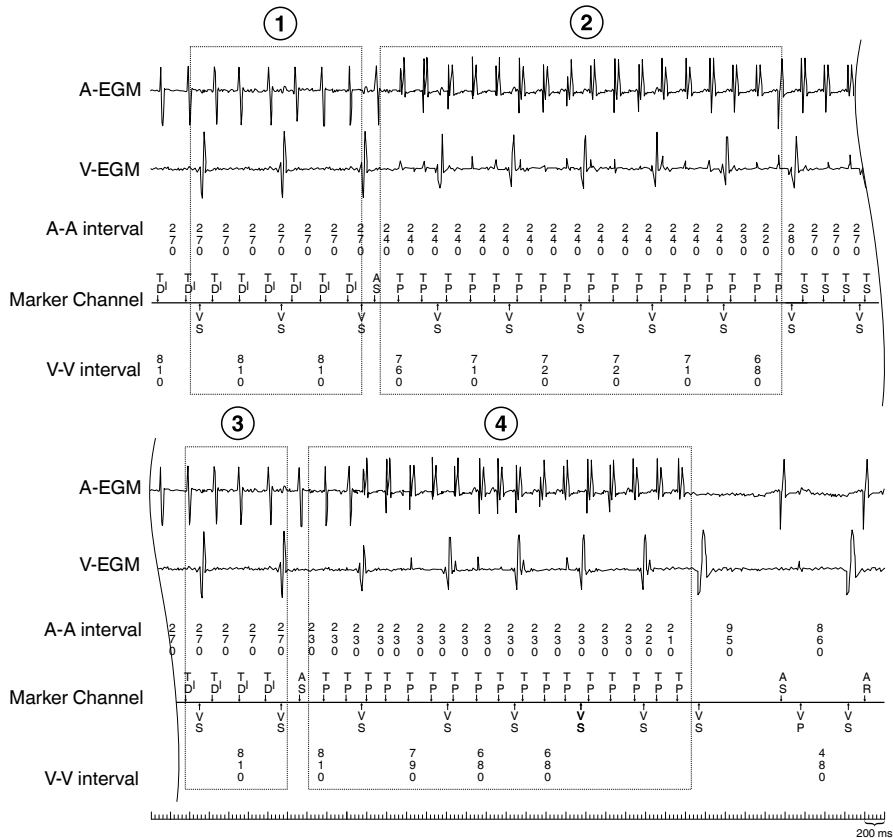
1 The device detects an AT/AF episode.

2 The first Burst+ sequence is delivered with 15 pulses at pacing intervals of 240 ms. The sequence continues with 2 additional pulses at intervals shorter than 240 ms. The interval is decremented by 10 ms for each additional pulse. This sequence fails to terminate the AT/AF episode.

3 The device redetects the AT/AF episode.

4 The second Burst+ sequence is delivered with 15 pulses at pacing intervals of 230 ms. The sequence continues with 2 additional pulses at intervals shorter than 230 ms. The interval is decremented by 10 ms for each additional pulse. This sequence terminates the AT/AF episode.

6.2.1.4 Operation of Ramp pacing

The Initial #S1 Pulses parameter sets the number of pulses in the first Ramp sequence. A-S1 Interval (%AA) and Interval Decrement are programmable parameters that determine the Ramp pacing intervals.

Each Ramp therapy sequence consists of the programmed number of pulses delivered at decreasing pacing intervals. In each sequence, the first pulse is delivered at a pacing interval determined by the A-S1 Interval (%AA) parameter as a percentage of the atrial tachycardia cycle length. The remaining pulses in the sequence are delivered at progressively shorter pacing intervals by subtracting the Interval Decrement value for each pulse.

If the atrial tachycardia is redetected after an unsuccessful sequence, the device applies the programmed A-S1 Interval (%AA) percentage to the new atrial tachycardia cycle length at redetection to determine the initial pacing interval for the next sequence. Each sequence contains one more pacing pulse than the previous sequence.

VVI ventricular backup pacing is available during Ramp pacing.

Figure 63. Example of Ramp pacing operation
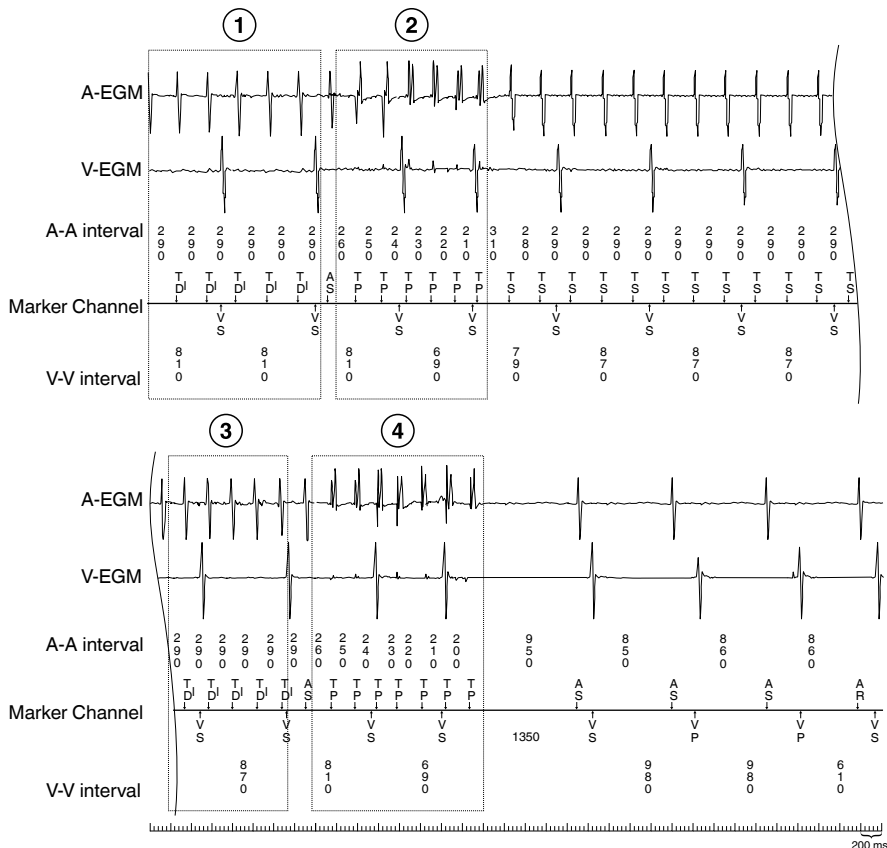
1 The device detects an AT/AF episode.

2 The first Ramp sequence is delivered with 6 pulses. The first interval is 260 ms, and each interval that follows is decremented 10 ms, the Interval Decrement value. This sequence fails to terminate the AT/AF episode.

3 The device redetects the AT/AF episode.

4 The second Ramp sequence is delivered with 7 pulses. The first interval is 260 ms, and each interval that follows is decremented 10 ms, the Interval Decrement value. This sequence terminates the AT/AF episode.

6.2.1.5 Ventricular backup pacing during an atrial ATP therapy

Ventricular backup pacing in the VVI mode is available during atrial ATP therapy delivery. The backup pacing is delivered either at the separately programmed Lower Rate or at the current pacing rate, whichever is faster. The backup pacing output is preset at 6 V and 1.5 ms.

The following options are available for enabling VVI Backup Pacing:

• On (Always): backup pacing is delivered during every atrial ATP therapy.

• On (Auto Enable): backup pacing is delivered if 1 of the 4 ventricular events preceding the therapy is paced. When Auto Enable is selected, the device monitors for rapidly conducting ventricular sense events that may occur during an ATP therapy delivery.

Note: VVI Backup Pacing could be competitive with intrinsic ventricular activity during the atrial ATP sequence.

6.2.2 Programming atrial ATP therapies

The following table shows how to navigate to parameters for therapies in the AT/AF zone. You can program therapies in the Fast AT/AF zone similarly, after selecting the Fast AT/AF Rx field in the AT/AF Detection and Therapies window.

Table 27. How to navigate to parameters for atrial ATP therapies in the AT/AF zone

Parameters	Path
AT/AF Rx Status Therapy Type	Params > (select the rightmost field in the AT/AF row) > AT/AF Rx
Burst+ therapy parameters: Initial #S1 Pulses A-S1 Interval (%AA) S1-S2 (%AA) S2-S3 Decrement Interval Decrement # Sequences	
Ramp therapy parameters: Initial #S1 Pulses A-S1 Interval (%AA) Interval Decrement # Sequences	
Shared A. ATP therapy parameters: A-A Minimum ATP Interval A. Pacing Amplitude A. Pacing Pulse Width VVI Backup Pacing VVI Backup Pacing Rate	

Warning: Do not program AT/AF Detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the device could inappropriately detect AT/AF, deliver atrial ATP to the ventricle, and possibly induce a life-threatening ventricular tachyarrhythmia.

AT/AF Detection – Make sure that AT/AF Detection is programmed on before programming atrial ATP therapies. The device does not deliver Atrial ATP therapies if AT/AF Detection is not programmed on.

6.2.3 Evaluation of atrial ATP therapies

6.2.3.1 The Quick Look II screen

To access Quick Look II screen information, select Data > Quick Look II.

Treated AT/AF episodes – This section includes a count of treated AT/AF episodes. You can select the Treated [>>] button to view the data for treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then select the Observations [>>] button to view related information.

6.2.3.2 AT/AF therapy counters

To access AT/AF therapy counter information, select Data > Clinical Diagnostics > Counters > [Open Data] > AT/AF Rx.

The AT/AF therapy counters provide information that helps you to evaluate the efficacy of atrial ATP therapies delivered since the last session.

The following therapy counter data is available for atrial ATP therapies:

AT/AF Rx – This counter reports the number of AT/AF episodes treated per programmed therapy and the percentage of successfully terminated episodes per programmed therapy.

Fast AT/AF Rx – This counter reports the number of Fast AT/AF episodes treated per programmed therapy and the percentage of successfully terminated episodes per programmed therapy. This information is shown on the screen only if AT/AF detection is programmed to 2 zones.

Treated episodes per cycle length – This counter reports the number of episodes treated per atrial cycle length and the percentage of successfully terminated episodes per atrial cycle length.

ATP Sequences – This counter reports the number of atrial ATP sequences delivered and the number aborted.

Note: The counter data for treated episodes per atrial cycle length and atrial ATP sequences is reported for Fast AT/AF zone only if AT/AF detection is programmed to 2 zones.

Glossary

2:1 block rate – a conduction ratio in which every second atrial event is refractory. This results in a ventricular pacing rate that is one half as fast as the atrial rate. Also known as second-degree Mobitz Type II AV block.

activities of daily living rate (ADL Rate) – the approximate target rate that the patient's heart rate is expected to reach during activities of daily living.

activities of daily living response (ADL response) – a programmable parameter that alters the slope of the rate response curve to adjust the targeted rate distribution in the submaximal rate range to match the patient's activity level.

activity sensor – accelerometer in the device that detects the patient's body movement.

antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

AT/AF detection – feature that analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. Depending on programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

AT/AF Interval – programmable interval used to define the AT/AF detection zone. The median atrial interval must be shorter than this value to detect an AT/AF episode.

Atrial antitachycardia pacing (ATP) – therapies that respond to an AT/AF episode or a Fast AT/AF episode with rapid sequences of pacing pulses to terminate detected atrial tachyarrhythmias.

Atrial Preference Pacing (APP) – atrial rhythm management feature that adapts the pacing rate to slightly higher than the intrinsic sinus rate.

Atrial Rate Stabilization (ARS) – atrial rhythm management feature that eliminates a prolonged pause following a premature atrial contraction (PAC).

Atrial Refractory Period (ARP) – interval that follows an atrial paced or sensed event during which the device senses events but responds to them in a limited way. This interval is applied when the device is operating in a single chamber, atrial pacing mode.

Atrial therapy scheduling – feature that enables the clinician to program the delivery of automatic atrial therapies. Each time that an AT/AF therapy is needed, the device schedules one of the available therapies based on clinician programming.

atrial tracking – dual chamber pacing operation that paces the ventricle in response to atrial events.

Auto PVARP – Adjusts PVARP (Post-Ventricular Atrial Refractory Period) in response to changes in the patient's heart rate or pacing rate. PVARP is longer at lower tracking rates to prevent pacemaker-mediated tachycardia (PMT) and shorter at higher rates to maintain 1:1 tracking.

AV synchrony – coordinated contraction of the atria and ventricles for most effective cardiac output.

blanking period – time interval during which sensing in a chamber is disabled to avoid oversensing.

Burst+ pacing – antitachycardia pacing (ATP) therapy that delivers sequences of atrial pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length, followed by up to 2 premature stimuli delivered at programmable intervals. With each sequence of Burst+ pacing delivered, the device shortens the pacing interval by a programmable interval.

Capture Management – feature that monitors pacing thresholds with daily pacing threshold searches and, if programmed to do so, adjusts the pacing amplitudes toward a target amplitude.

Cardiac Compass Trends – overview of the patient's condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm, such as frequency of arrhythmias, heart rates, and device therapies.

Conducted AF Response – feature that adjusts the pacing rate to help promote a regular ventricular rate during AT/AF episodes.

crosstalk – condition when pacing in one chamber is sensed as intrinsic activity in another chamber.

Decision Channel annotations – annotations to stored and telemetered EGM that document details about tachyarrhythmia detection operations.

device reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to default reset values. This operation triggers a device status indicator.

device status indicator – value recorded in device memory to signify a condition or problem that may affect device operation and that requires attention.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that may interfere with device operations, such as sensing, or may potentially damage device circuitry.

EOS (End of Service) – battery status indicator displayed by the programmer to indicate that the device should be replaced immediately and that it may not operate per specifications.

ERI (Elective Replacement Indicator) – battery status indicator for when replacement of the device is recommended. Key device parameters are automatically switched. For example, pacing mode switches to VVI and Lower Rate goes to 65 bpm.

event – a sensed or paced beat.

evoked response detection – the act of detecting the electrical signal generated by the contracting myocardium immediately following a pacing pulse.

exertion rate range – rates at or near the Upper Sensor Rate that are achieved during vigorous exercise.

Flashback Memory – diagnostic feature that records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Holter telemetry – telemetry feature that transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and programmer.

hysteresis – a pacing operation and programmable parameter that allows a longer escape interval after a sensed event, giving the heart a greater opportunity to beat on its own.

last session – refers to the last time the device was successfully interrogated before the current interrogation. A session ends 8 hours after the last interrogation.

median atrial interval – the seventh in a numerically ordered list of the 12 most recent A-A intervals.

Medtronic CareAlert Monitoring – the continuous monitoring for, and silent, wireless transmission of, alert data between an implanted device and the Medtronic CareLink Network.

Medtronic CareAlert notifications – alert information sent via the Medtronic CareLink Network that notifies clinics and clinicians of events that impact patients or their implanted devices.

Medtronic CareLink Network – Internet-based service that allows a patient to transmit cardiac device information from home or other locations to the physician over a secure server. The CareLink Network may be unavailable in some geographic locations.

Medtronic patient monitor – optional instrument used in the patient's home that receives data from an implanted device via telemetry and transmits that data to the Medtronic CareLink Network.

Mode Switch – feature that switches the device pacing mode from a dual chamber atrial tracking mode to a nontracking mode during an atrial tachyarrhythmia. This feature prevents rapid ventricular pacing that may result from tracking a high atrial rate and restores the programmed pacing mode when the atrial tachyarrhythmia ends.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI SureScan – a feature that permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing.

MVP (Managed Ventricular Pacing) – atrial-based pacing mode that is designed to switch to a dual chamber pacing mode in the presence of AV block. The MVP feature is intended to reduce unnecessary right ventricular pacing by promoting intrinsic conduction. The MVP modes are AAIR<=>DDDR and AAI<=>DDD.

Non-Competitive Atrial Pacing (NCAP) – programmable pacing feature that prohibits atrial pacing within a programmable interval after a refractory atrial event.

oversensing – inappropriate sensing of cardiac events or noncardiac signals. Examples include far-field R-waves, T-waves, myopotentials, and electromagnetic interference.

Paced AV (PAV) interval – programmable delay between an atrial pace and its corresponding scheduled ventricular pace.

pacemaker-mediated tachycardia (PMT) – a rapid, inappropriately paced rhythm that can occur with atrial tracking modes. PMT results when a device senses and tracks retrograde P-waves in the DDD mode or the DDDR mode.

pacing threshold – minimum pacing output that consistently captures the heart.

PMOP (Post Mode Switch Overdrive Pacing) – atrial intervention feature that works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

Pre-arrhythmia EGM storage – programmable option to record EGM from before the onset or detection of a tachyarrhythmia. While this feature is operating, the device records EGM continuously. If a tachyarrhythmia episode occurs, the most recently collected EGM is added to the episode record to document the rhythm at onset.

PVAB (Post-Ventricular Atrial Blanking) – interval after ventricular events during which atrial events are ignored by bradycardia pacing features or are not sensed by the device, depending on the programmed PVAB method.

PVARP (Post Ventricular Atrial Refractory Period) – atrial refractory period following a ventricular event used to prevent inhibition or pacemaker-mediated tachycardias (PMTs) in dual chamber pacing modes.

PVC (premature ventricular contraction) – a sensed ventricular event that directly follows any other ventricular event with no atrial event between them.

PVC Response – feature that extends PVARP following a premature ventricular contraction (PVC) to avoid tracking a retrograde P-wave and to prevent retrograde conduction from inhibiting an atrial pace.

Quick Look II data – overview data summarizing the most important indicators of system operation and the patient's condition, including information about device and lead status, pacing therapy, arrhythmia episodes, and system-defined observations.

Ramp pacing – antitachycardia pacing (ATP) therapy that delivers pacing pulses with progressively shorter pacing intervals per pulse. Each sequence of Ramp pacing that is delivered during a therapy includes an additional pacing pulse.

Rate Adaptive AV (RAAV) – dual chamber pacing feature that varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases to maintain 1:1 tracking and AV synchrony.

Rate Drop Response – feature that monitors the heart for a significant drop in rate and responds by pacing the heart at an elevated rate for a programmed duration.

Rate Drop Response episodes data – feature that displays beat-to-beat data that is useful in analyzing Rate Drop Response episodes and the events leading up to those episodes.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

rate profile – rate histogram of the sensor rates used by Rate Profile optimization to automatically adjust Rate Response settings.

Rate Profile Optimization – feature that monitors the patient's daily and monthly sensor rate profiles and adjusts the rate response curves over time to achieve a prescribed target rate profile.

Rate Response – feature that adjusts the cardiac pacing rate in response to changes in sensed patient activity.

Reactive ATP – feature that allows the device to repeat programmed atrial antitachycardia pacing (ATP) therapies during long AT/AF episodes. Therapies are repeated after a programmed time interval or when the atrial rhythm changes in regularity or cycle length.

refractory period – time interval during which the device senses events normally but classifies them as refractory and responds to them in a limited way.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look II and Battery and Lead Measurements screens. On both screens, this information includes a graphical display for easy reference and the estimated number of years or months of remaining longevity. On the Battery and Lead Measurements screen, the Minimum and Maximum number of years or months of remaining device longevity are also provided.

Resume – programming command that reinstates automatic tachyarrhythmia detection.

retrograde conduction – electrical conduction from the ventricles to the atria.

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.

Sensed AV (SAV) interval – programmable delay following an atrial sensed event that schedules a corresponding ventricular pace.

sensed event – electrical activity across the sensing electrodes that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

Sensing Integrity Counter – diagnostic counter that records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate double-counted R-waves, lead fracture, or a loose setscrew.

sensor rate – the pacing rate determined by the level of patient activity and the programmed rate response parameters; this rate is adjusted between the Upper Sensor Rate and the operating Lower Rate.

Sleep – feature that causes the device to pace at a slower rate during a programmed sleep period.

supraventricular tachycardia (SVT) – a rapid heart rhythm that originates at or above the atrioventricular node.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

undersensing – failure of the device to sense intrinsic cardiac activity.

Ventricular Rate Stabilization (VRS) – ventricular rhythm management feature that adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

Ventricular Safety Pacing (VSP) – pacing therapy feature that prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

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