Medtronic

ADVISA DR MRI™ SURESCAN™ A2DR01, ADVISA SR MRI™ SURESCAN™ A3SR01

MR Conditional digital dual chamber pacemaker with SureScan™ Technology (OAE-DDDR)

MR Conditional digital single chamber pacemaker with SureScan™ Technology (VVIR)

Clinician Manual

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

ADVISA DR MRI™ SURESCAN™ A2DR01, ADVISA SR MRI™ SURESCAN™ A3SR01

Clinician Manual

A guide to the operation and programming of the Model A2DR01 Advisa DR MRI SureScan MRI dual chamber pacemaker (OAE-DDDR), Model A3SR01 Advisa SR MRI SureScan single chamber pacemaker (VVIR)

Contents

1 System overview

1.1 Introduction

1.1.1 About this manual

This manual describes the operation and intended use of the Advisa DR MRI SureScan Model A2DR01 and Advisa SR MRI SureScan Model A3SR01 systems.

Advisa DR MRI SureScan – is a dual chamber implantable pacemaker that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing and atrial tachyarrhythmia therapies.

Advisa SR MRI SureScan – is a single chamber implantable pacemaker that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing therapies.

Unless otherwise noted, all information in this manual applies to the Advisa DR MRI SureScan dual chamber device.

Feature-specific information in this manual that may also apply to the Advisa SR MRI SureScan single chamber device is provided in Section 1.4, "Advisa DR and SR MRI feature model matrix", page 16. In addition, specific single chamber device information is provided in the following locations:

- Section 1.3, "Advisa SR MRI system description", page 14
- Chapter 6, "Advisa SR MRI - Implanting the device", page 87
- Appendix B, "Advisa SR MRI - Quick reference", page 295
- Appendix D, "Advisa SR MRI device parameters", page 315

The following manuals and documents also contain information about the device:

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

Reference manual – This manual contains information about device features. The reference manual applies to multiple models of IPG devices.

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.

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.

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

1.1.1.1 Manual conventions

Throughout this manual, the word “device” refers to the implanted Advisa DR MRI SureScan or Advisa SR MRI SureScan device.

The symbol ◈ in parameter tables indicates the Medtronic nominal value for that parameter.

The programmer screen image examples in this manual were produced using a Medtronic programmer. These screen images are provided for reference only and may not match the final software.

The names of on-screen buttons are shown within brackets: [Button Name].

Programming instructions in this manual are often represented by a programming block, which describes the path through the application software to specific screens or parameters. The following conventions are used in programming blocks:

- The “⇒” symbol precedes the screen text you can select to navigate to a new screen.
- The “▷” symbol precedes the name of a parameter you can program for a feature.
- When a navigation step refers to a field on the screen that is labeled with both a row title and a column title, the “ | ” character is used to divide the separate titles. Parameter values, however, do not use this convention.
- When a particular value for a parameter must be selected to make the remaining parameters or navigation possible, that value appears within <brackets>.

Here is an example of a programming block using these conventions:

Select Params icon
- ⇒ Screen text to select…
  - ⇒ Screen field Row Title | Column Title…
    - ▷ Parameter Name <Required Value>
    - ▷ Parameter Name
    - ▷ Parameter Name

1.1.2 Product literature

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

- Read the product literature provided for information about prescribing, implanting, and using the device, and for 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 provide them with any patient information materials packaged with the device.

1.1.3 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 address or telephone number listed on the back cover.

1.1.4 Customer education

For specific customer education, contact your local Medtronic representative.

1.1.5 Notice

The Patient Information screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the Patient Information screen. Medtronic SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

1.2 Advisa DR MRI system description

The Medtronic Advisa DR MRI SureScan Model A2DR01 dual chamber implantable pacemaker is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing and atrial tachyarrhythmia therapies.

The device senses the electrical activity of the patient's heart using the electrodes of the implanted leads. It then analyzes the heart rhythm based on selectable detection parameters.

The device automatically detects atrial tachyarrhythmias (AT/AF) and provides treatment with antitachycardia pacing therapies. The device monitors the heart rhythm for ventricular tachyarrhythmias and uses detection criteria to distinguish between true ventricular arrhythmias and rapidly conducted supraventricular tachycardia (SVT). The device responds to bradyarrhythmias by providing bradycardia pacing therapy.

The device also provides diagnostic and monitoring information that assists with system evaluation and patient care.

Leads – The lead system used with this device must provide sensing and pacing to the right ventricle (RV) and to the atrium (A). Do not use any lead with this device without first verifying lead and connector compatibility.

For information about selecting and implanting SureScan leads for this device, refer to Section 5.2, "Selecting and implanting the leads", page 78.

Warning: Bipolar or unipolar leads may be used with the Advisa DR MRI SureScan device, but if leads other than bipolar SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

MRI SureScan feature – The pacemaker becomes part of a Medtronic SureScan pacing system when connected to Medtronic SureScan leads and other predefined conditions are met. Labeling for SureScan pacing system components contains the SureScan symbol and the MR Conditional symbol.

SureScan logo

MR Conditional symbol. The Medtronic SureScan pacing system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for important information about procedures and MRI-specific warnings and precautions.**

Rate response – Rate response is controlled through an activity-based sensor.

Implantable device system – The Advisa DR MRI SureScan Model A2DR01 device and the pacing leads constitute the implantable portion of the device system.

Programmer and software – The Medtronic programmer and software are used to program this device. You will need to use the programming head for communications with this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Medtronic analyzer – The system supports the use of the Medtronic analyzer, an accessory of the Medtronic programmer. The system allows you to have a device session and an analyzer session running at the same time, to switch quickly from one to the other without having to end or restart sessions, and to send data from the analyzer to the programmer.

Medtronic patient monitor – Patients use the patient monitor and a home telephone line to transmit information from their implanted device to their physician. Patients collect information from the device by placing a telemetry head over the device. The monitor then transmits the information over the home telephone line to the CareLink Network, where it can be viewed by the clinic. Refer to the monitor literature for connection and usage information.

Transtelephonic monitor – Patients may use a transtelephonic monitor to transmit ECG information from the implanted device to their physician over a home telephone line. During a transtelephonic session, the patient places a magnet over the device to initiate magnet mode operation, which temporarily provides asynchronous pacing at a fixed rate. At the end of the session, the patient removes the magnet to restore operation of the pacemaker to its permanent status. Refer to the monitor literature for connection and usage information.

Model 2696 InCheck Patient Assistant – Patients can use the Model 2696 InCheck Patient Assistant to perform the following tasks:

- Initiate recording of cardiac event data in the device memory. Cardiac event data can be viewed either on the programmer or using CareLink. In addition, when the InCheck Patient Assistant is activated, the EGM signals of the programmed EGM sources and markers are stored in the device and are available for review using CareLink. The Medtronic patient monitor transmits the EGM data and markers from the patient's device to the CareLink Network. You can identify patients who have new, not previously viewed patient-activated episodes and then proceed to view their EGM data using the Detailed EGM Viewer on CareLink.
- Verify whether the implanted device has detected a suspected atrial tachyarrhythmia.

Contents of sterile package – The package contains one implantable pacemaker and one torque wrench.

1.3 Advisa SR MRI system description

The Medtronic Advisa SR MRI SureScan Model A3SR01 single chamber implantable pacemaker is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single chamber rate-responsive bradycardia pacing and tachyarrhythmia monitoring.

The device senses the electrical activity of the patient's heart using the electrodes of the implanted lead. It then analyzes the heart rhythm based on selectable detection parameters.

The device monitors the heart rhythm for ventricular tachyarrhythmias. The device responds to bradyarrhythmias by providing bradycardia pacing therapy.

The device also provides diagnostic and monitoring information that assists with system evaluation and patient care.

Lead – The lead system used with this device must provide sensing and pacing to the right ventricle (RV). Do not use any lead with this device without first verifying lead and connector compatibility.

For information about selecting and implanting SureScan leads for this device, refer to Section 6.2, "Selecting and implanting the lead", page 90.

Warning: A bipolar or unipolar lead may be used with the Advisa SR MRI SureScan device, but if a lead other than a bipolar MRI SureScan lead is used, the system is contraindicated for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

MRI SureScan feature – The pacemaker becomes part of a Medtronic SureScan pacing system when connected to a Medtronic SureScan lead and other predefined conditions are

met. Labeling for SureScan pacing system components contains the SureScan symbol and the MR Conditional symbol.

SureScan logo

MR Conditional symbol. The Medtronic SureScan pacing system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. **Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for important information about procedures and MRI-specific warnings and precautions.**

Rate response – Rate response is controlled through an activity-based sensor.

Implantable device system – The Advisa SR MRI SureScan device and the pacing lead constitute the implantable portion of the device system.

Programmer and software – The Medtronic programmer and software are used to program this device. You will need to use the programming head for communications with this device. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Medtronic analyzer – The system supports the use of the Medtronic analyzer, an accessory of the Medtronic programmer. The system allows you to have a device session and an analyzer session running at the same time, to switch quickly from one to the other without having to end or restart sessions, and to send data from the analyzer to the programmer.

Medtronic patient monitor – Patients use the patient monitor and a home telephone line to transmit information from their implanted device to their physician. Patients collect information from the device by placing a telemetry head over the device. The monitor then transmits the information over the home telephone line to the CareLink Network, where it can be viewed by the clinic. Refer to the monitor literature for connection and usage information.

Transtelephonic monitor – Patients may use a transtelephonic monitor to transmit ECG information from the implanted device to their physician over a home telephone line. During a transtelephonic session, the patient places a magnet over the device to initiate magnet mode operation, which temporarily provides asynchronous pacing at a fixed rate. At the end of the session, the patient removes the magnet to restore operation of the pacemaker to its permanent status. Refer to the monitor literature for connection and usage information.

Model 2696 InCheck Patient Assistant – Patients can use the Model 2696 InCheck Patient Assistant to perform the following tasks:

- Initiate recording of cardiac event data in the device memory. Cardiac event data can be viewed either on the programmer or using CareLink. In addition, when the InCheck Patient Assistant is activated, the EGM signals of the programmed EGM sources and markers are stored in the device and are available for review using CareLink. The Medtronic patient monitor transmits the EGM data and markers from the patient's device to the CareLink Network. You can identify patients who have new, not previously viewed patient-activated episodes and then proceed to view their EGM data using the Detailed EGM Viewer on CareLink.

Contents of sterile package – The package contains one implantable pacemaker and one torque wrench.

1.4 Advisa DR and SR MRI feature model matrix

Feature availability for each device model is marked with an "X" in the corresponding column.

Table 1. Product feature relationship

	Advisa DR MRI	Advisa SR MRI
Features	**A2DR01**	**A3SR01**
AT/AF Burden Observations	X	—
AT/AF Detection	X	—
AT/AF Monitor	X	—
Atrial 50 Hz Burst In-Office	X	—
Atrial ATP	X	—
Atrial Capture Management (ACM)	X	—
Atrial Preference Pacing	X	—
Atrial Rate Stabilization	X	—
Auto PVARP	X	—
Cardiac Compass	X	X
Conducted AF Response	X	X
EGM Pre-Storage Control	X	X
Extended Upper Rates	X	X (sensor)
Flashback - Atrial Episodes	X	—
Flashback - Ventricular Episodes	X	X
Heart Failure Management report	X	—
Longevity Estimator	X	X
Managed Ventricular Pacing (MVP)	X	—

Table 1. Product feature relationship (continued)

	Advisa DR MRI	Advisa SR MRI
Features	**A2DR01**	**A3SR01**
Mode Switch	X	—
Model 2696 InCheck Patient Assistant support	X	X
MRI SureScan Interface	X	X
Non-Competitive Atrial Pacing	X	—
Pacemaker-Mediated Tachycardia	X	—
Post-Mode Switch Overdrive Pacing	X	—
PVC Response	X	—
Rate Adaptive AV	X	—
Rate Drop Response	X	—
Rate Histograms report	X	X
Rate Hysteresis	X	X
Rate Profile Optimization	X	X
Reactive ATP	X	—
Sleep	X	X
TherapyGuide	X	—
Ventricular Capture Management (VCM)	X	X
Ventricular Rate Stabilization	X	X
Ventricular Safety Pacing	X	—
VT Monitor	X	X

1.5 Indications and usage

Advisa DR and SR MRI systems are indicated for the following:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity
- Accepted patient conditions warranting chronic cardiac pacing include:
  - Symptomatic paroxysmal or permanent second- or third-degree AV block
  - Symptomatic bilateral bundle branch block
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The Advisa DR MRI device is also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm
- Vasovagal syndromes or hypersensitive carotid sinus syndromes

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

1.6 Contraindications

The Advisa DR and SR MRI systems are contraindicated for:

- Concomitant implant with another bradycardia device
- Concomitant implant with an implantable cardioverter defibrillator

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician.

- Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate.
- Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter.
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance.
- ATP therapy is contraindicated in patients with an accessory antegrade pathway.

1.7 MRI conditions for use

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan pacing system.

The following symbol is related to the magnetic resonance (MR) environment and is used to indicate the safety of devices and components in the MR environment.

MR Conditional symbol. The Medtronic SureScan pacing system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

Cautions:

- Instruct the patient not to take the Patient Assistant (handheld activator) into Zone 4 (magnet room), as defined by the American College of Radiology. Doing so could damage the Patient Assistant or the MR scanner. The Patient Assistant is MR Unsafe.
- Instruct the patient not to take the Medtronic CareLink Home Monitor into Zone 4 (magnet room). The Medtronic CareLink Home Monitor is MR Unsafe.
- Do not bring the Medtronic programmer into Zone 4 (magnet room). The Medtronic programmer is MR Unsafe.

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads. To verify that components are part of a SureScan pacing system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Cardiology requirements:

- Patients and their implanted systems must be screened to meet the following requirements:
  - The patient has no lead extenders, lead adaptors or abandoned leads.
  - The patient has no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history.
  - The SureScan pacing system is implanted in the left or right pectoral region.
  - The pace polarity parameters are set to Bipolar for programming the MRI SureScan mode to On.
  - The lead impedance value is ≥ 200 ohms (Ω) and ≤ 1500 Ω.
  - The SureScan device is operating within the projected service life.
  - For patients whose device will be programmed to an asynchronous pacing mode when the MRI SureScan mode is programmed to On, no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms.

Caution: It is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms for pacemaker-dependent patients. A higher pacing capture threshold may indicate an issue with the implanted lead.

Note: Before performing a MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

Training requirements:

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

Patient monitoring requirements

- Continuous patient monitoring is required during the MRI scan
- In the event that patient rescue is required, an external defibrillator must be immediately available.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for MRI-specific warnings and precautions.

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Electrical isolation during implant – Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever tachyarrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.

Lead compatibility – Although Medtronic device connector modules conform to international Connector Standards, this device has not been tested for use with non-Medtronic leads. The known potential adverse consequences of using such a combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

A complete SureScan pacing system includes a SureScan device connected to SureScan leads. **Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.**

2.2 Explant and disposal

Consider the following information related to device explant and disposal:

- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

2.3 Handling and storage instructions

Carefully observe these guidelines when handling or storing the device.

2.3.1 Device handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This product is for single use only and is not intended to be resterilized.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

Fluid immersion – Do not immerse the device in fluid or flush the connector ports at the time of implant. Doing so could adversely affect the performance of the device and lead system.

“Use by” date – Do not implant the device after the “Use by” date because the battery longevity could be reduced.

Single use – This product is intended for single use only. Do not resterilize and re-implant the explanted product.

2.3.2 Device storage

Avoid magnets – To avoid damaging the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Temperature limits – Store and transport the package between –18°C and +55°C (0°F and 131°F). Electrical reset may occur at temperatures below –18°C (0°F). Device longevity may decrease and performance may be affected at temperatures above +55°C (131°F).

2.4 Lead evaluation and lead connection

Refer to the lead technical manuals for specific instructions and precautions about lead handling.

A Medtronic MRI SureScan system includes a SureScan device connected to SureScan leads. **Before performing an MRI procedure, refer to the Medtronic MRI Technical Manual for additional information.**

Torque wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches (for example, a blue-handled or right-angled hex wrench) have torque capabilities greater than the lead connector can tolerate.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Plug any unused lead ports to protect the device.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

2.5 Device operation

Warning: Bipolar or unipolar leads may be used with the Advisa MRI SureScan device, but if leads other than bipolar SureScan leads are used, the system is contraindicated for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Atrial Capture Management – Atrial Capture Management feature does not adjust atrial outputs to values greater than 5.0 V or 1.0 ms. If the patient needs atrial pacing output greater

than 5.0 V or 1.0 ms, manually program the atrial amplitude and the pulse width. If a lead dislodges partially or completely, Atrial Capture Management feature may not prevent loss of capture.

Atrial lead maturation – Do not program AT/AF Detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately one 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.

Device status indicators – If any of the device status indicators (for example, Electrical Reset) are displayed on the programmer after interrogating the device, inform a Medtronic representative immediately. If these device status indicators are displayed, therapies may not be available to the patient.

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.

Electrical reset – Electrical reset can be caused by exposure to temperatures below –18°C (0°F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial reset occurs, pacing resumes in the programmed mode with many of the programmed settings retained. If a full reset occurs, the device operates in VVI mode at 65 bpm. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

End of Service (EOS) indicator – Replace the device immediately if the programmer displays an EOS indicator. The device may soon lose the ability to pace, sense, and deliver therapy adequately.

Extended Upper Tracking Rate – When programming Upper Tracking Rates of 190, 200, or 210 bpm, be careful to ensure that these rates are appropriate for the patient.

False bipolar pathway with unipolar lead – When implanting a unipolar lead, ensure that the tip setscrew is properly engaged and that all electrical contacts are sealed to prevent electrical leakage. Electrical leakage may cause the device to inappropriately identify a unipolar lead as bipolar, resulting in loss of output.

Magnets – Placing a magnet over the device suspends tachyarrhythmia detection and initiates asynchronous, fixed-rate bradycardia pacing. The programming head contains a magnet that can cause magnet operation to occur. However, magnet operation does not occur if telemetry between the device and the programmer is established or if the MRI SureScan mode is programmed to On.

Pace polarity – Pace polarity must be bipolar to program the MRI SureScan mode to On.

PMT (pacemaker-mediated tachycardia) Intervention – Even with the PMT Intervention feature programmed to On, PMTs may still require clinical intervention, such as device reprogramming, drug therapy, or lead evaluation.

Pacing and sensing safety margins – Lead maturation (at least one month after implant) may cause sensing amplitudes to decrease and pacing thresholds to increase, which can cause undersensing or a loss of capture. Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Programmers – Use only Medtronic programmers and application software to communicate with the device. Programmers and software from other manufacturers are not compatible with Medtronic devices.

Rate control – Decisions regarding rate control should not be based on the ability of the device to prevent atrial arrhythmias.

Rate-responsive modes – Do not program rate-responsive modes for patients who cannot tolerate rates above the programmed Lower Rate. Rate-responsive modes may cause discomfort for those patients.

RV Capture Management – The RV Capture Management feature does not program right ventricular outputs to values greater than 5.0 V or 1.0 ms. If the patient needs right ventricular pacing output greater than 5.0 V or 1.0 ms, manually program right ventricular amplitude and pulse width. If a lead dislodges partially or completely, the RV Capture Management feature may not prevent loss of capture.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

Single chamber atrial modes – Do not program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing does not occur in these modes.

Slow retrograde conduction and PMT – Slow retrograde conduction may induce pacemaker-mediated tachycardia (PMT) when the VA conduction time is greater than 400 ms. Programming PMT Intervention can help prevent PMT only when the VA conduction time is less than 400 ms.

Testing for cross-stimulation – At implant, and regularly when atrial ATP therapy is enabled, conduct testing at the programmed atrial ATP output settings to ensure that

ventricular capture does not occur. Testing for cross-stimulation is particularly important when the lead is placed in the inferior atrium.

2.5.1 Pacemaker-dependent patients

Ventricular Safety Pacing – Always program Ventricular Safety Pacing (VSP) to On for pacemaker-dependent patients. Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing in the ventricle.

ODO and OVO pacing modes – Pacing is disabled under ODO or OVO pacing modes. Do not program the ODO or OVO mode for pacemaker-dependent patients. Instead, use the Underlying Rhythm Test to provide a brief period without pacing support.

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.

Underlying Rhythm Test – Use caution when using the Underlying Rhythm Test to inhibit pacing. The patient is without pacing support when pacing is inhibited.

2.6 Potential adverse events

The following are known potential adverse events associated with the use of pacing systems:

- acceleration of tachyarrhythmias (caused by device)
- air embolism
- bleeding
- body rejection phenomena including local tissue reaction
- cardiac dissection
- cardiac perforation
- cardiac tamponade
- chronic nerve damage
- death
- endocarditis
- erosion
- erosion through the skin
- excessive fibrotic tissue growth
- extrusion
- fibrillation or other arrhythmias
- fluid accumulation
- formation of hematomas or cysts
- heart block
- heart wall or vein wall rupture
- hematoma/seroma
- infection
- keloid formation
- lead abrasion and discontinuity
- lead migration/dislodgment
- muscle stimulation, nerve stimulation, or both
- myocardial damage
- myocardial irritability
- myopotential sensing

- pericardial effusion
- pneumothorax
- threshold elevation
- thrombolytic and air embolism
- tissue damage due to heating of device or lead (during an MRI procedure)
- valve damage
- venous or cardiac perforation
- pericardial rub
- rejection phenomena (local tissue reaction, fibrotic tissue formation, device migration)
- thromboemboli
- thrombosis
- transvenous lead-related thrombosis
- venous occlusion

3 Clinical data

3.1 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals.

The following clinical studies are related to this device:

Advisa DR MRI system study – This clinical study, which evaluated the safety and efficacy of the Advisa DR MRI SureScan pacing system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature. This study supports removal of the C1-T12 positioning restriction, so that any region of the body can be scanned when the MR Conditions for Use are followed.

Atrial Capture Management (ACM) study – This clinical study, which evaluated the Atrial Capture Management feature in EnPulse pacemakers, provides support for the Atrial Capture Management feature in Advisa DR MRI SureScan Model A2DR01 devices.

Atrial Fibrillation Symptoms Mediated by Pacing to Mean Rates (AF SYMPTOMS) – This study evaluated the long-term effects of Conducted AF Response in patients with atrial fibrillation and intact atrioventricular (AV) conduction. It provides support for the Conducted AF Response feature in Advisa DR MRI SureScan Model A2DR01 and Advisa SR MRI SureScan Model A3SR01 devices. Note that the Ventricular Response Pacing (VRP) feature mentioned in the study is called Conducted AF Response in the Advisa DR MRI SureScan Model A2DR01 and Advisa SR MRI SureScan Model A3SR01 devices

Atrial Septal Pacing Efficacy Trial (ASPECT) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the atrial intervention pacing therapies.

Atrial Therapy Efficacy and Safety Trial (ATTEST) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the Advisa DR MRI SureScan Model A2DR01 devices.

EnRhythm clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm Model P1501DR devices, provides support for MVP mode pacing and the Reactive ATP feature in the Advisa DR MRI SureScan Model A2DR01 devices.

GEM III DR Model 7275 MVP study – This clinical study, which evaluated the performance of MVP mode pacing in the GEM III DR Model 7275 devices, provides support for MVP mode in the Advisa DR MRI SureScan Model A2DR01 devices.

Kappa 700 clinical study – This study, which evaluated the safety and clinical performance of the Kappa 700 pacemakers, provides support for the Right Ventricular Capture Management feature and other bradycardia pacing features.

Marquis MVP download study – This clinical study, which evaluated the performance of MVP mode pacing in the Marquis DR Model 7274 devices, provides support for MVP mode in the Advisa DR MRI SureScan Model A2DR01 devices.

Reducing Episodes by Septal Pacing Efficacy Confirmation Trial (RESPECT) – This clinical study evaluated the efficacy of the intervention pacing therapies on symptomatic AT/AF episodes in subjects where the lead was placed in the Bachmann's Bundle region. The results of the study failed to demonstrate effectiveness of the intervention pacing therapies. Evaluation of the RESPECT study data indicated that the intervention pacing features did not significantly reduce the rate of symptomatic AT/AF episodes and these results did not confirm the findings from previous trials. The pre-specified subgroups were tested for therapeutic effect, but none had results suggesting benefit. When intervention pacing algorithms were programmed ON, atrial pacing percentage increased by 18.1% ($P<0.001$) with a modest, yet statistically significant, increase in mean heart rate of 2.4 beats per minute ($P<0.001$).

Revo MRI SureScan pacing system clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm MRI SureScan pacing system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature. This study was conducted with the C1 – T12 MRI scan exclusion zone in place.

SureScan Pacing System Post-Approval Study – This clinical study, which evaluated safety and performance of approved systems in a magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature.

4 Using the programmer

4.1 Establishing telemetry between the device and the programmer

You can establish telemetry between the device and the programmer by using a Medtronic programming head. You can also establish telemetry by using a Medtronic CareLink Programmer with Conexus telemetry in the nonwireless telemetry mode. Refer to the programmer reference guide for information about setting up the programmer for a patient session.

4.1.1 How to establish telemetry between the device and the programmer

Place the programming head over the device to establish telemetry between the programmer and the device. Successful interrogation or programming of the device verifies that reliable communication between the device and the programmer has occurred.

Note: The programming head contains a magnet that can suspend tachyarrhythmia detection. When telemetry between the device and programmer is established, detection is not suspended.

When the programming head is placed over the device and telemetry is established, the amber light on the programming head turns off, and 1 or more of the green indicator lights on the programming head illuminate. You can find the optimal position for the programming head by moving it around the implanted device until the greatest number of green lights illuminate. Position the programming head so at least 2 of the green lights illuminate in order to ensure reliable telemetry has been established. If the programming head slides off the patient, the session does not terminate. Place the programming head back over the device to resume programming or interrogating the device.

Note: More information about the general use of the programming head is available in the programmer reference guide.

4.1.2 How to maintain reliable telemetry

You can expect reliable telemetry between the implanted device and the programmer in a typical examination room or operating room. If you are having trouble maintaining consistent, reliable telemetry between a patient's implanted device and the programmer, remove any sources of electromagnetic interference (EMI) that may be affecting the telemetry signal, and position the programming head so that at least 2 of the green lights on the programming head are illuminated.

Note: If programming is disrupted by EMI or loss of telemetry, you must reestablish telemetry and program the device again.

4.2 Conducting a patient session

The programmer interrogates the patient's device at the start of a patient session. Because the programmer collects and stores data on a session-by-session basis, you need to start a new session for each patient. You must end the previous session before starting a session with another patient.

4.2.1 Starting a patient session

Caution: A programmer failure (for example, a faulty touch pen) could result in inappropriate programming or the inability to terminate an action or an activity in process. In the event of a programmer failure, immediately turn the programmer power off to deactivate telemetry and terminate any programmer controlled activity in process.

Note: During an initial interrogation, only Emergency programmer functions are available.

4.2.1.1 How to start a patient session

1. Turn the programmer power on.
2. Place the programming head over the device and establish telemetry.
3. Press the "I" button on the programming head, or select [Find Patient…].

4.2.2 Device and telemetry effects during a patient session

Tachyarrhythmia detection during a session – Placing a magnet over the device suspends tachyarrhythmia detection and initiates asynchronous, fixed-rate bradycardia pacing. The programming head contains a magnet that can cause magnet operation to occur. However, magnet operation does not occur if telemetry between the device and programmer is established.

Marker transmissions during a session – The device continuously transmits Marker Channel and supplementary marker data while telemetry is established and the programming head is positioned over the device. The device stops these transmissions when you lift the programming head, unless the Holter Telemetry feature is programmed to On. If Holter Telemetry is programmed to On, the device transmits Marker Channel and supplementary marker data regardless of the position of the programming head.

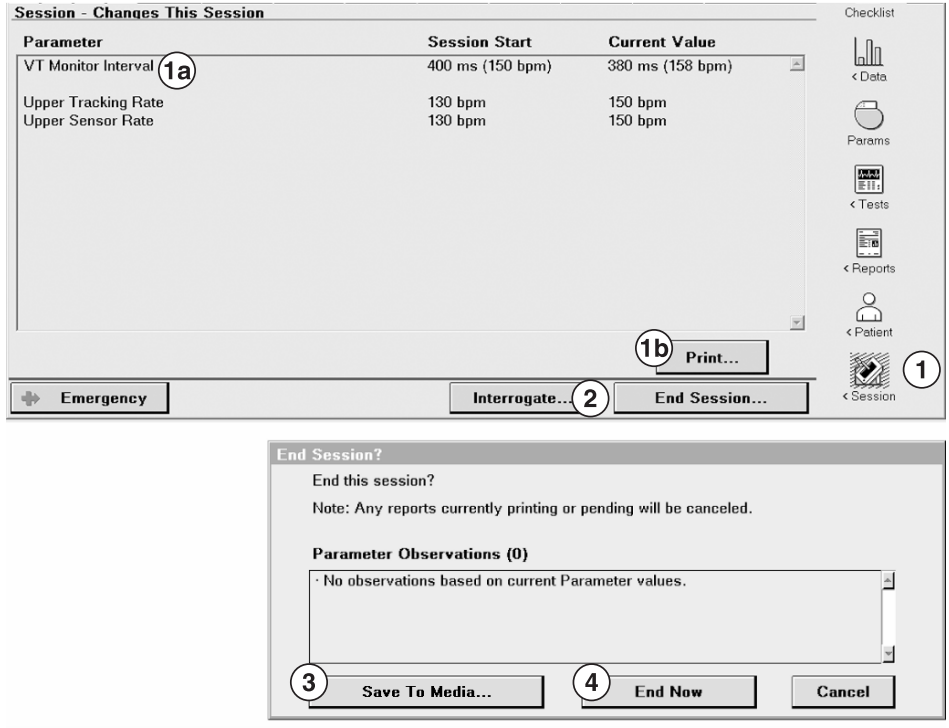
4.2.3 How to interrogate the device during the session

At the start of the patient session the programmer interrogates the device. You can manually interrogate the device at any time during the patient session by performing the following steps:

1. Select [Interrogate…] from the Command bar. You may also interrogate the device by pressing the “I” button on the programming head.
2. To gather information collected since the last patient session, select the Since last session option from the interrogation window. If you want to gather all of the information from the device, select the All option.
3. Select [Start].

4.2.4 Ending a patient session

4.2.4.1 How to end a patient session



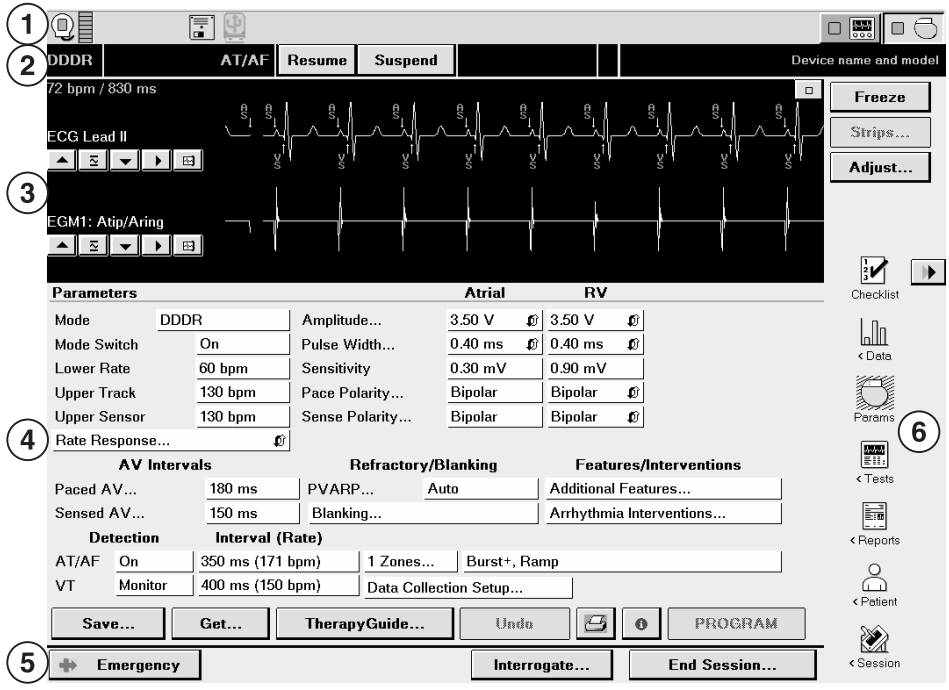
1. To review or print a list of changes made during this session, select Session > Changes This Session.
   a. Review the programming changes made during the patient session.
   b. To print a record of the changes, select [Print…].
2. Select [End Session…].
3. To save the session data to a USB flash drive or a disk, select [Save To Media…].
4. To end the session and return to the Select Model screen, select [End Now].

4.3 Display screen features

The programmer display screen is an interface that displays text and graphics. It is also a control panel that displays buttons and menu options that you can select by using the touch pen.

The main elements of a typical display screen during a patient session are shown in Figure 1.

Figure 1. Main elements of a display screen



1 Task bar
2 Status bar
3 Live Rhythm Monitor window
4 Task area
5 Command bar
6 Tool palette

4.3.1 Task bar

The display screen features a task bar at the very top of the screen. You can use the task bar to note the status of programmer-specific features such as the Analyzer.

The task bar also includes a graphical representation of the telemetry strength light array on the programming head.

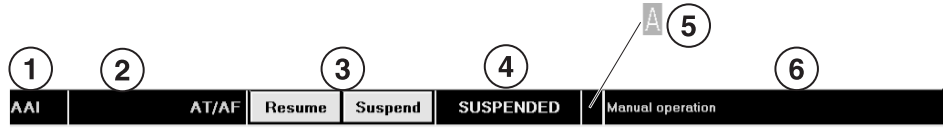
Figure 2. Task bar display

1 Telemetry icon and telemetry strength indicator
2 Diskette indicator
3 USB indicator
4 Analyzer icon
5 Device icon

4.3.2 Status bar

When the device has been interrogated, you can use the status bar at the top of the display screen (located immediately below the task bar) to perform some basic functions and to note the current status of the device.

Figure 3. Status bar display



1 Currently active pacing mode
2 Programmed detection and therapy configuration
3 Buttons used to resume or suspend detection
4 Automatic detection status
5 Indicator that an episode is in progress if AT/AF Detection is On
6 Either the current implant detection, episode, therapy, or manual operation status, or the device name and model number

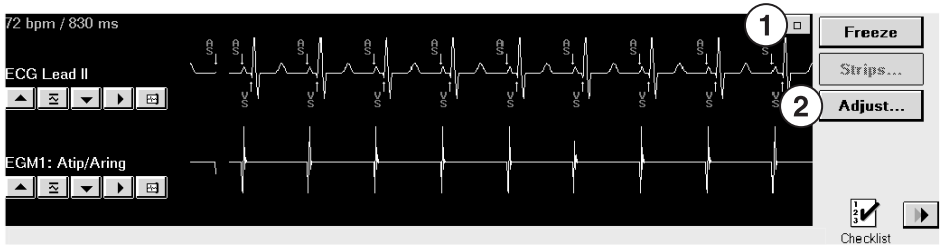
4.3.3 Live Rhythm Monitor window

The Live Rhythm Monitor window displays ECG, Marker Channel, Marker Intervals, and telemetered EGM waveform traces. In addition to waveform traces, the Live Rhythm Monitor shows the following information:

- Heart rate and rate interval are displayed if telemetry has been established with the device.
- The annotations above the waveform trace show the point at which parameters are programmed.

The Live Rhythm Monitor appears in the partial view by default, as shown in Figure 4. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window or by selecting the [Adjust…] button. For more information about the Live Rhythm Monitor, see Section 4.10, “Working with the Live Rhythm Monitor”, page 54.

Figure 4. Live Rhythm Monitor window



1 The location of the square button
2 The location of the [Adjust…] button

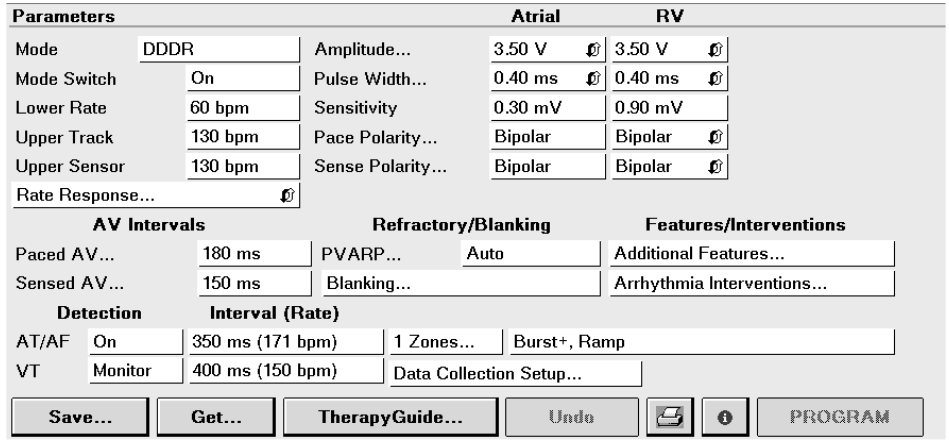
4.3.4 Task area

The portion of the screen between the Live Rhythm Monitor window near the top of the screen and the command bar at the bottom of the screen changes according to the task or function you select.

One example of a task area is the Parameters screen, which is used to view and program device parameters as described in Section 4.6, “Viewing and programming device parameters”, page 41.

Task areas display differently when you perform other functions such as diagnostics and system tests.

Figure 5. Task area of the screen



4.3.5 Tool palette

The buttons and icons along the right edge of the screen are referred to as the “tool palette”. You can use these tools to display a task or function screen. After starting a patient session, the tool palette is displayed on all but the Emergency or Live Rhythm Monitor Adjust… screens, making it quick and easy to move to the desired task or function.

Each of the icons acts like a button. To select an icon, touch the icon with the touch pen. Each option in the tool palette is described in Table 2.

Table 2. Tool palette options

	The [Freeze] button captures a segment of the Live Rhythm Monitor display.
	The [Strips…] button accesses the waveform strips saved since the start of the session.
	The [Adjust…] button opens a window of options for adjusting the Live Rhythm Monitor display.
	The Checklist icon opens the Checklist screen for simplified navigation through a set of follow-up tasks. The Checklist [>>] button navigates to the next task in the Checklist.
	The Data icon displays options for viewing device information and diagnostic data.

Table 2. Tool palette options (continued)

	The Params icon displays the Parameters screen for viewing and programming device parameters.
	The Tests icon displays options for performing system tests and EP studies.
	The Reports icon displays options for printing reports.
	The Patient icon displays options for accessing the TherapyGuide screen or the Patient Information screen.
	The Session icon displays options for adjusting preferences, viewing parameter changes made during the session, saving data, and ending the session.

4.3.6 Buttons

Buttons, such as those shown in Figure 6, respond when you "select" them by touching them with the tip of the touch pen.

Figure 6. Display screen buttons

Buttons with a less distinctly shaded label are inactive and do not respond if you select them.

Selecting a button with the touch pen causes one of the following responses:

- Buttons such as the [PROGRAM] button execute a command directly.
- Buttons such as the [Save…] and [Get…] buttons open a window that prompts another action. The labels on these buttons end with an ellipsis.

A procedure may instruct you to "press and hold" a button. In such cases, touch the tip of the touch pen to the button and continue to maintain pressure against the button. The button continues to respond to the touch pen until you remove the touch pen from the button.

4.3.7 Command bar

The bar at the bottom of the screen always shows the buttons for programming Emergency parameters, interrogating the device, and ending the patient session.

Note: The [Interrogate…] and [End Session…] buttons do not appear on the Emergency screen.

Figure 7. Command bar

4.4 Enabling emergency VVI pacing

You can use emergency VVI pacing to quickly enable 70 bpm, high-output ventricular unipolar pacing to restore ventricular support in an emergency situation.

4.4.1 Considerations for emergency VVI pacing

Parameter values – Emergency VVI pacing reprograms pacing parameters to emergency settings. For a list of the emergency VVI parameter settings, see Section C.1 for the dual chamber MRI device or see Section D.1 for the single chamber MRI device. To terminate emergency VVI pacing, you must reprogram pacing parameters from the Parameters screen.

4.4.2 How to enable emergency VVI pacing

1. During a patient session, establish telemetry with the device.
2. Press the red mechanical emergency VVI button on the programmer. Emergency VVI pacing is enabled, and the programmer displays the Emergency screen.

Note: You can also enable emergency VVI pacing by selecting the on-screen [Emergency] button. Emergency VVI pacing is enabled, and the programmer displays the Emergency screen.

Note: MRI SureScan operation is disabled when emergency VVI pacing is programmed.

4.5 Streamlining implant and follow-up sessions with Checklist

Use the Checklist feature to cycle through common tasks that are performed during an implant session or a follow-up session. When you select a task, the associated programmer screen for that task appears. Once you complete a task, you can either go back to the Checklist or continue on to the screen associated with the next task. You can use the standard checklists created by Medtronic, or you can create customized checklists that reflect your personal workflow.

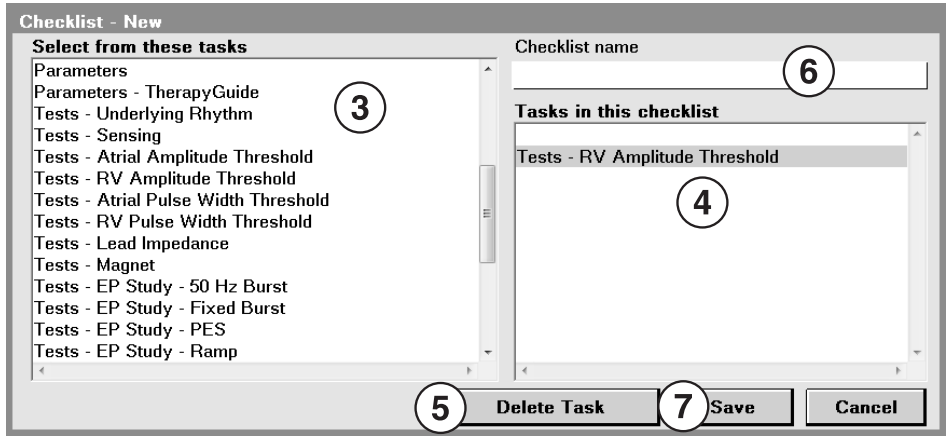
4.5.1 How to use a standard checklist

1. Select the Checklist icon on the right side of the programmer screen. Two standard checklists are available: the Medtronic Standard Followup checklist and the Medtronic Standard Implant checklist.
2. Select the checklist you want from the Checklist field.
3. Select either the [>>] button next to the Checklist icon or the [Go To Task] button to start using the checklist.
4. Use the [>>] button to continue from one task to the next. Any time you want to return to the Task list, select the Checklist icon.
5. To repeat a task or perform a task out of order, select the task and use the [Go To Task] button or the [>>] button.

Once you have completed all the tasks on the Task list, [>>] and [Go To Task] become inactive. However, you can still select a task and use either button to complete the task. You can also use [>>] to advance through the tasks on the list.

Check marks appear next to the names of any programmer screens that were visited during a session.

4.5.2 How to create and edit a custom checklist



1. Select the Checklist icon.
2. Select [New…] from the Checklist screen.
3. Choose the tasks you want in your customized checklist from the box on the left.
4. The tasks you select appear in the box on the right. You can add the same task more than once. If you want a new task to appear somewhere else in the list rather than at the end, highlight the task that the new task should follow, and select the new task. The new task appears below the highlighted task.
5. To delete a task, highlight the task in the Tasks in this checklist box and select [Delete Task].
6. To name your checklist, select the Checklist name field, and enter a name.
7. Select [Save].

To edit a custom checklist, select the checklist in the Checklist field and select [Edit…]. Add or delete tasks as needed. Then select [Save].

To rename a custom checklist, select the checklist in the Checklist field and select [Edit…]. Change the name and select [Save].

To delete a custom checklist, select the checklist from the Checklist field and select [Delete]. After a custom checklist has been deleted, it cannot be restored. The Medtronic Standard Followup checklist and the Medtronic Standard Implant checklist cannot be edited or deleted.

4.6 Viewing and programming device parameters

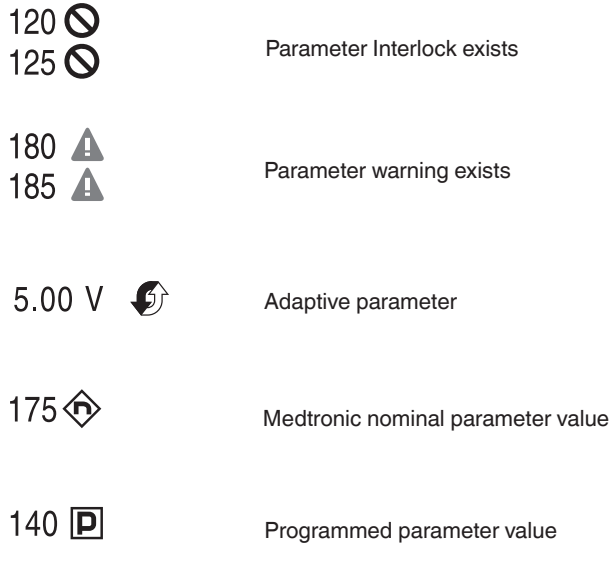
The Parameters screen is used for viewing and programming parameters that control device functions and data collection. All device parameters that you can view and program appear as “active fields” in the task area. Active fields, which appear as unshaded boxes next to parameter names, respond to the touch pen. Some active fields pertain to only 1 parameter, while other fields provide access to groups of parameters. If a parameter cannot be programmed, no active field appears next to its name. All permanent parameter changes can be programmed at the Parameters screen.

After you select new values for parameters, the new values are designated as pending values. A field containing a pending value has a dashed rectangle as its border. Values remain pending until they are programmed to device memory.

4.6.1 Understanding the symbols used on the Parameters screen

Certain combinations of parameter values are restricted because they are invalid or result in undesirable interactions. The programmer recognizes these combinations and may not allow programming until all parameter conflicts are resolved and all parameter selection requirements are met. A symbol that provides the status of a parameter value appears next to the value in the selection window. The following symbols can appear next to a parameter value.

Figure 8. Symbols that appear with parameter values



Parameter interlock exists – When an interlock symbol appears next to a parameter value, it indicates that the parameter value conflicts with the setting of another present or pending value. Select another value or resolve the conflicting parameter value before programming the parameter.

Parameter warning exists – When an exclamation point enclosed in a triangle appears next to a parameter value, a warning message is available regarding that value. The message can be viewed either by selecting the message button or by reselecting that parameter. In the latter case, the warning is displayed as a warning note in the selection window. These parameter values can be programmed.

Adaptive parameter – When the adaptive symbol appears next to a parameter value on the Parameters screen, it indicates that the programmed value can be changed automatically by the device. The symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value, only that it is able to be adapted.

Medtronic nominal parameter value – When the “n” symbol appears next to a parameter value, it indicates that the value is the Medtronic nominal value.

Programmed parameter value – When the “P” symbol appears next to a parameter value, it indicates that the value is the programmed value.

The programmer may display a message button next to the [PROGRAM] button that, when selected, provides access to additional information about the pending parameters. The message button has one of the symbols described in Table 3. When the message button is selected, the programmer opens a second window displaying one or more messages.

Table 3. Symbols that appear on the message button

Symbol	Explanation
	Parameter interlock message
	Parameter warning message
	Parameter informational message

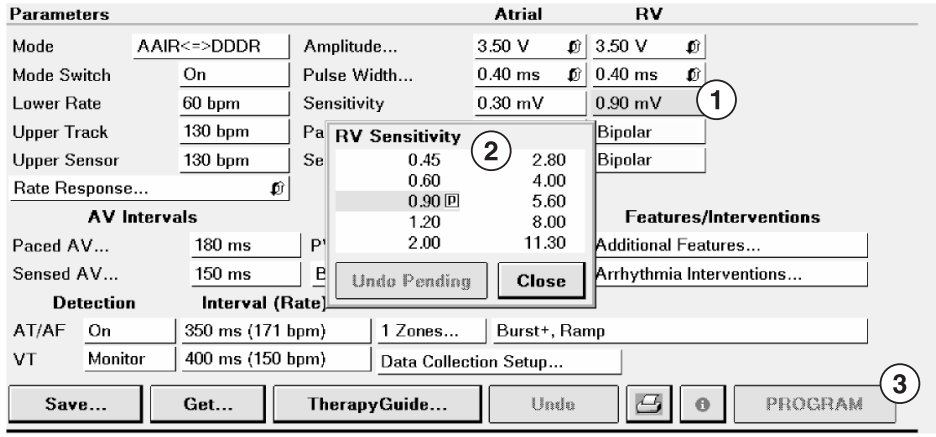
Parameter interlock message – This button indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Select this button for a message that describes the conflict.

Parameter warning message – This button indicates that there is a warning associated with programming one or more of the pending parameter values. Select this button to view the warning message and recommendations.

Parameter informational message – This button indicates that there is an informational message regarding one or more of the parameter values. Select this button to view the message.

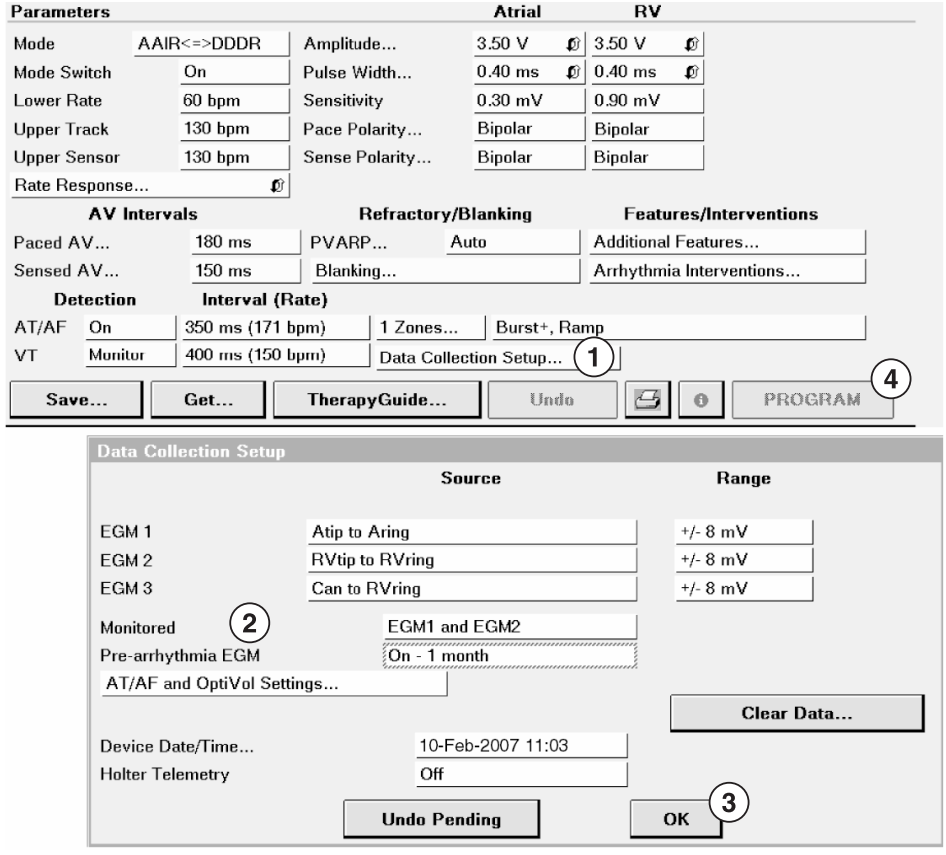
If there are multiple messages regarding the pending parameter values, the most significant message determines the symbol that appears on the button.

4.6.2 How to access parameters



1. Select a parameter field. If there are only 2 values, such as Off and On, the parameter field typically switches to the alternate value. If there are more than 2 values, a window opens showing available values for that parameter.
2. Select a new value from this window. This new value displays as a pending value, and the window showing available values for that parameter closes. You can also select [Close] to close the window without changing the original value of the parameter.
3. Select [PROGRAM] to program the new value to the device memory.

4.6.3 How to access a group of related parameters



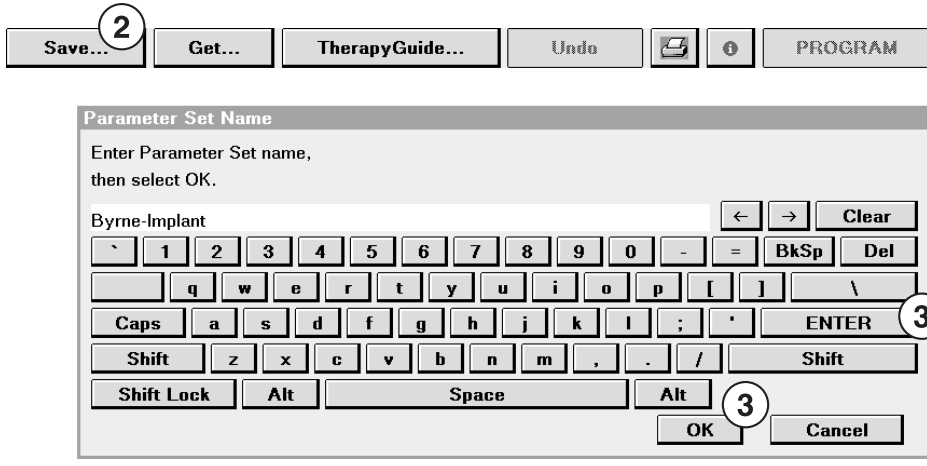
1. Select a parameter or a parameter field that ends with an ellipsis or a parameter field that contains a list of parameter names. A screen appears that displays related secondary parameter fields. In the example shown, Data Collection Setup… was chosen.
2. Select new values for the desired secondary parameters. New values are displayed as pending values.
3. Select [OK] to close the secondary parameters screen and return to the Parameters screen.
4. Select [PROGRAM] to program the new values to device memory.

4.7 Saving and retrieving a set of parameter values

Custom sets of parameter values can be saved on the programmer hard drive and retrieved either in the current patient session or in subsequent patient sessions. This flexibility allows you to save and quickly access a custom set of parameter values for a particular clinical situation. For example, you may want to save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you need to repeatedly program a particular set of parameters.

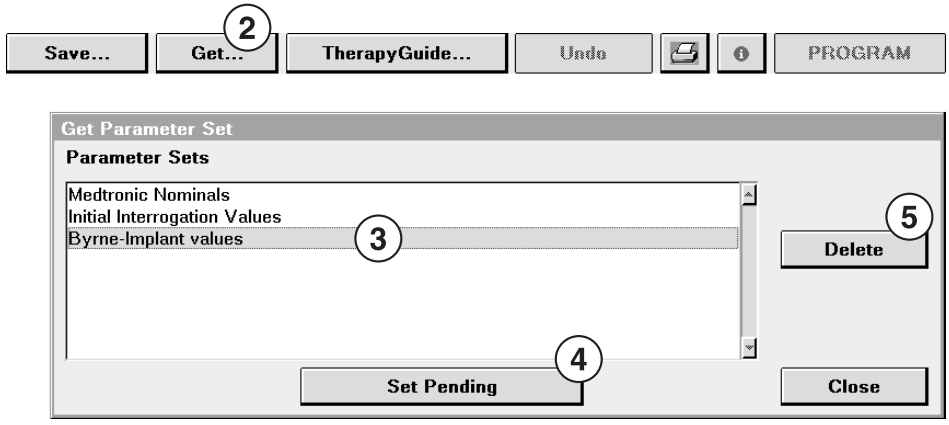
The [Save…] button opens a window where you can assign a name to the set of parameter values presently displayed by the Parameters screen. A saved parameters set can include both programmed and pending values. The [Get…] button opens the Get Parameter Set window to retrieve a Medtronic Nominals parameter set, an Initial Interrogation parameter set, or a custom parameter set.

4.7.1 How to save a set of parameter values



1. Select the Params icon. Make the desired parameter selections.
2. Select [Save…] to open the Parameter Set Name window.
3. Type a name for the parameter set, and select either [OK] or [ENTER].
4. If a parameter set exists with that name, you either need to confirm that you want to replace the existing set with a new set, or you need to change the name of the new set of parameters.

4.7.2 How to retrieve a set of parameter values



1. Select the Params icon.
2. Select [Get…] to open the Get Parameter Set window.
3. Select the parameter set you want to retrieve.
4. Select [Set Pending].
5. Optionally, to remove an unneeded parameter set from the list, select the parameter set and select [Delete].

You can select the following options from the Get Parameter Set window:

- Medtronic Nominals: Values chosen as nominal values for the device by Medtronic. The Medtronic Nominals cannot be customized or deleted.
- Initial Interrogation Values: The permanently programmed parameter values as determined by the first interrogation of the device during the patient session.
- Custom sets of values: All custom sets of values that were saved previously.

4.8 Using TherapyGuide to select parameter values

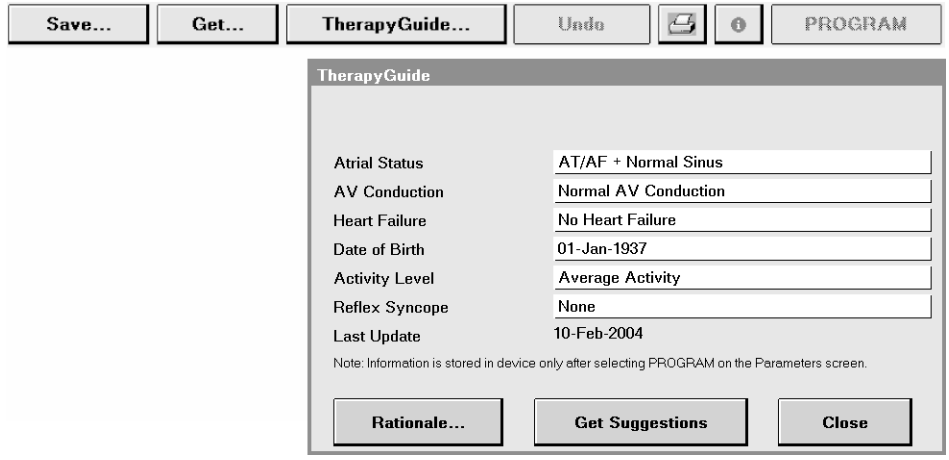
Caution: TherapyGuide does not replace a physician's expert judgment. The physician's knowledge of the patient's medical condition goes beyond the set of inputs presented to TherapyGuide. The physician is free to accept, reject, or modify any of the suggested parameter values.

TherapyGuide offers a simple clinically focused method to obtain suggested parameter values. At implant or at an early follow-up appointment, information can be entered about the patient's clinical conditions. Based on those inputs, the programmer suggests parameter values. The suggestions are based on clinical studies, literature, current practice, and physician feedback.

4.8.1 Operation of TherapyGuide

The patient's clinical conditions are entered in the TherapyGuide window, which is accessed from the Parameters screen or by selecting Patient > TherapyGuide.

Figure 9. TherapyGuide window



Based on a set of selected clinical conditions, TherapyGuide provides suggested values for many programmable parameters. The clinical conditions influencing these parameter suggestions are shown in Table 4. This table presents an overview, but the Rationale window shows how the suggested values for parameters relate to specific settings for the clinical conditions.

If a parameter is not influenced by the clinical conditions, TherapyGuide may either recommend the Medtronic nominal value for that parameter or make no recommendation.

If the suggested value for a parameter is different than the programmed value, the parameter value appears as a pending value. If the suggested value is identical to the programmed value, it does not appear as a pending value.

Table 4. How programming suggestions are determined

Programming suggestions	Clinical conditions
Pacing Mode	Atrial Status AV Conduction Reflex Syncope
Lower Rate	Atrial Status Date of Birth Reflex Syncope
Upper Tracking Rate	Date of Birth
AV intervals	Date of Birth
Rate Response (including Upper Sensor Rate)	Atrial Status Heart Failure Date of Birth Activity Level
Rate Drop Response	Atrial Status Reflex Syncope
VT Monitor	Date of Birth
AT/AF Detection	Date of Birth

4.8.2 Considerations for TherapyGuide

TherapyGuide and the Patient Information screen – The clinical conditions can also be programmed into device memory from the Patient Information screen. Refer to Section 4.9, “Viewing and entering patient information”, page 50.

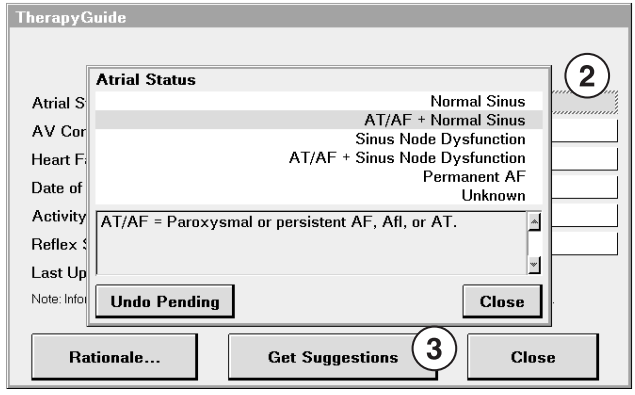
Last Update status – The date indicates when changes in clinical conditions were last programmed into device memory.

Printing the clinical conditions – The clinical conditions can be printed from the Patient Information screen. The clinical conditions are also included in the Initial Interrogation Report and in the Save to Media file.

Appearance of the [TherapyGuide…] button – The appearance of the [TherapyGuide…] button changes about 3 months after implant.

4.8.3 How to obtain a set of suggested values

1. On the Parameters screen, select [TherapyGuide…] to open the TherapyGuide window.
2. For each clinical condition, select the field next to the condition, and choose one of the listed inputs.



Note: If you want to program only the choices for clinical conditions without programming any parameter changes into device memory, select [Close] and [PROGRAM].

3. After selecting the clinical conditions, select [Get Suggestions]. The TherapyGuide window closes, and suggested changes to parameter values appear as pending values on the Parameters screen.

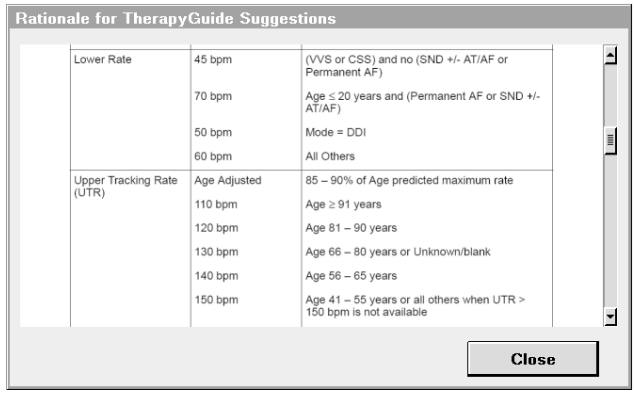
   Notes:

   - Information is stored in device memory only after you select [PROGRAM] on the Parameters screen.
   - If you select [Undo] on the Parameters screen, all pending parameter values and the pending clinical conditions are cleared.

4. Review the settings and verify that the new settings are appropriate for the patient.
5. To adjust any of the pending values, select [Undo Pending] within the parameter value window, or select a different parameter value. Repeat this step to adjust other parameter values as desired.
6. Select [PROGRAM] to enter the pending parameter values and the pending clinical conditions into device memory.

4.8.4 How to view the rationale for TherapyGuide suggestions

1. On the Parameters screen, select [TherapyGuide…] to open the TherapyGuide window.
2. Select [Rationale…] to open the Rationale window.



3. Select [Close] twice to return to the Parameters screen.

4.9 Viewing and entering patient information

Devices can store patient-related information that you can view and print during a patient session. This information is typically programmed into the device at the time of implant, but it can be revised at any time.

When you enter the patient's clinical conditions (Date of Birth and History) and program them into device memory, they are available to the TherapyGuide feature. For more information, see Section 4.8, "Using TherapyGuide to select parameter values", page 46.

The patient's name and ID and the device serial number are printed on all full-size and strip chart reports.

Note: The Patient Information screen should not be used in the place of the patient's medical chart (refer to Section 1.1.5, "Notice", page 11 in the Introduction).

If you enter text that does not fit in the parameter display area, the entry is shortened. The full entry is visible on the Patient Information Report. When displayed or printed from other screens, the text entry may be shortened.

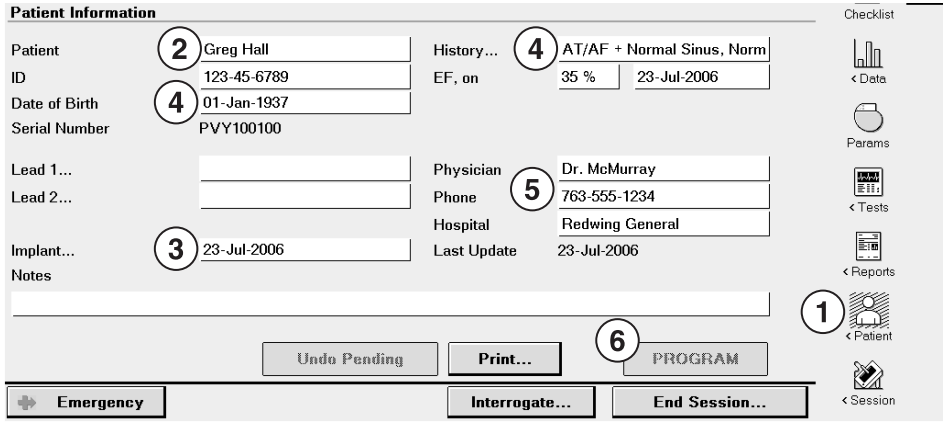
If you start a concurrent analyzer session during the device session, you can export analyzer lead measurements. The exported measurements appear as pending parameter values in the Implant window, which is accessed from the Patient Information screen. These pending values are programmed from the Patient Information screen.

Table 5. Description of the patient information

Information field	Description and required action
Patient	Enter the patient's name (up to 30 characters).
ID	Enter the patient ID (up to 15 characters).
Date of Birth	Select the patient's date of birth.
Serial Number (not selectable)	Displays the serial number of the implanted device.
Lead 1… Lead 2…	Enter detailed information for up to 2 leads: Select the Model, Position, and Manufacturer from lists of options. Enter the Serial Number and Implant Date.
Implant…	Either export lead data from the analyzer, or enter lead data using the submenus.
Notes	Enter notes about the patient or other information.
History…	Enter the patient's clinical conditions. This information is made available to TherapyGuide.
EF, on	Select the ejection fraction from a table of values in the first field, and enter the date in the second field.
Physician Phone	Select the physician's name and phone number from a list. If they are not listed, add them to the list, and select them.
Hospital	Select the hospital name from a list. If it is not listed, add it to the list, and select it.
Last Update (not selectable)	Displays the date of the last Patient Information update.

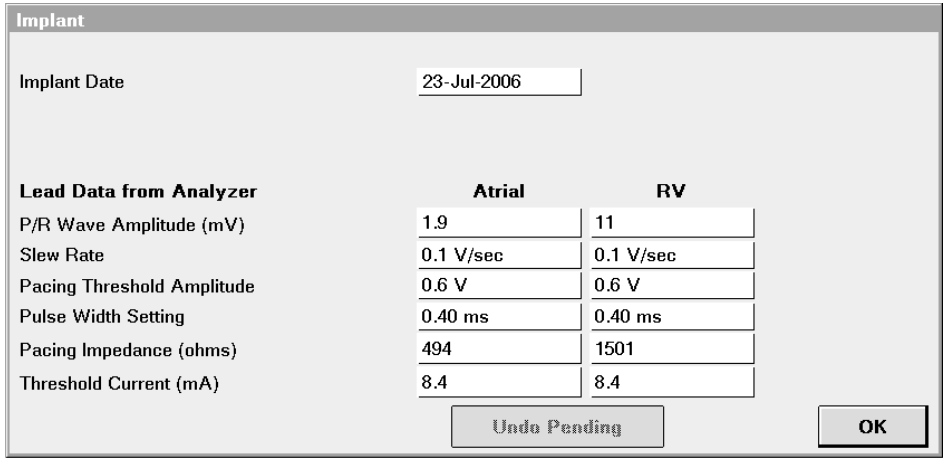
4.9.1 How to view and enter patient information

1. Select Patient > Patient Information. The Patient Information screen is displayed.



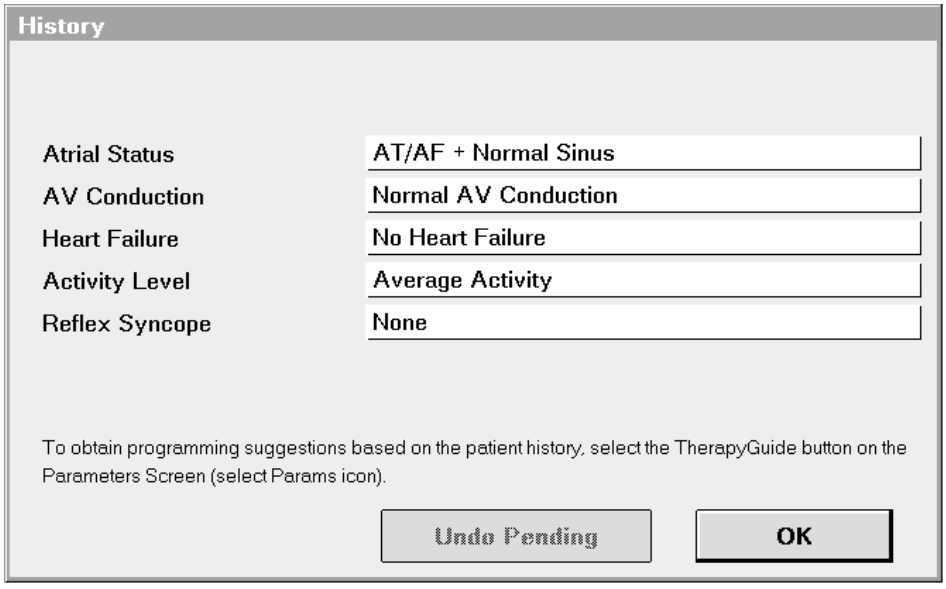
2. Select each text field to enter or change its content.

3. Enter the implant information by selecting the Implant… field. For each lead, enter lead data measured with the Analyzer. Then select [OK].



Note: If an implant procedure is in progress, consider making the measurements in a concurrent analyzer session. Measurements can be exported directly to the Implant window (see Section 4.9.2). Otherwise, select a value for each parameter.

4. To enter the patient's clinical conditions, which are made available to TherapyGuide, perform the following steps:
   a. Select Date of Birth, enter the date, and select [OK].
   b. Select the History… field to open the History window. Enter the appropriate clinical conditions, and select [OK].



5. Select the Physician (or Phone) and the Hospital fields, and select this information from lists. To add new information to a list, select [Modify List…] and [Add…]. Type in your addition and select [OK].
6. When all of the information has been entered, select [PROGRAM].

4.9.2 How to export saved lead measurements to the Implant window

When analyzer and device sessions are running concurrently, you can export the saved lead measurements from the analyzer session into the Implant window in the device session.

1. From the device session, launch a new analyzer session by selecting the Analyzer icon, which is located on the taskbar.

2. Make the desired lead measurements. Identify the measurements by lead type when you save them.
3. Select [View Saved…].
4. Select which saved measurements to export. You can select up to one measurement for each lead type.
5. Select [Export]. The selected settings are exported to the Implant window in the device session.
6. When you are finished, select [Close].
7. Return to the device session by selecting the Device icon on the task bar.

The data is mapped to Atrial and RV columns in the Implant window. As described in Section 4.9.1, you can add or change an exported measurement by selecting a field in the Implant window. The exported values are programmed from the Patient Information screen.

4.10 Working with the Live Rhythm Monitor

The Live Rhythm Monitor window displays ECG waveform traces, Marker Channel telemetry with marker annotations and marker intervals, and telemetered EGM waveform traces on the programmer screen. The Live Rhythm Monitor window also displays the patient's heart rate and interval in the upper left corner of the window. You can view live waveform traces, freeze waveform traces, record live waveform traces from the programmer's strip chart recorder, and recall any saved waveform strips before ending a patient session.

By default, the Live Rhythm Monitor appears in partial view. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window or by selecting [Adjust…]. The display of waveform traces in the Live Rhythm Monitor window depends on which waveform source is selected and how waveform traces are arranged in the full-screen view.

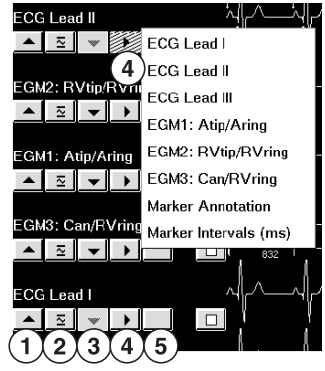
4.10.1 Viewing live waveform traces

The Live Rhythm Monitor can display up to 6 different waveforms during a patient session:

- The ECG Lead I, ECG Lead II, and ECG Lead III waveforms display ECG signals that are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer.
- The EGM1, EGM2, and EGM3 signals are telemetered from the device and are selected from programmable EGM sources. You can choose the sources of EGM1, EGM2, and EGM3 when you set up data collection. The programmer cannot display or record an EGM waveform trace until the current EGM Range setting has been interrogated from the device. See Section 7.4, “Viewing Arrhythmia Episodes data and setting data collection preferences”, page 110 for more information about EGM sources.

4.10.1.1 How to select and adjust the waveforms

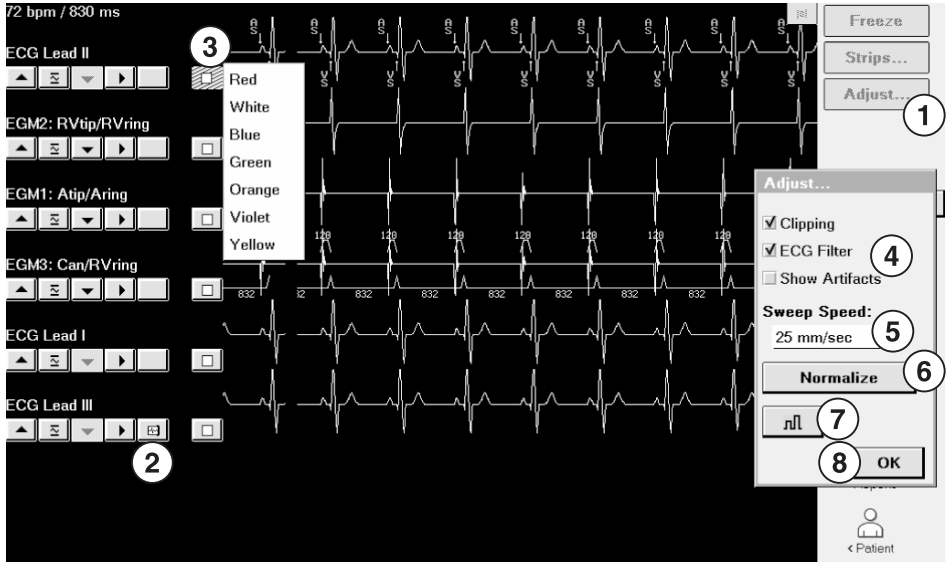
You can use the waveform adjustment button bar to change the appearance of the waveforms in view.



1. Select the up arrow button to increase the size of the waveform trace.
2. Select the normalize button to restore the waveform trace to its default size.
3. Select the down arrow button to decrease the size of the waveform trace.
4. Select the forward arrow button to choose which waveform trace to display.
5. Select the waveform print selection button to select the waveform trace for printing, if available. You can select up to 2 waveform traces for printing.

4.10.1.2 How to change the appearance of the waveform

You can use the Adjust window to make additional changes to the waveform display.



1. Select [Adjust…] to display the full screen Live Rhythm Monitor and the Adjust window.
2. Adjust the size, source, and print selection options for each waveform trace using the waveform adjustment button bar.
3. Select the color button to change the color of a waveform.
4. Select or clear the Clipping, ECG Filter, and Show Artifacts check boxes as desired.
   - Clipping truncates the tops and bottoms of waveform traces at a 22 mm boundary.
   - ECG Filter changes the bandwidth of waveforms to improve the clarity of the displayed ECG in the presence of interference. (Select the check box to set the bandwidth to 0.5 to 40 Hz, or clear the check box to set the bandwidth to 0.05 to 100 Hz.)
   - Show Artifacts displays pacing artifacts superimposed over waveform traces.
5. Select a Sweep Speed if desired. Sweep Speed controls how quickly the waveform is drawn across the display. Selecting a fast Sweep Speed produces a wide waveform. Selecting a slow Sweep Speed produces a narrow waveform. Sweep Speed can be set to 12.5; 25; 50; or 100 mm/s.
6. Select [Normalize] to equalize the spacing between the waveform traces and to resize each trace to its default setting.

7. Select the calibrate button to add a reference signal to the analog output, the screen, and the real-time strip recorder or Electronic Strip Chart (eStrip) recorder, whichever is available.
8. When you are finished making adjustments, select [OK].

4.10.1.3 How to interpret Marker Channel annotations and symbols

Marker Channel annotations appear as 2 characters above or below the Marker Channel waveform trace. These annotations indicate events such as pacing, sensing, detection, and delivered therapies.

Real-time waveform recordings also display symbols that appear above or below their associated Marker Channel annotations. The symbols sometimes appear compressed, depending on the printout speed of the programmer strip chart recorder, if available. The symbols do not appear on screens or in episode recordings.

See the figures that follow for examples of Marker Channel annotations and symbols.

Note: Any interruption in telemetry with the device may result in missing marker annotations and symbols on the waveform trace display.

Figure 10. Pacing Marker Channel annotations and symbols

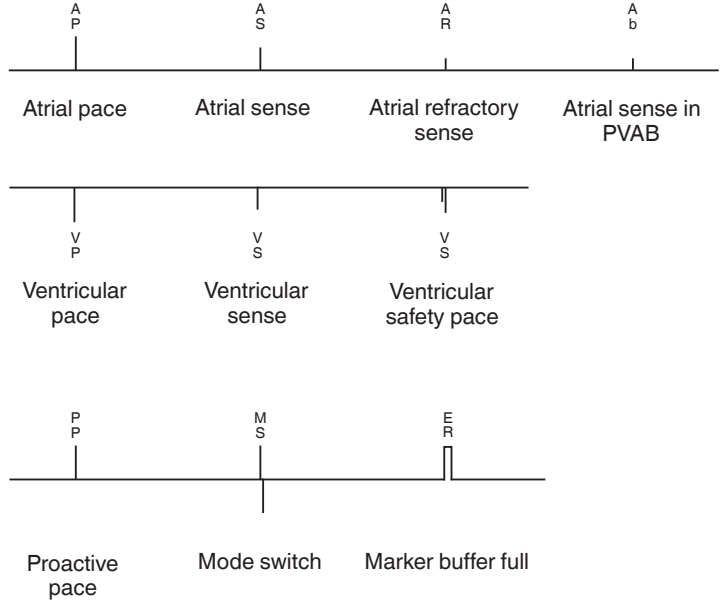
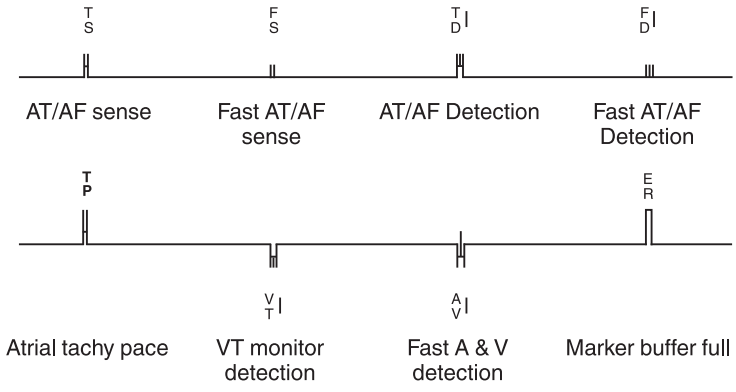


Figure 11. Detection and therapies Marker Channel annotations and symbols



4.10.2 Recording live waveform traces

At any time during a patient session, you can record a continuous, live waveform trace of the patient's ECG and EGM[1] on the programmer strip chart recorder.

Note: Because the printed waveform strip is of a higher resolution than the programmer display, the printed waveform strip may show artifacts and events that do not appear on the programmer display.

A printout of the live waveform trace includes the following information:

- ECG and EGM traces
- an indication of an executed command when confirmation of the command is received
- test values during system tests
- telemetry markers that show telemetry from the programmer to the device (programming the device) and telemetry from the device to the programmer (confirming the programming)
- Decision Channel annotations. See Section 7.4, "Viewing Arrhythmia Episodes data and setting data collection preferences", page 110 for more information about Decision Channel annotations.

Printing a report while recording a live waveform trace – If you select an option from the Print menu while recording a live waveform trace, the report goes to the print queue.

[1] The programmer cannot display or record an EGM trace until the device has been interrogated.

Alternatively, if you start recording a live waveform trace while the programmer is printing a report, the report stops printing and returns to the print queue.

Note: This interruption to printing applies only to reports printed on the programmer strip chart recorder. Printing to a separate printer is not affected.

EGM Range – The programmer cannot display or record an EGM waveform trace until the current EGM Range setting has been interrogated from the device. If you program an EGM Range setting during a recording, the programmer marks the change with a vertical dotted line on the paper recording. EGM and Marker Channel telemetry can be momentarily interrupted during interrogation or programming.

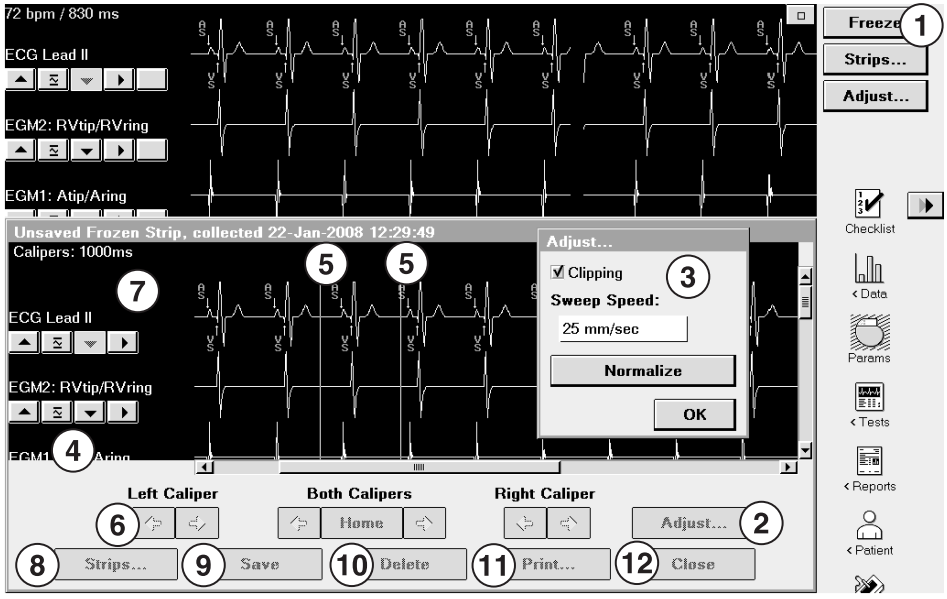
4.10.3 Freezing live waveform traces

The Freeze feature enables you to freeze the last 15 s of all live waveform traces displayed in the expanded Live Rhythm Monitor window.

You can use controls in the frozen strip viewing window to perform the following functions:

- View earlier or later portions of the strip by using the horizontal scroll bar.
- See frozen waveform strips that are not visible in the window by using the vertical scroll bar.
- Measure a time interval with on-screen calipers.

Figure 12. Interpreting the frozen strip viewing window

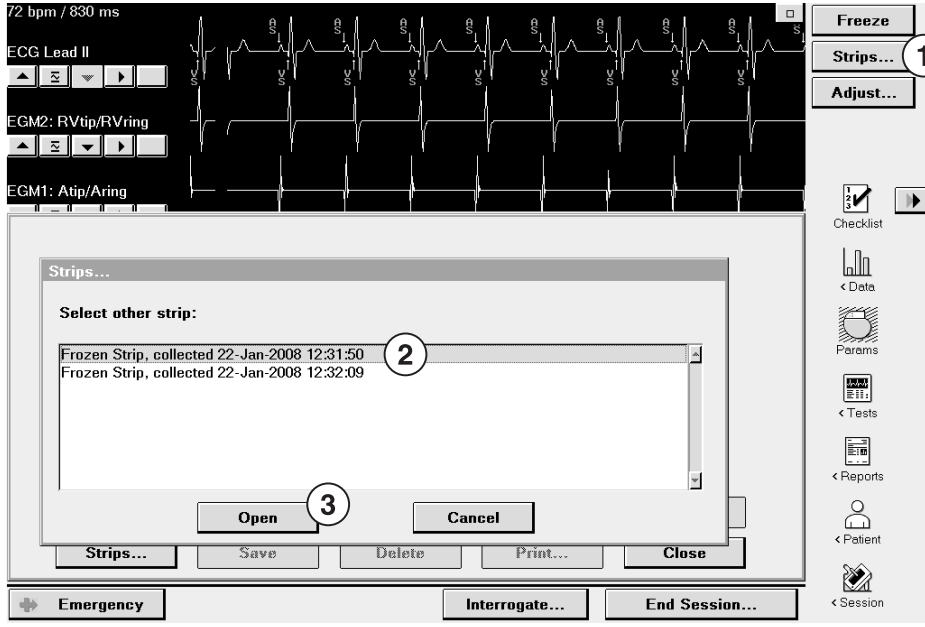


1 The [Freeze] button freezes a live waveform trace and displays it in the frozen strip viewing window on the programmer screen.
2 The [Adjust…] button opens the Adjust window for the strip viewer.
3 The Adjust window offers display options for the strip viewer, which is similar to the Adjust window for the Live Rhythm Monitor.
4 The Waveform adjustment button bar allows you to normalize the trace, resize the trace, and change the waveform source.
5 The on-screen calipers define time intervals.
6 The Arrow buttons move the on-screen calipers to show the beginning and the end of a time interval.
7 The Calipers measurement is the time interval between the on-screen calipers.
8 The [Strips…] button opens a list of other frozen strips.
9 The [Save] button saves the on-screen frozen strip.
10 The [Delete] button deletes the on-screen frozen strip (if it was saved).
11 The [Print…] button prints the on-screen frozen strip.
12 The [Close] button closes the frozen strip viewing window.

4.10.4 Recalling waveform strips

Before ending the patient session, you can recall any waveform strip collected and saved during the session in order to view, adjust, and print the waveform strip.

4.10.4.1 How to recall a waveform strip



1. Select [Strips…] in the tool palette or in the strip viewer.
2. Select a strip to view.
3. Select [Open]. The strip viewer displays the selected strip.

4.11 Saving and retrieving device data

The programmer allows you to save interrogated device data from a patient session to a disk, if equipped with a disk drive, or to a USB flash drive. Later, while no patient session is in progress, you can use the Read From Media application on the programmer to retrieve, view, and print previously saved data.

4.11.1 Saving device data

Any operation that normally uses a disk to read or write data, such as saving session data, reloading session data, or saving reports to a PDF file, uses a USB flash drive if it is inserted. When a USB flash drive is inserted in the programmer, the disk drive becomes unavailable. Disks may be used when no USB flash drive is inserted.

Storage requirements – To ensure the integrity and security of patient information, use a USB flash drive or a disk that is reserved for storage of programmer data.

Interrogate first – Interrogate the device before saving data to a USB flash drive or a disk because the programmer saves only the data it has interrogated. If the Interrogate How Much? window is displayed, select All to save a record of all the information from the device. If an issue needs to be investigated, selecting the All option provides more data for analysis.

Emergency functions while saving – During the save operation, the [Emergency] button remains displayed, and all Emergency functions are available. If an error occurs during a save, there may be a delay in initiating the Emergency screens. Therefore, it is suggested that you not save to media during EP studies or when it is possible that Emergency functions will be needed immediately. If an Emergency function is used during a save operation, the device aborts the save operation.

4.11.1.1 Considerations for saving device data on a USB flash drive

Insert only one USB flash drive – Insert only one writable USB flash drive at a time. Inserting additional USB flash drives results in an error during data-saving operations and the USB indicator becomes unavailable.

Progress indicator – While a Save To Media action is in progress, the progress indicator and the message “Save To Media - In Progress” are displayed. The progress indicator displays the completion percentage. Before removing the USB flash drive, wait a few seconds after the progress indicator shows 100%.

Programmer powered on – Insert a USB flash drive only if the programmer is powered on. Insert a writable USB flash drive in the programmer using any available USB port. A slight delay may occur while the USB flash drive is authorized. The USB indicator on the task bar turns green to indicate that the USB flash drive is available for use and the disk icon becomes unavailable.

Do not insert or remove a USB flash drive during the following operations:

- programming a device
- performing a Save To Media task
- performing a reload session data operation
- saving a report as a PDF file

4.11.1.2 How to save device data to a USB flash drive

1. Select [Interrogate…] to interrogate the device.
2. Insert a USB flash drive into the USB port on the programmer.

3. Select Session > Save To Media….
4. Select [Save].

You can also Save To Media when you select [End Session…].

4.11.1.3 Preparing to save data to a disk

The disk must be a formatted, IBM-compatible, 90 mm (3.5 inch) disk.

If you save data to a disk that is corrupt or is not IBM-formatted, the programmer may become unresponsive. If this situation occurs, remove the disk, turn off the programmer, and then turn it on again. Normal operation should resume. Inform your Medtronic representative of this occurrence.

4.11.1.4 How to save device data to a disk

1. Select [Interrogate…] to interrogate the device.
2. Select Session > Save To Media….
3. Insert a disk into the programmer disk drive.
4. Select [Save].

You also have the option to Save To Media when you select [End Session…].

4.11.2 Retrieving device data

When the programmer has read the data that was saved during a patient session, it presents the information in a read-only view. In the read-only view, the data is presented in a slightly different way than what is seen in a live session. No Live Rhythm Monitor window is displayed because this is not a live session. Instead, the Live Rhythm Monitor window is replaced with the device model and the words Read From Media. While in the Read From Media application, the programmer allows you to view the saved data, print reports, and display all programmed parameter values.

Reports that have been saved to media can only be viewed on a computer. They cannot be viewed on the programmer itself. After saving, remove the storage media (USB flash drive or disk) containing the reports and insert it into a computer equipped to display files that are in PDF format.

All reports from one patient's session are contained in one PDF file.

Warning: The Read From Media application is designed only for viewing saved data while no patient session is in progress. You cannot program a device or deliver Emergency therapies from the Read From Media application.

Device testing – You cannot perform tests on the device when reading data from media.

4.11.2.1 How to read device data from a USB flash drive or a disk

1. Insert a USB flash drive or a disk that contains information saved during a patient session.
2. From the Select Model screen, select the product category from the View list.
3. Select the Read From Media version of the device.
4. Select [Start].
5. Select [OK] after reading the warning message that informs you that programming a device and emergency operations are not possible while you are in the Read From Media application.
6. Select [Open File…].
7. Select the data record that displays the desired device serial number, date, and time.
8. Select [Open File]. The Read From Media screen displays information from the saved session.

4.12 Using SessionSync to transfer device data to the Paceart system

The SessionSync feature provides network connectivity between the Medtronic CareLink programmer and the Medtronic Paceart data management system. By using your clinic network, the programmer can send downloaded device data using the SessionSync feature to the data management system for later analysis and patient management.

The programmer indicates the connection status of the programmer to the data management system through the SessionSync status icon in the task bar and the SessionSync Status screen.

Procedures in this topic describe how to configure the SessionSync network connection, how to enable and disable the SessionSync feature, and how to determine the status of the data transfer.

See the Medtronic programmer reference guide for instructions describing how to connect an Ethernet cable from the programmer to your clinic's network.

4.12.1 Configuring the SessionSync network connection

You must configure the programmer network settings to allow for data transfer.

4.12.1.1 Preparing to configure the SessionSync network connection

Physical connection – See the Medtronic programmer reference guide for instructions describing how to connect an Ethernet cable from the programmer to your clinic's network.

Gateway address – Prior to configuring the network connection, you will need to know your SessionSync Gateway address. If you do not have your SessionSync Gateway address, contact your clinic's technical support or Medtronic Paceart technical support at 1-800-PACEART.

4.12.1.2 How to configure the SessionSync network connection

1. From the Desktop, select Programmer > SessionSync Network Configuration….
2. Enter the Clinic Name.
3. Enter the IP address or hostname of the SessionSync Gateway.
4. Select [OK].

4.12.2 Enabling and disabling the SessionSync feature

Typically, the SessionSync feature is enabled only once, when it is first installed. When the SessionSync feature is enabled, any device application that is capable of using the SessionSync feature has SessionSync functionality.

The SessionSync icon is grayed out when the feature is disabled. Within a patient session, the SessionSync functions are not available. The SessionSync feature cannot be used until you have ended the session and reenabled the feature.

4.12.2.1 How to enable and disable the SessionSync feature

1. From the Desktop, select Programmer > Preferences.
2. Select SessionSync from the index menu.
3. Select Enabled to enable the SessionSync feature, or select Disabled to disable the SessionSync feature.

4.12.3 Viewing the SessionSync data transfer status

The programmer indicates the status of the SessionSync feature through the SessionSync icon in the task bar and through the SessionSync Status screen.

When all components of the SessionSync icon are grayed out in the task bar, it means that the SessionSync feature has been disabled under the programmer preferences. No data transfer can occur in this state.

The SessionSync status does not dynamically update when the SessionSync Status window is open. To update the status, select the [Update Status] button.

4.12.3.1 How to view the status of the SessionSync feature from the programmer task bar

The programmer task bar displays a SessionSync icon that indicates the current data transfer activity and the status of the communication link between the programmer and data management system. If the SessionSync feature is not installed on the programmer, the icon will not be visible in the task bar.

Figure 13. SessionSync icon on the programmer task bar

Figure 14. SessionSync icon indicators

1 Data management system status. Blue: all session data has been transferred to the data management system. Gray: no session data has been transferred to the data management system.
2 Connection status. Green: a valid connection exists between the programmer and the data management system. Red circle with a strike through: device application does not support the SessionSync feature. Not visible: no valid connection exists between the programmer and the data management system.
3 Programmer status. Blue: session data files are in the transfer queue. Gray: no session data files are in the transfer queue.

4.12.3.2 How to view the status of the SessionSync feature from the SessionSync Status screen

The SessionSync Status screen displays information about the data files being transferred to the data management system using the SessionSync feature. Each status message includes the date, time, and event information for the associated SessionSync event.

1. From the Desktop, select Programmer > SessionSync Status.
2. Select the [Update Status] button.

4.13 Printing reports

The programmer provides flexibility in printing reports that are available from the system. You can print informative standard reports, and you can access print functions in a variety of ways. You can also specify when to print a particular report and which printer to use.

4.13.1 Setting preferences for printing, reports, and tests

Preferences allow you to select print options, such as number of copies, printer type, and whether to print now or later. They also allow you to select report options for printing reports at the beginning, during, or at the end of a patient session.

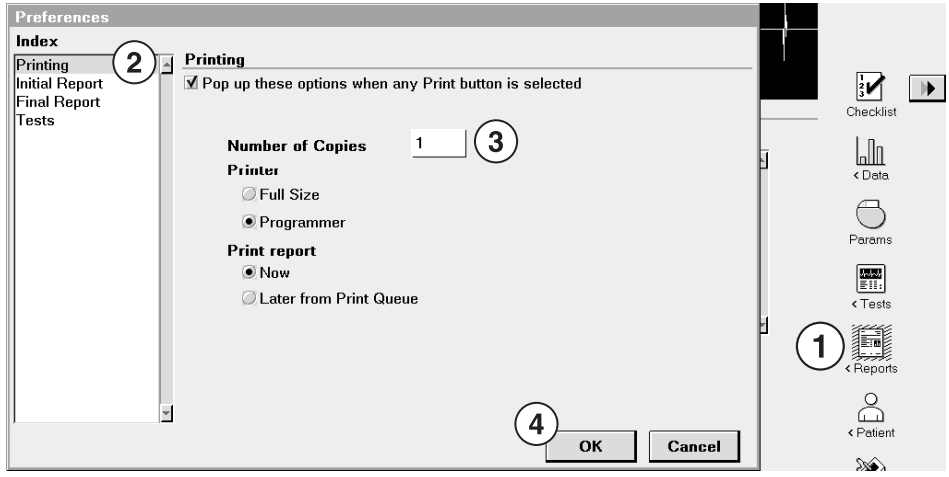
Printing preferences are applied automatically whenever you select the [Print…] button or the Print icon. If you prefer to set print preferences each time you print a report, select the check box next to “Pop up these options when any Print button is selected”. When you select this check box, a Print Options window appears each time that you select the [Print…] button or Print icon.

For more information about setting up an external full-size printer, see the user guide for your Medtronic programmer.

Report preferences are applied variously, depending on which report is being produced. These are described in the several procedures found in the following sections.

Tests preferences control how waveform traces are arranged in the live rhythm display.

4.13.1.1 How to set printing preferences



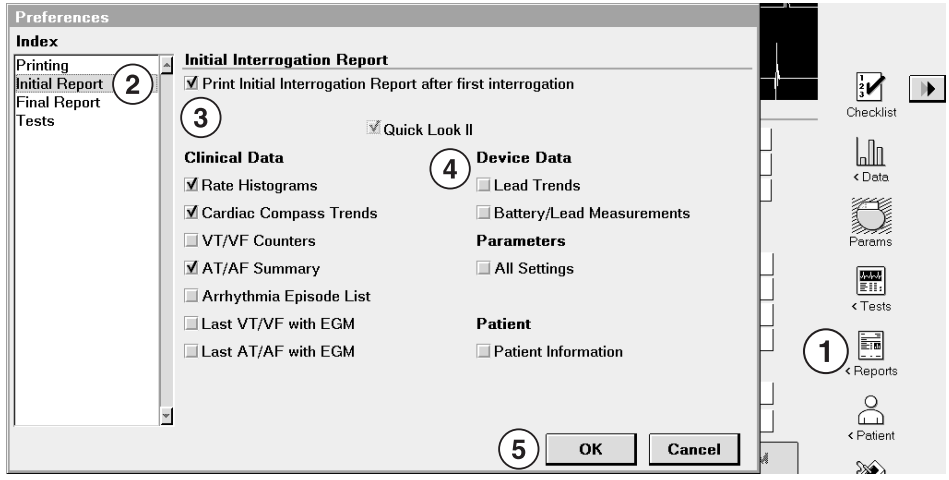
1. After starting a patient session, select Reports > Preferences….
2. From the Index selection box, select the Printing option.
3. Select your printing preferences as desired.
4. Select [OK].

Basic printing preferences take effect immediately.

4.13.2 Printing an Initial Interrogation Report

The programmer automatically prints certain reports after the first interrogation in a patient session if you set Initial Report preferences to do so. The reports that print automatically after the first interrogation in a patient session are collectively called the Initial Interrogation Report. The Quick Look II Report is always a part of the Initial Interrogation Report. You can also select other reports to print as part of the Initial Interrogation Report.

4.13.2.1 How to set Initial Report preferences



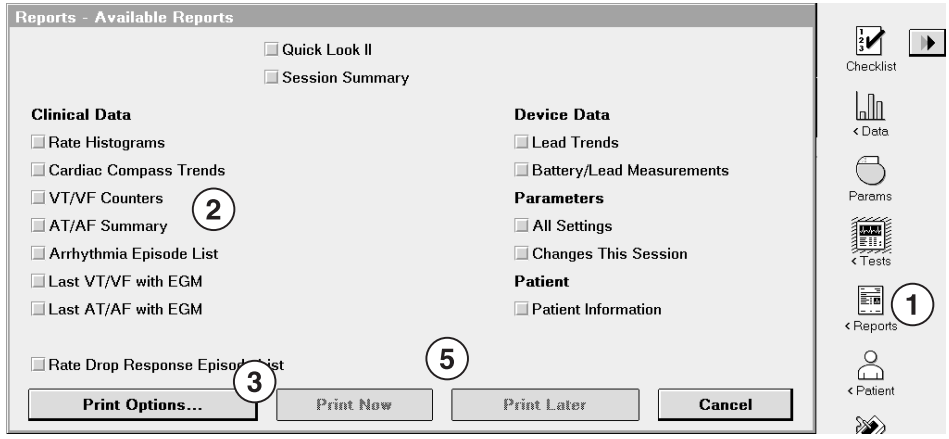
1. After starting a patient session, select Reports > Preferences….
2. From the Index selection box, select the Initial Report option.
3. Select the check box next to “Print Initial Interrogation Report after first interrogation”, if desired. The report prints automatically at the beginning of a patient session after the device is interrogated.
4. Select the additional reports to include in the Initial Interrogation Report.
5. Select [OK].
6. To print an Initial Interrogation Report for a patient session that is in progress, end and restart the patient session. The Initial Interrogation Report prints automatically after interrogation.

Initial Report preferences take effect at the start of a new session and remain in effect until you change them and start a new session.

4.13.3 Printing reports during a patient session

The programmer allows you to specify a particular set of reports for printing and to print a report based on the screen you are viewing.

4.13.3.1 How to print a customized set of reports



1. To print a customized set of reports, select Reports > Available Reports….
2. Select the reports you want to print. A report can be printed only if its data has been collected. If no data has been collected, the name of the report appears gray.
3. Select [Print Options…] if it is available. If not, continue with Step 5.
4. Select printing preferences as desired.
5. Select [Print Now] for immediate printing, or select [Print Later] to add the print request to the print queue.

4.13.3.2 How to print a report on a specific programming screen

1. Select [Print…] or select the Print icon on the programmer screen.
2. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the report prints according to the previously set printing preferences.

4.13.4 Printing a summary report for the patient session

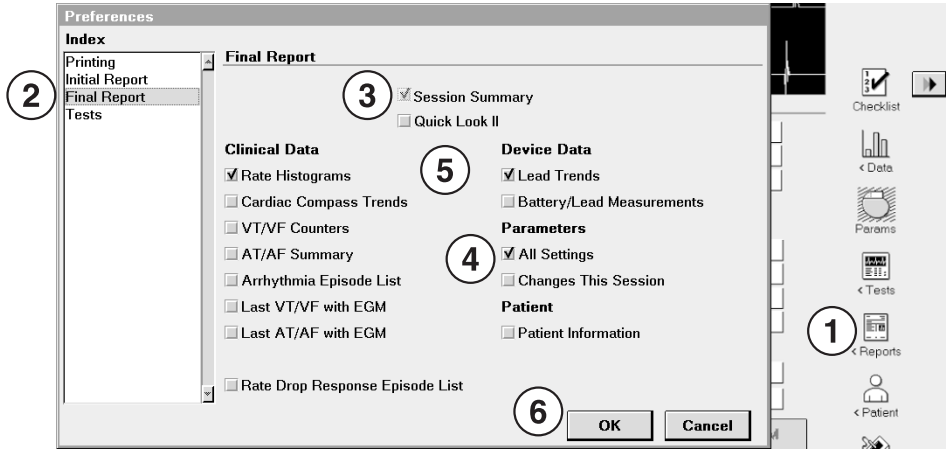
The system allows you to print a summary report at the end of a patient session.

4.13.4.1 How to print a summary report for the patient session

1. Select Reports > Final Report….
2. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the Session Summary Report and other reports you have selected print according to the previously set printing preferences. For more information, see Section 4.13.4.2.

4.13.4.2 How to set Final Report preferences

You can select the reports you want printed as a part of the Final Report. The Session Summary Report always prints when a Final Report print request is made.



1. Before ending a patient session, select Reports > Preferences….
2. From the Index selection box, select the Final Report option.
3. The Session Summary check box is selected and cannot be unselected. This ensures that at least one report prints when a Final Report print request is made.
4. If this is the first time you are establishing Final Report preferences, the Parameters – All Settings selection should be selected.
5. Select the additional reports to include in the Final Report.
6. Select [OK].

Note: The selections you make using the Final Report Preferences feature remain between sessions and across all applications.

To print the selections you made using the Final Report Preferences feature, follow the steps in Section 4.13.4.1.

4.13.5 Managing the Print Queue

The Print Queue window indicates the printing status of reports that you select to print as you progress through a patient session.

When you end the patient session, the Print Queue window is still available. It lists any reports held from that session and other previous sessions.

4.13.5.1 How to use the Print Queue window during a patient session

At the start of a patient session, the Print Queue window is empty because it lists reports selected to print in the current session only. If you select [Print Later] for a report, the report is held in the print queue.

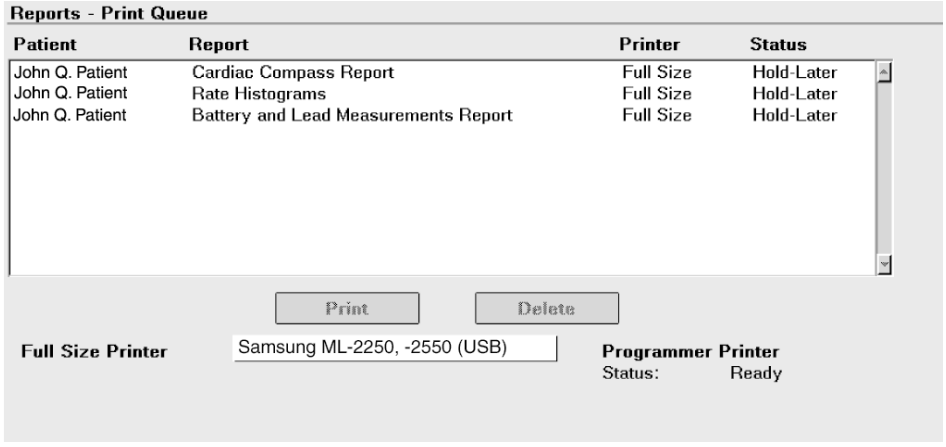
To display the Print Queue window during a patient session, select Reports > Print Queue. From this window, you can check the status of print jobs from the current patient session only. You can print or delete a print job from the queue. A report cannot be deleted if its status is “printing” or “waiting”.

4.13.5.2 How to use the Print Queue window outside of a patient session

The Print Queue window is available outside of a patient session. To display the Print Queue window when you are not in a patient session, select the Print Queue icon from the Select Model screen. The Print Queue window lists any reports held from that session and other previous sessions. You can print or delete a print job from the queue. A report cannot be deleted if its status is “printing” or “waiting”.

4.13.5.3 Interpreting the Print Queue Status column

The Print Queue Status column lists the print status for each report to be printed by the programmer:

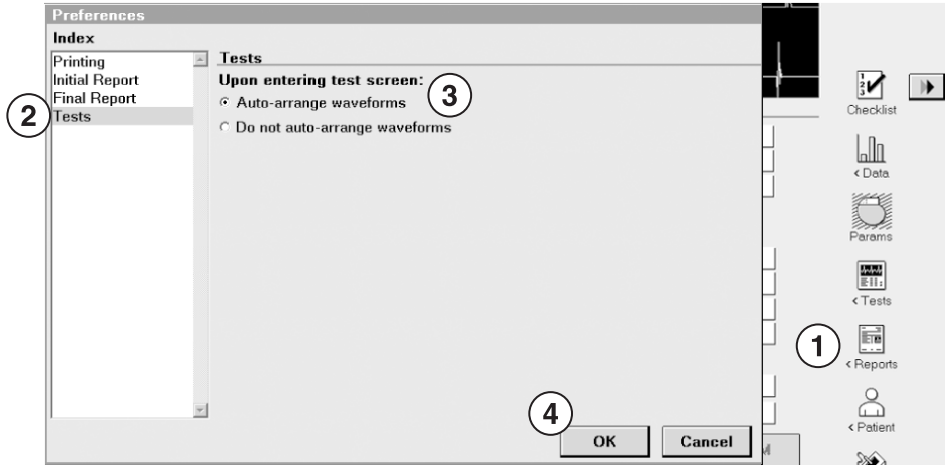


- Printing: Indicates that a report is currently being printed.
- Deleting: Indicates that a report is currently being deleted (after the [Delete] button is selected).
- Waiting: Indicates that a report is waiting to be printed while another report is printing.
- Hold-Later: Indicates that a report is on hold until you request that it be printed (using the [Print] button). A Hold-Later status can also mean that the printing of a report was interrupted by the start of a recording or that the printer is not operational (because it is out of paper, for example).
- Done: Indicates that a report has been printed.

4.13.6 Setting Tests preferences

The Tests preferences in the Index selection box allows you to choose how waveform traces are displayed during a selected follow-up test. You can choose to make the live rhythm display arrange the waveforms to show the EGM of the heart chamber being tested, or to keep the waveform arrangement unchanged.

4.13.6.1 How to set Tests preferences



1. Select Reports > Preferences….
2. From the Index selection box, select the Tests option.
3. Choose the desired option (“Auto-arrange waveforms” or “Do not auto-arrange waveforms”).
4. Select [OK].

For more information on tests, see Chapter 11, “Testing the system”, page 274.

5 Advisa DR MRI - Implanting the device

5.1 Preparing for an implant

The following implant procedures are provided for reference only. Proper surgical procedures and sterile techniques are the responsibility of the physician. Each physician must apply the information in these procedures according to professional medical training and experience.

For information about replacing a previously implanted device, see Section 5.7, “Replacing a device”, page 85.

Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant.

5.1.1 Instruments, components, and accessories required for an implant

The following non-implanted instruments are used to support the implant procedure:

- Medtronic programmer with a programming head
- Model 9995 software application
- Medtronic Analyzer or equivalent pacing system analyzer
- external defibrillator

The following sterile system components and accessories are used to perform the implant:

- implantable device and lead system components
- programming head sleeve

  Note: If a sterilized programming head is used during an implant, a sterile programming head sleeve is not necessary.

- pacing system analyzer cables
- lead introducers appropriate for the lead system
- extra stylets of appropriate length and shape

5.1.2 Setting up the programmer and starting the application

See the programmer reference guide for instructions about how to set up the programmer. The Model 9995 software should be installed on the programmer. Establish telemetry with the device and start a patient session.

5.1.3 Considerations for preparing for an implant

Review the following information before implanting the leads or device:

Before performing an MRI procedure, refer to the Medtronic MRI Technical Manual for MRI-specific information.

Warning: Bipolar or unipolar leads may be used with the Advisa DR MRI SureScan device, but if leads other than bipolar SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

Warning: Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing, implant procedures, and post-implant testing.

Caution: The device is intended for implant in the pectoral region with Medtronic transvenous leads. No claims of safety and efficacy can be made with regard to other acutely or chronically implanted lead systems that are not manufactured by Medtronic.

Caution: For AT/AF Detection, unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, AT/AF Detection must be programmed to Monitor and Capture Management must be programmed to Off.

Caution: Do not implant the device after the "Use by" date on the package label. Battery longevity could be reduced.

Medtronic SureScan feature – To retain the ability to safely scan the SureScan system during MRI procedures, consideration of the following items is required. Refer to the MRI Technical Manual for additional information.

- The device must be implanted in either the left or right pectoral region.
- A complete SureScan system includes a SureScan device connected to one SureScan atrial pacing lead and one SureScan right ventricular pacing lead.
- The patient must not have any abandoned leads, adaptors, or lead extenders. Abandoned leads or previously implanted non-MRI labeled leads compromise the ability to safely scan the MRI SureScan system during future MRI procedures. Consider the risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the Medtronic MRI SureScan system.

5.1.4 How to prepare the device for implant

Before opening the sterile package, perform the following steps to prepare the device for implant:

1. Interrogate the device and print an Initial Interrogation Report.

   Caution: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.

2. Check the Initial Interrogation Report to confirm that the battery voltage is at least 2.85 V at room temperature.

   If the device has been exposed to low temperatures, then the battery voltage will be temporarily lower. Allow the device to warm to room temperature for at least 48 hours and check the battery voltage again. If an acceptable battery voltage cannot be obtained, contact a Medtronic representative.

   Note: The device automatically measures the battery voltage several times a day. At midnight, the device calculates the automatic daily battery voltage by averaging the measurements taken during the previous 24 hours. The most recent automatic daily battery voltage measurement is displayed on the Battery and Lead Measurements screen.

3. Select Params > Data Collection Setup > Device Date/Time… to set the internal clock of the device to the correct date and time.
4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is not programmed to On.

   Notes:

   - Do not enable a pacing feature that affects the pacing rate (for example, Ventricular Rate Stabilization) before implanting the device. Doing so may result in a pacing rate that is faster than expected.
   - Patient information typically is entered at the time of initial implant, and it can be revised at any time.

5.2 Selecting and implanting the leads

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan system includes a Advisa DR MRI SureScan device connected to Advisa DR MRI SureScan pacing leads. To verify that components are part of a Advisa DR MRI SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan. **Before performing an MRI procedure, refer to the MRI Technical Manual for additional information.**

Use the guidelines in this section to select leads that are compatible with the device. The appropriate techniques for implanting the leads may vary according to physician preference and the patient's anatomy or physical condition. Consult the technical manuals supplied with the leads for specific implant instructions.

5.2.1 Selecting the leads

Do not use any lead with this device without first verifying lead and connector compatibility.

The device is typically implanted with the following MRI SureScan leads:

- 1 bipolar transvenous lead in the right ventricle (RV) for sensing and pacing
- 1 bipolar transvenous lead in the atrium (A) for sensing and pacing. Use of a bipolar atrial lead with ring and tip electrodes spaced ≤ 10 mm apart to reduce far-field R-wave sensing is recommended.

5.2.2 How to verify lead and connector compatibility

Warning: Verify lead and connector compatibility before using a lead with this device. Using an incompatible lead may damage the connector, resulting in electrical current leakage or resulting in an intermittent electrical connection.

Note: Medtronic 3.2 mm low-profile leads are not directly compatible with the device IS-1 connector block.

Lead adaptors may compromise patient safety during an MRI scan. **Refer to the MRI Technical Manual for additional information.**

Use the information in Table 6 to select a compatible lead.

Table 6. Lead and connector compatibility

Connector port	Primary leads
A, V	IS-1[a] bipolar and IS-1 unipolar

[a] IS-1 refers to the international standard ISO 5841-3.

5.2.3 Implanting the leads

Implant the leads according to the instructions in the technical manuals supplied with the leads unless suitable chronic leads are already in place.

Warning: Pinching the lead can damage the lead conductor or insulation, which may result in the loss of sensing or pacing therapy.

Transvenous leads – If you use a subclavian approach to implant a transvenous lead, position the lead laterally to avoid pinching the lead body between the clavicle and the first rib.

5.3 Testing the lead system

After the leads are implanted, test the lead system to verify that the sensing and pacing values are acceptable.

5.3.1 Considerations for testing the lead system

Bipolar leads – When measuring sensing and pacing values, measure between the tip (cathode) and ring (anode) of each bipolar pacing/sensing lead.

Unipolar leads – When measuring sensing and pacing values, measure between the tip (cathode) of each unipolar pacing/sensing lead and an indifferent electrode (anode) used in place of the device can.

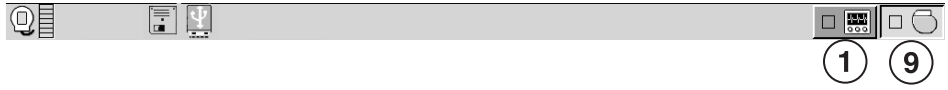
5.3.2 How to verify and save the sensing and pacing values

Medtronic recommends that you use a Medtronic analyzer to perform sensing and pacing measurements. When the analyzer and the device sessions are running concurrently, you can export the saved lead measurements from the analyzer session into the patient information parameters in the device session. Refer to the analyzer technical manual for detailed procedures about performing the lead measurements.

Note: If you perform the lead measurements using an implant support instrument other than a Medtronic analyzer, enter the measurements in the device session manually.

Note: Do not measure the intracardiac EGM that is telemetered from the device to assess sensing.

1. From the device session, launch a new analyzer session by selecting the Analyzer icon, which is located on the task bar.



2. Measure the EGM amplitude, slew rate, and capture threshold using a Medtronic analyzer.
3. Use the information in Table 7 to verify that the measured values are acceptable.

   Note: The measured pacing lead impedance is a reflection of measuring equipment and lead technology. Refer to the lead technical manual for acceptable impedance values.

4. Select [Save…] at the bottom of the column that corresponds to the lead you are testing.
5. In the Lead field, select the type of lead you are testing and then select [Save].
6. Select [View Saved…].
7. Select the saved measurements that you want to export. You can select 1 measurement for each lead type.
8. Select [Export] and [Close]. The selected measurements are exported to the Implant… field on the Patient Information screen in the device session.
9. Select the Device icon on the task bar to return to the device session.
10. Select Patient > Patient Information and then select [PROGRAM] to program the imported values into the device memory.

Table 7. Acceptable sensing and pacing values

Measurements required	Acute transvenous leads	Chronic leads[a]
P-wave EGM amplitude (atrial)	≥ 2 mV	≥ 1 mV
R-wave EGM amplitude (RV)	≥ 5 mV	≥ 3 mV
Slew rate		
	≥ 0.5 V/s (atrial)	≥ 0.3 V/s (atrial)
	≥ 0.75 V/s (RV)	≥ 0.5 V/s (RV)
Capture threshold (0.5 ms pulse width)		
	≤ 1.5 V (atrial)	≤ 3.0 V (atrial)
	≤ 1.0 V (RV)	≤ 3.0 V (RV)

[a] Chronic leads are leads implanted for 30 days or more.

5.4 Connecting the leads to the device

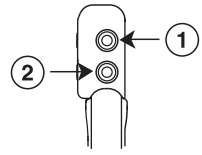
The following procedure describes how to connect the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

Warning: After connecting the leads, verify that the lead connections are secure by gently tugging on each lead. A loose lead connection may result in inappropriate sensing, which can result in false tracking and false inhibition of pacing, or inappropriate atrial tachyarrhythmia therapy.

Caution: Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew.

See Figure 15 for information about the lead connector ports on the device.

Figure 15. Lead connector ports

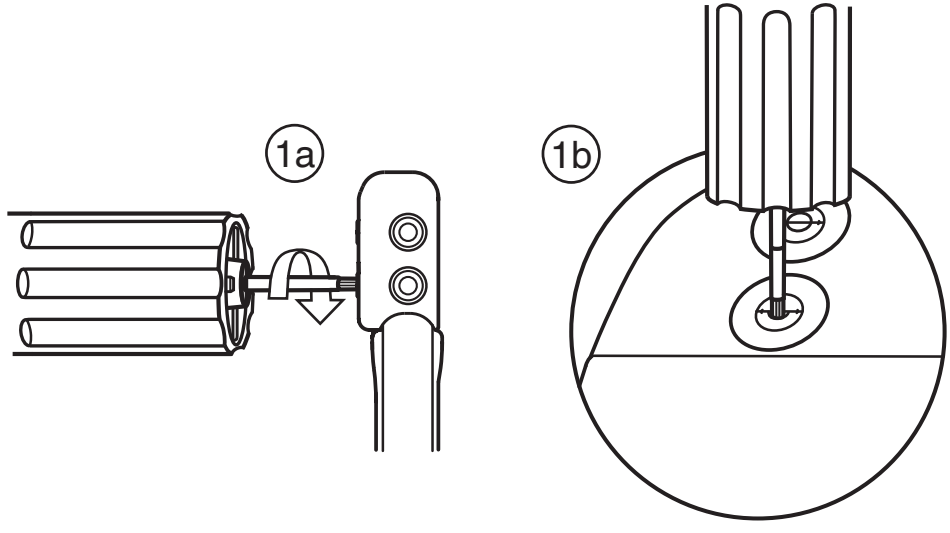


1 IS-1 connector port, A
2 IS-1 connector port, RV

5.4.1 How to connect a lead to the device

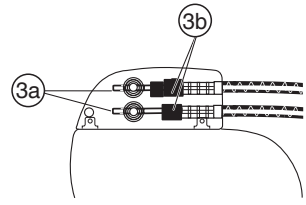
1. Insert the torque wrench into the appropriate setscrew.
   a. If the port is obstructed by the setscrew, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 16).
   b. Leave the torque wrench in the setscrew until the lead connection is secure. This allows a pathway for venting trapped air when the lead connector is inserted into the connector port.

Figure 16. Inserting the torque wrench into the setscrew



2. Push the lead connector into the connector port until the lead connector pin is clearly visible in the pin viewing area. No sealant is required.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side or end.
   a. The lead connector pin should be clearly visible beyond the setscrew block (see Figure 17).
   b. The lead connector ring should be completely inside the spring contact block. There is no setscrew in this location (see Figure 17).

Figure 17. Confirming the lead connection



4. Tighten the setscrew by turning it clockwise until the torque wrench clicks. Remove the torque wrench.

5. Gently tug on the lead to confirm a secure fit. Do not pull on the lead until the setscrew has been tightened.
6. Repeat these steps for each lead.

5.5 Positioning and securing the device

Caution: Program AT/AF Detection to Monitor to avoid inappropriate therapy delivery while closing the pocket.

Note: Implant the device within 5 cm (2 in) of the surface of the skin to optimize post-implant ambulatory monitoring.

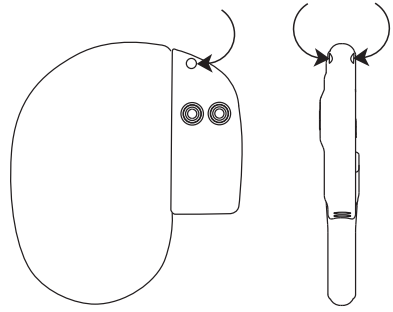
5.5.1 How to position and secure the device

1. Verify that each lead connector pin is fully inserted into the connector port and that all setscrews are tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 18). Do not kink the lead body.

Figure 18. Rotating the device to wrap the leads

3. Place the device and the leads into the surgical pocket.
4. Use nonabsorbable sutures to secure the device within the pocket and minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture hole on the device (see Figure 19).

Figure 19. Locating the suture hole



5. Suture the pocket incision closed.

5.6 Completing the implant procedure

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.

5.6.1 How to complete programming the device

1. If unipolar leads are implanted, you may want to manually complete the Implant Detection process.
   a. Select the Params icon.
   b. Program the Pace Polarity and Sense Polarity parameters to Unipolar.
   c. Select Additional Features… and program the Implant Detection parameter to Off/Complete.
2. Verify that the pacing, detection, and atrial ATP therapies parameters are programmed to values that are appropriate for the patient.
3. Enter the patient's information.
4. Program the Data Collection Setup parameters.

5.6.2 How to assess the performance of the device and the leads

After implanting the device, x-ray the patient as soon as possible to verify device and lead placement. Before the patient is discharged from the hospital, assess the performance of the implanted device and leads.

1. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.
2. Check the pacing and sensing values, and adjust the values if necessary.
3. Interrogate the device, and print a Final Report to document the postoperative programmed device status.

5.7 Replacing a device

To retain the ability to safely scan the SureScan pacing system during future MRI scans, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Bipolar or unipolar leads may be used with the Advisa DR MRI SureScan device, but if leads other than bipolar MRI SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Abandoned leads or previously implanted non-MRI labeled leads may compromise patient safety during an MRI scan. When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before removing these leads to maintain the ability to safely scan the SureScan system. Refer to the Medtronic MRI Technical Manual for additional information.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the device when the lead is disconnected, or when the device is removed from the pocket while the device is operating in unipolar pacing mode.

Caution: Disable tachyarrhythmia detection to avoid inappropriate therapy delivery while explanting the device.

Caution: For AT/AF Detection, unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, AT/AF Detection must be programmed to Monitor and Capture Management must be programmed to Off.

Note: To meet the implant requirements, you may need to reposition or replace the chronic leads. For more information, see Section 5.2, "Selecting and implanting the leads", page 78.

Note: Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. Contact your Medtronic representative for information about lead pin caps. Any unused or abandoned leads present may compromise patient safety during an MRI scan. Refer to the Medtronic MRI Technical Manual for additional information.

5.7.1 How to explant and replace a device

1. Program the device to a mode that is not rate-responsive to avoid potential rate increases while explanting the device.
2. Dissect the leads and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrews in the connector block.
4. Gently pull the leads out of the connector ports.
5. Evaluate the condition of each lead (see Section 5.3, “Testing the lead system”, page 79). Replace a lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. If you explant the lead, return it to Medtronic for analysis and disposal.
6. Connect the leads to the replacement device (see Section 5.4, “Connecting the leads to the device”, page 81).

   Note: Lead adaptors may be needed to connect the leads to the replacement device. However, lead adaptors do compromise the ability to safely perform an MRI scan on the SureScan system in the future. **Refer to the Medtronic MRI Technical Manual for additional information.** Contact a Medtronic representative for questions about lead adaptor compatibility or SureScan safety.

7. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 5.5, “Positioning and securing the device”, page 83).
8. Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

Note: Disposal of explanted devices or leads is subject to local, state, and federal regulations.

6 Advisa SR MRI - Implanting the device

6.1 Preparing for an implant

The following implant procedures are provided for reference only. Proper surgical procedures and sterile techniques are the responsibility of the physician. Each physician must apply the information in these procedures according to professional medical training and experience.

For information about replacing a previously implanted device, see Section 6.7, “Replacing a device”, page 97

Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant.

6.1.1 Instruments, components, and accessories required for an implant

The following non-implanted instruments are used to support the implant procedure:

- Medtronic programmer with a programming head that is appropriate for the programmer model you are using.
- Model 9995 software application
- Medtronic analyzer or equivalent pacing system analyzer
- external defibrillator

The following sterile system components and accessories are used to perform the implant:

- implantable device and lead system components
- programming head sleeve

  Note: If a sterilized programming head is used during an implant, a sterile programming head sleeve is not necessary.

- pacing system analyzer cables
- lead introducers appropriate for the lead system
- extra stylets of appropriate length and shape

6.1.2 Setting up the programmer and starting the application

See the programmer reference guide for instructions about how to set up the programmer. The Model 9995 software should be installed on the programmer. Establish telemetry with the device and start a patient session.

6.1.3 Considerations for preparing for an implant

Review the following information before implanting the lead or device:

Before performing an MRI procedure, refer to the Medtronic MRI Technical Manual for MRI-specific information.

Warning: Bipolar or unipolar leads may be used with the Advisa SR MRI SureScan device, but if leads other than bipolar SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

Warning: Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing, implant procedures, and post-implant testing.

Caution: The device is intended for implant in the pectoral region with a Medtronic transvenous lead. No claims of safety and efficacy can be made with regard to other acutely or chronically implanted lead systems that are not manufactured by Medtronic.

Caution: Do not implant the device after the "Use by" date on the package label. Battery longevity could be reduced.

Medtronic SureScan feature – To retain the ability to safely scan the SureScan system during MRI procedures, consideration of the following items is required. Refer to the MRI Technical Manual for additional information.

- The device must be implanted in either the left or right pectoral region.
- A complete SureScan system includes a SureScan device connected to a SureScan right ventricular pacing lead.

- The patient must not have any abandoned leads, adaptors, or lead extenders. Abandoned leads or previously implanted non-MRI labeled leads compromise the ability to safely scan the MRI SureScan system during future MRI procedures. Consider the risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the Medtronic MRI SureScan system.

6.1.4 How to prepare the device for implant

Before opening the sterile package, perform the following steps to prepare the device for implant:

1. Interrogate the device and print an Initial Interrogation Report.

   Caution: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.

2. Check the Initial Interrogation Report to confirm that the battery voltage is at least 2.85 V at room temperature.

   If the device has been exposed to low temperatures, then the battery voltage will be temporarily lower. Allow the device to warm to room temperature for at least 48 hours and check the battery voltage again. If an acceptable battery voltage cannot be obtained, contact a Medtronic representative.

   Note: The device automatically measures the battery voltage several times a day. At midnight, the device calculates the automatic daily battery voltage by averaging the measurements taken during the previous 24 hours. The most recent automatic daily battery voltage measurement is displayed on the Battery and Lead Measurements screen.

3. Select Params > Data Collection Setup > Device Date/Time… to set the internal clock of the device to the correct date and time.
4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is not programmed to On.

   Notes:

   - Do not enable a pacing feature that affects the pacing rate (for example, Ventricular Rate Stabilization) before implanting the device. Doing so may result in a pacing rate that is faster than expected.
   - Patient information typically is entered at the time of initial implant, and it can be revised at any time.

6.2 Selecting and implanting the lead

Use the guidelines in this section to select a lead that is compatible with the device. The appropriate techniques for implanting the lead may vary according to physician preference and the patient's anatomy or physical condition. Consult the technical manuals supplied with the lead for specific implant instructions.

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan system includes an Advisa SR MRI SureScan device connected to a SureScan pacing lead. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan. **Before performing an MRI procedure, refer to the MRI Technical Manual for additional information.**

6.2.1 Selecting the lead

Do not use any lead with this device without first verifying lead and connector compatibility.

Note: A Medtronic MRI SureScan system includes a Medtronic MRI SureScan device connected to a Medtronic MRI SureScan lead. **Before performing an MRI procedure, refer to the Medtronic MRI Technical Manual for additional information.**

The device is typically implanted with 1 bipolar transvenous lead in the right ventricle (RV) for sensing and pacing.

6.2.2 How to verify lead and connector compatibility

Warning: Verify lead and connector compatibility before using a lead with this device. Using an incompatible lead may damage the connector, resulting in electrical current leakage or resulting in an intermittent electrical connection.

Note: Medtronic 3.2 mm low-profile leads are not directly compatible with the device IS-1 connector block.

Lead adaptors may compromise patient safety during an MRI scan. **Refer to the MRI Technical Manual for additional information.**

Use the information in Table 8 to select a compatible lead.

Table 8. Lead and connector compatibility

Connector port	Primary leads
V	IS-1[a] bipolar and IS-1 unipolar

[a] IS-1 refers to the international standard ISO 5841-3:2000.

6.2.3 Implanting the lead

Implant the lead according to the instructions in the technical manual supplied with the lead, unless a suitable chronic lead is already in place.

Warning: Pinching the lead can damage the lead conductor or insulation, which may result in the loss of sensing or pacing therapy.

Transvenous lead – If you use a subclavian approach to implant a transvenous lead, position the lead laterally to avoid pinching the lead body between the clavicle and the first rib.

6.3 Testing the lead system

After the lead is implanted, test the lead system to verify that the sensing and pacing values are acceptable:

6.3.1 Considerations for testing the lead system

Bipolar lead – When measuring sensing and pacing values, measure between the tip (cathode) and ring (anode) of each bipolar pacing/sensing lead.

Unipolar lead – When measuring sensing and pacing values, measure between the tip (cathode) of each unipolar pacing/sensing lead and an indifferent electrode (anode) used in place of the device can.

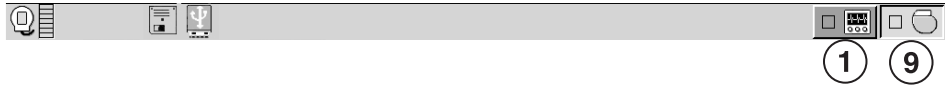
6.3.2 How to verify and save the sensing and pacing values

Medtronic recommends that you use a Medtronic analyzer to perform sensing and pacing measurements. When the analyzer and the device sessions are running concurrently, you can export the saved lead measurements from the analyzer session into the patient information parameters in the device session. Refer to the analyzer technical manual for detailed procedures about performing the lead measurements.

Note: If you perform the lead measurements using an implant support instrument other than a Medtronic analyzer, enter the measurements in the device session.

Note: Do not measure the intracardiac EGM that is telemetered from the device to assess sensing.

1. From the device session, launch a new analyzer session by selecting the Analyzer icon, which is located on the task bar.



2. Measure the EGM amplitude, slew rate, and capture threshold using a Medtronic Analyzer.
3. Use the information in Table 9 to verify that the measured values are acceptable.

   Note: The measured pacing lead impedance is a reflection of measuring equipment and lead technology. Refer to the lead technical manual for acceptable impedance values.

4. Select [Save…] at the bottom of the column that corresponds to the lead you are testing.
5. In the Lead field, select the type of lead you are testing and then select [Save].
6. Select [View Saved…].
7. Select the saved measurements that you want to export. You can select 1 measurement for each lead type.
8. Select [Export] and [Close]. The selected measurements are exported to the Implant… field on the Patient Information screen in the device session.
9. Select the Device icon on the task bar to return to the device session.
10. Select Patient > Patient Information and then select [PROGRAM] to program the imported values into the device memory.

Table 9. Acceptable sensing and pacing values

Measurements required	Acute transvenous leads	Chronic leads[a]
R-wave EGM amplitude (RV)	≥ 5 mV	≥ 3 mV
Slew rate		
	≥ 0.75 V/s (RV)	≥ 0.5 V/s (RV)
Capture threshold (0.5 ms pulse width)		
	≤ 1.0 V (RV)	≤ 3.0 V (RV)

[a] Chronic leads are leads implanted for 30 days or more.

6.4 Connecting the lead to the device

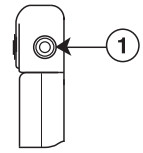
The following procedure describes how to connect the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

Warning: After connecting the lead, verify that the lead connection is secure by gently tugging on the lead. A loose lead connection may result in inappropriate sensing, which can result in false inhibition of pacing.

Caution: Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew.

See Figure 20 for information about the lead connector port on the device.

Figure 20. Lead connector port

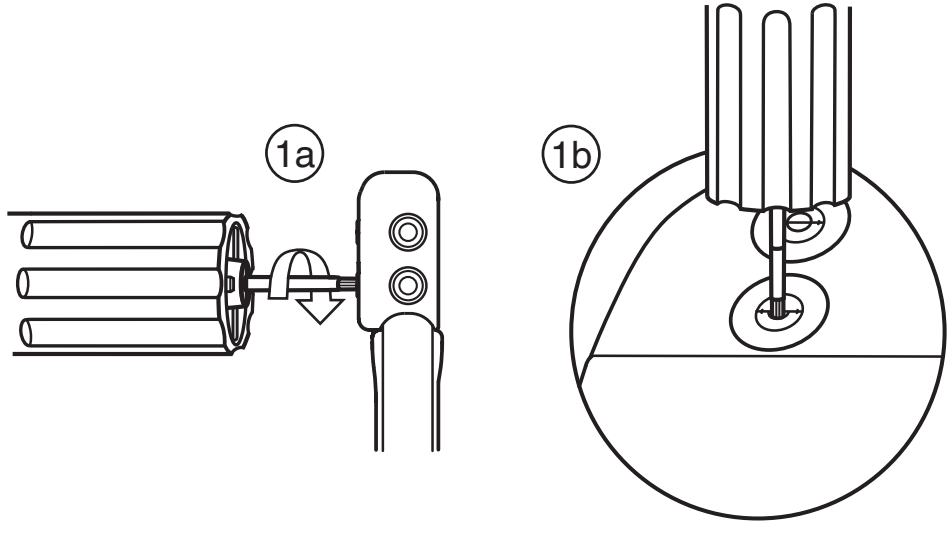


1 IS-1 connector port, RV

6.4.1 How to connect a lead to the device

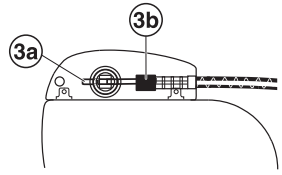
1. Insert the torque wrench into the setscrew.
   a. If the port is obstructed by the setscrew, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 21).
   b. Leave the torque wrench in the setscrew until the lead connection is secure. This allows a pathway for venting trapped air when the lead connector is inserted into the connector port.

Figure 21. Inserting the torque wrench into the setscrew



2. Push the lead connector into the connector port until the lead connector pin is clearly visible in the pin viewing area. No sealant is required.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side or end.
   a. The lead connector pin should be clearly visible beyond the setscrew block (see Figure 22).
   b. The lead connector ring should be completely inside the spring contact block. There is no setscrew in this location (see Figure 22).

Figure 22. Confirming the lead connection



4. Tighten the setscrew by turning it clockwise until the torque wrench clicks. Remove the torque wrench.
5. Gently tug on the lead to confirm a secure fit. Do not pull on the lead until the setscrew has been tightened.

6.5 Positioning and securing the device

Note: Implant the device within 5 cm (2 in) of the surface of the skin to optimize post-implant ambulatory monitoring.

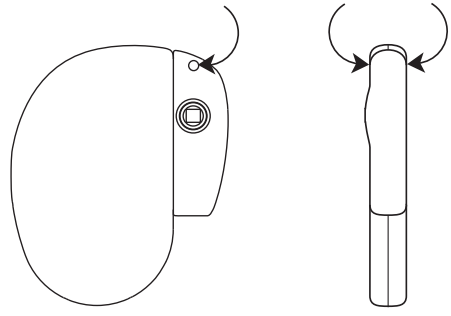
6.5.1 How to position and secure the device

1. Verify that the lead connector pin is fully inserted into the connector port and that the setscrew is tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 23). Do not kink the lead body.

Figure 23. Rotating the device to wrap the lead

3. Place the device and the lead into the surgical pocket.
4. Use nonabsorbable sutures to secure the device within the pocket and minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture hole on the device (see Figure 24).

Figure 24. Locating the suture hole



5. Suture the pocket incision closed.

6.6 Completing the implant procedure

6.6.1 How to complete programming the device

1. If a unipolar lead is implanted, you may want to manually complete the Implant Detection process.
   a. Select the Params icon.
   b. Program the Pace Polarity and Sense Polarity parameters to Unipolar.
   c. Select Additional Features… and program the Implant Detection parameter to Off/Complete.
2. Verify that the pacing and monitor parameters are programmed to values that are appropriate for the patient.
3. Enter the patient's information.
4. Program the Data Collection Setup parameters.

6.6.2 How to assess the performance of the device and the lead

After implanting the device, x-ray the patient as soon as possible to verify device and lead placement. Before the patient is discharged from the hospital, assess the performance of the implanted device and lead.

1. Monitor the patient's electrocardiogram until the patient is discharged. If the lead dislodges, it usually occurs during the immediate postoperative period.
2. Check the pacing and sensing values, and adjust the values if necessary.
3. Interrogate the device, and print a Final Report to document the postoperative programmed device status.

6.7 Replacing a device

To retain the ability to safely scan the SureScan pacing system during future MRI scans, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Bipolar or unipolar leads may be used with the Advisa SR MRI SureScan device, but if a lead other than a bipolar MRI SureScan lead is used, the system is contraindicated for MRI scans. Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.

Warning: Abandoned leads or previously implanted non-MRI labeled leads may compromise patient safety during an MRI scan. When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before removing these leads to maintain the ability to safely scan the SureScan system. Refer to the Medtronic MRI Technical Manual for additional information.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the device when the lead is disconnected, or when the device is removed from the pocket while the device is operating in unipolar pacing mode.

Note: To meet the implant requirements, you may need to reposition or replace the chronic lead. For more information, see Section 6.2, "Selecting and implanting the lead", page 90.

Note: Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. Contact your Medtronic representative for information about lead pin caps. Any unused or abandoned leads present may compromise patient safety during an MRI scan. Refer to the Medtronic MRI Technical Manual for additional information.

6.7.1 How to explant and replace a device

1. Program the device to a mode that is not rate-responsive to avoid potential rate increases while explanting the device.
2. Dissect the lead and the device free from the surgical pocket. Do not nick or breach the lead insulation.

3. Use a torque wrench to loosen the setscrew in the connector block.
4. Gently pull the lead out of the connector port.
5. Evaluate the condition of the lead (see Section 6.3, “Testing the lead system”, page 91). Replace the lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. If you explant the lead, return it to Medtronic for analysis and disposal.
6. Connect the lead to the replacement device (see Section 6.4, “Connecting the lead to the device”, page 92).

   Note: Lead adaptors may be needed to connect the lead to the replacement device. However, lead adaptors do compromise patient safety during an MRI scan. **Refer to the Medtronic MRI Technical Manual for additional information.** Contact a Medtronic representative for questions about lead adaptor compatibility or SureScan safety. **Refer to the Medtronic MRI Technical Manual for additional information.**.
7. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 6.5, “Positioning and securing the device”, page 95).
8. Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

Note: Disposal of explanted devices or leads is subject to local, state, and federal regulations.

7 Conducting a patient follow-up session

7.1 Patient follow-up guidelines

Schedule regular patient follow-up sessions during the service life of the device. The first follow-up session should occur within 72 hours of implant so that the patient can be checked for lead dislodgment, wound healing, and postoperative complications.

During the first few months after implant, the patient may require close monitoring. Schedule follow-up sessions at least every 3 months to monitor the condition of the patient, the device, and the leads and to verify that the device is configured appropriately for the patient.

7.1.1 Follow-up tools

The system provides several tools that are designed to increase the efficiency of follow-up sessions.

Quick Look II screen – The Quick Look II screen appears when you start the programmer application. It provides a summary of the most important indicators of the system operation and the patient's condition since the last follow-up session.

You can perform the following tasks from the Quick Look II screen:

- Assess that the device is functioning correctly.
- Review information about arrhythmia episodes and therapies.
- Review any observations in the Observations window.

You can compare the information on the Quick Look II screen with historical information about the patient contained in printed reports. For information about printing reports, see Section 4.13, "Printing reports", page 67. The printed reports should be retained in the patient's file for future reference.

Checklist – The Checklist feature provides a standard list of tasks to perform at a follow-up session. You can also customize your own checklists. For more information, see Section 4.5, "Streamlining implant and follow-up sessions with Checklist", page 39.

Cardiac Compass Report – The Cardiac Compass Report provides a picture of the patient's condition during the last 14 months. Graphs show the amount of time in AT/AF, the ventricular rate during AT/AF, the percent of pacing per day, the average ventricular rate, and the hours of patient activity per day. Dates and event annotations allow you to correlate trends from different graphs. For more information, see Section 7.3, "Viewing long-term clinical trends with the Cardiac Compass Report", page 106.

7.1.2 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 by viewing the Live Rhythm Monitor and by printing the EGM and Marker Channel traces. If you identify issues with the patient's presenting rhythm, review the device settings and reprogram the device to values that are appropriate for the patient.

7.1.3 Verifying the status of the implanted system

To verify that the device and leads are functioning correctly, review the device and lead status information, lead trends data, and Observations available from the Quick Look II screen.

For detailed information about viewing and interpreting all of the information available from the Quick Look II screen, see Section 7.2, "Viewing a summary of recently stored data", page 102.

7.1.3.1 How to review the battery voltage and device status indicators

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.

On the Quick Look II screen, review the Remaining Longevity. On the Battery and Lead Measurements screen (accessed by selecting the [>>] button next to the Remaining Longevity field on the Quick Look II screen), review the battery voltage and compare it to the Recommended Replacement Time (RRT). If the displayed voltage is at or below the displayed RRT value or if the RRT indicator is displayed, schedule an appointment to replace the device. For more information, see Section A.2, "Replacement indicators", page 288 for Advisa DR, and Section B.2, "Replacement indicators", page 296 for Advisa SR.

7.1.3.2 How to assess the performance of the device and leads

1. To review trends in pacing impedance, capture thresholds, and P-wave and R-wave amplitude, select the [>>] button next to the lead trend graphs on the Quick Look II screen. The programmer displays a detailed history of automatic impedance, capture threshold, and sensing measurements. For more information about viewing lead performance trends data, see Section 7.9, "Viewing detailed device and lead performance data", page 127.

2. If you also want to gather real-time information about the performance of the device and leads during the follow-up session, you can perform the following tests:
   - Lead Impedance Test: Compare the results of the test to previous lead impedance measurements to determine if there have been significant changes since the last follow-up session. For more information, see Section 11.3, “Measuring lead impedance”, page 276.
   - Sensing Test: Compare the test results to previous P-wave and R-wave amplitude measurements. For more information, see Section 11.4, “Performing a Sensing Test”, page 277.
   - Pacing Threshold Test: Use the test to review the patient’s capture thresholds. Determine the appropriate amplitude and pulse width settings to ensure capture and maximize battery longevity. For more information, see Section 11.2, “Measuring pacing thresholds”, page 274.

7.1.4 Verifying the clinical effectiveness of the implanted system

You can use the information available from the Quick Look II screen and in printed reports to assess whether the device is providing adequate clinical support for the patient.

7.1.4.1 How to assess effective pacing therapy

1. Interview the patient to confirm that the patient is receiving adequate cardiac support for daily living activities.
2. Review the pacing percentages on the Quick Look II screen, and view or print a Rate Histogram Report.
3. View or print the Cardiac Compass Report for review and comparison with patient history. Cardiac Compass trends 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, see Section 7.3, “Viewing long-term clinical trends with the Cardiac Compass Report”, page 106.

Note: The Rate Histograms report can also be used to assess the patient’s pacing and sensing history.

7.1.4.2 How to assess accurate tachyarrhythmia detection

The system provides diagnostic episode records to help you accurately classify the patient’s tachyarrhythmias. Review the tachyarrhythmia episode records since the last session and the Quick Look II Observations. For more information, see Section 7.4, “Viewing Arrhythmia Episodes data and setting data collection preferences”, page 110.

Caution: Use caution when reprogramming the detection or sensing parameters to ensure that appropriate sensing is maintained. For more information, see Section 8.1, “Sensing intrinsic cardiac activity”, page 140.

7.1.4.3 How to assess appropriate tachyarrhythmia therapy

1. In the Quick Look II Observations section, review any observations that relate to therapy delivery.
2. Check tachyarrhythmia episode records to determine the effectiveness of therapies that have been delivered.
3. Adjust the therapy parameters as needed.

7.2 Viewing a summary of recently stored 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 screen provides a summary of the most important indicators of the system operation and patient’s condition. It includes links to more detailed status and diagnostic information stored in the device. Device and lead status information indicates whether the system is operating as expected. Information about arrhythmia episodes and therapies provided gives a picture of the patient’s clinical status since the last follow-up appointment. System-defined observations alert you to unexpected conditions and suggest how to optimize the device settings.

Note: The Quick Look II screen shows information collected since the last patient session and stored in the device memory. Programming changes made during the current session may also affect the Quick Look II Observations.

7.2.1 How to view the Quick Look II screen

The Quick Look II screen is automatically displayed after the patient session is started. You can also access the Quick Look II screen through the Data icon.

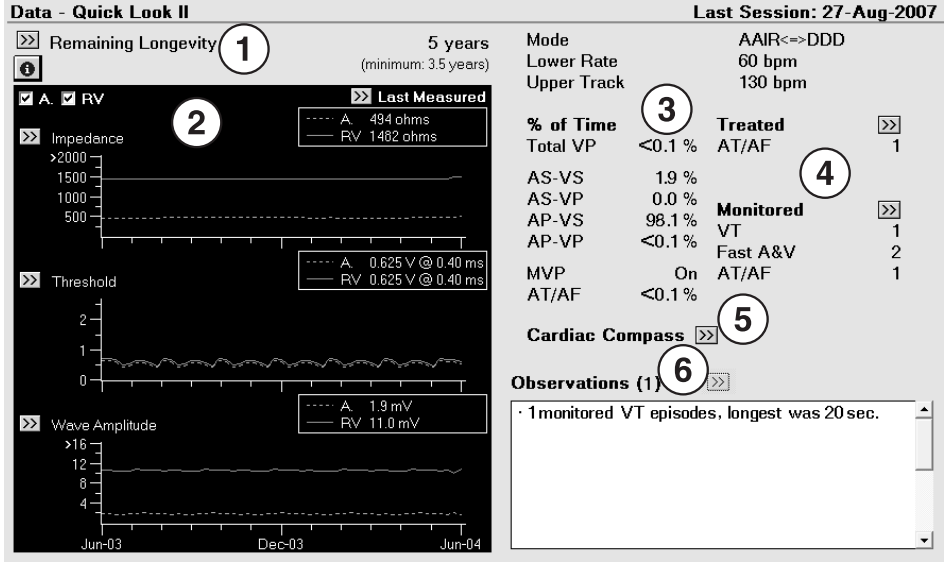
Select Data icon
⇒ Quick Look II

You can update the Quick Look II data during a session by reinterrogating the device.

7.2.2 Information provided by the Quick Look II screen

The Quick Look II screen shows information in 5 sections.

Figure 25. Quick Look II screen



1 Battery information
2 Lead status and trends
3 Pacing and sensing percentages
4 Arrhythmia episode information
5 Observations

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.

7.2.2.1 Assessing the device and lead status

Battery information – Battery voltage is measured daily and displayed on the Battery and Lead Measurements screen. You can access the Battery and Lead Measurements screen by selecting the [>>] button next to the Remaining Longevity field. The Battery and Lead Measurements screen and its associated printed report provide the most recent battery voltage measurement, as well as the Recommended Replacement time (RRT) indicator with date and time, if applicable. For more information about viewing battery and lead measurement data, see Section 7.9, “Viewing detailed device and lead performance data”, page 127.

If 3 consecutive automatic daily battery voltage measurements are less than or equal to the Recommended RRT value, the date when the battery reached RRT is displayed on the Quick Look II screen and in the Initial Interrogation Report. For information on the RRT value, see Section A.2, “Replacement indicators”, page 288 for Advisa DR, and Section B.2, “Replacement indicators”, page 296 for Advisa SR.

Lead status and trends – Information about lead status allows you to assess the performance and integrity of leads and identify any unusual conditions. The “Last Measured” column shows the most recently measured lead impedance for each lead.

Select the [>>] button in the “Last Measured” column to see more detailed lead measurements and relevant programmed settings.

The lead trend graphs on the Quick Look II screen show lead impedance, capture threshold, and sensing amplitude measurements recorded over the last 12 months.

Select the [>>] button beside any of the lead trend graphs to see more detailed information about lead performance. The detailed trend graphs display up to 15 of the most recent daily measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week).

For more information about lead performance graphs, see Section 7.9, “Viewing detailed device and lead performance data”, page 127.

7.2.2.2 Assessing the patient’s condition

Pacing and sensing information – This information can help to assess the patient’s AV conduction status and evaluate the effectiveness of programmed device settings.

Information about atrial and ventricular pacing and sensing is shown as percentages of the total time during the reporting period. This includes the percentage of time that AS-VS, AS-VP, AP-VS, and AP-VP event sequences occurred.

“MVP On” and “MVP Off” refer to the currently programmed pacing mode, not the usage of MVP mode pacing since the last session. If the device was programmed to an MVP mode during the reporting period, a high percentage of ventricular pacing may indicate that the patient has heart block.

The percentage of time that the patient experienced AT/AF can help you to assess the need to adjust the patient’s device or drug-based therapies. The time in AT/AF is calculated from the point of AT/AF onset. For more information, see Section 9.1, “Detecting atrial tachyarrhythmias”, page 237.

Note: The paced and sensed event counters do not count all events recorded by the device. For example, a ventricular safety pace is considered to be a pace, and the preceding ventricular sense is not counted. Due to rounding, percentages may not add up to 100%.

Arrhythmia episode information – This section shows the number of treated and monitored arrhythmia episodes that have occurred since the last patient session.

Select the [>>] button to review details of all arrhythmia episodes. For more information about the Arrhythmia Episodes Data screen, see Section 7.4, “Viewing Arrhythmia Episodes data and setting data collection preferences”, page 110.

7.2.2.3 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 when the device is approaching RRT or End of Service (EOS). An observation is also reported if a device reset has occurred.
- 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.

  Note: Refer to the Medtronic MRI Technical Manual for additional information about SureScan pacing systems.

- Clinical status observations alert you to abnormal patient conditions, such as low activity rates, unexpectedly high heart rates, or high arrhythmia burden.

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 clinical status observation conditions – The clinical status observations related to high arrhythmia burden and high heart rates are triggered by programmable conditions. If the AT/AF burden or the ventricular heart rate during AT/AF rises above a programmed threshold, the appropriate observation appears on the Quick Look II screen. These thresholds can be programmed from the data collection setup screen.

Select Params icon
- ⇒ Data Collection Setup…
  - ⇒ AT/AF Settings…
    - ▷ AT/AF Daily Burden
    - ▷ Avg. V. Rate During AT/AF Burden
    - ▷ Avg. V. Rate During AT/AF V. Rate

7.3 Viewing long-term clinical trends with the Cardiac Compass Report

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.

The Cardiac Compass Report provides a picture of the patient's condition during the last 14 months. Graphs show the amount of time in AT/AF, the ventricular rate during AT/AF, the percent of pacing per day, the average ventricular rate, the hours of patient activity per day, and information related to heart failure. Dates and event annotations allow you to correlate trends from different graphs. The report can help you to assess whether device therapies or antiarrhythmic drugs are effective.

Cardiac Compass trend data is available on the programmer screen or as a printed report.

The Cardiac Compass Report is based on data and measurements collected daily. Data storage for the Cardiac Compass Report 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 Cardiac Compass trend data. Storage continues until the 14-month storage capacity is filled. At that point, the oldest stored data is overwritten with new data.

Notes:

- The time annotations displayed on the report are based on the device clock.
- You cannot manually clear the Cardiac Compass trend data.

7.3.1 How to view and print Cardiac Compass Trends

Cardiac Compass trend data is available on the Cardiac Compass Trends programmer screen or in a printed report.

To view Cardiac Compass Trends on the programmer screen, select the Cardiac Compass [>>] button on the Quick Look II screen.

You can view or print Cardiac Compass Trends starting from the Data icon:

Select Data icon
⇒ Clinical Diagnostics
⇒ Cardiac Compass Trends

You can print the Cardiac Compass Trends report starting from the Reports icon:

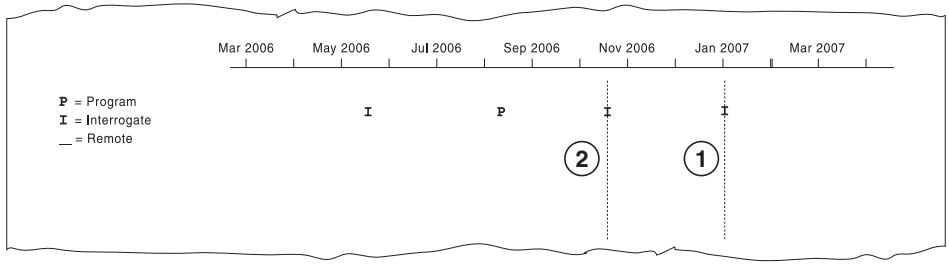
Select Reports icon
⇒ Available Reports…
⇒ Cardiac Compass Trends

7.3.2 Information provided by the Cardiac Compass Report

The Cardiac Compass Report shows events that have occurred during the reporting period. Trend graphs show the amount of time in AT/AF arrhythmias, ventricular rate during AT/AF, pacing and rate response information, and information related to heart failure.

7.3.2.1 Event information

Figure 26. Event annotations



1 Current session indicator
2 Last session indicator

Programming and interrogation events – The report shows when the device was interrogated or programmed to allow possible correlations between device parameter changes and other clinical trends.

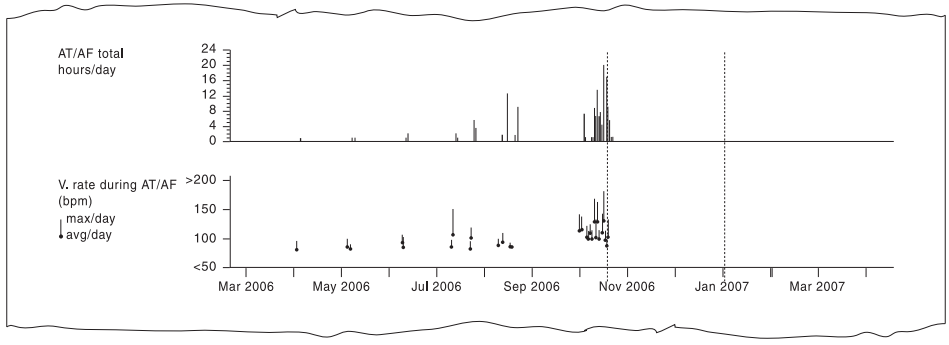
When the patient is evaluated during an office visit, the report records an “I” for a day on which the device is interrogated and a “P” for a day on which any programmable parameter is changed (except for temporary changes). If the device is interrogated and programmed on the same day, only a “P” is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

When the patient is evaluated during a Medtronic patient monitor session, the report records an “I” with a line beneath it.

Two vertical lines run through all the graphs to indicate the beginning of the current session and the beginning of the last session, if applicable.

7.3.2.2 Assessing AT/AF arrhythmia information

Figure 27. 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. It 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 about AT/AF Detection, see Section 9.1, “Detecting atrial tachyarrhythmias”, page 237.

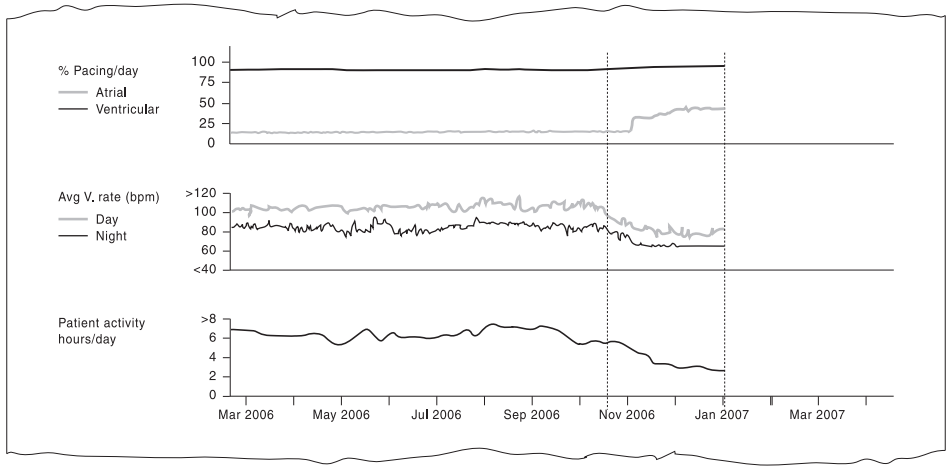
Ventricular rate during AT/AF – You can use this trend to perform the following assessments:

- 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.

7.3.2.3 Assessing pacing and rate response information

Figure 28. Pacing and rate response 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 AS-VS, AS-VP, AP-VS, and AP-VP event sequences. Atrial refractory events are excluded.

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 midnight and 04:00 (as indicated by the device clock).

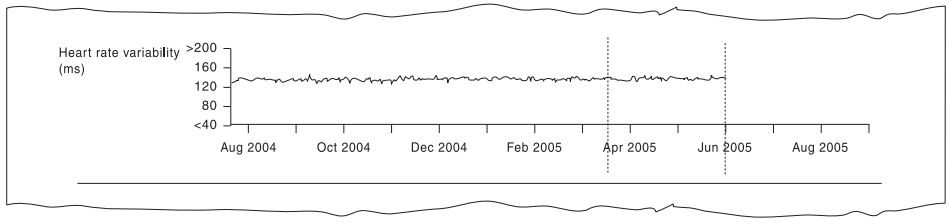
Patient activity – The patient activity trend may provide the following information:

- 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 device uses data derived from the rate response accelerometer to determine daily patient activity.

7.3.2.4 Assessing heart failure information

Figure 29. Heart failure trend graph



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 (ms) for each day.

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

7.4 Viewing Arrhythmia Episodes data and setting data collection preferences

The system provides a clinically-oriented arrhythmia episode log that enables you to quickly view summary and detailed diagnostic data for arrhythmia episodes. Episode information is available in several formats, including interval plot diagrams, EGMs, and text summaries. Various filtering tools are available to give you precise control over the types of data displayed.

7.4.1 How to view the Arrhythmia Episodes data

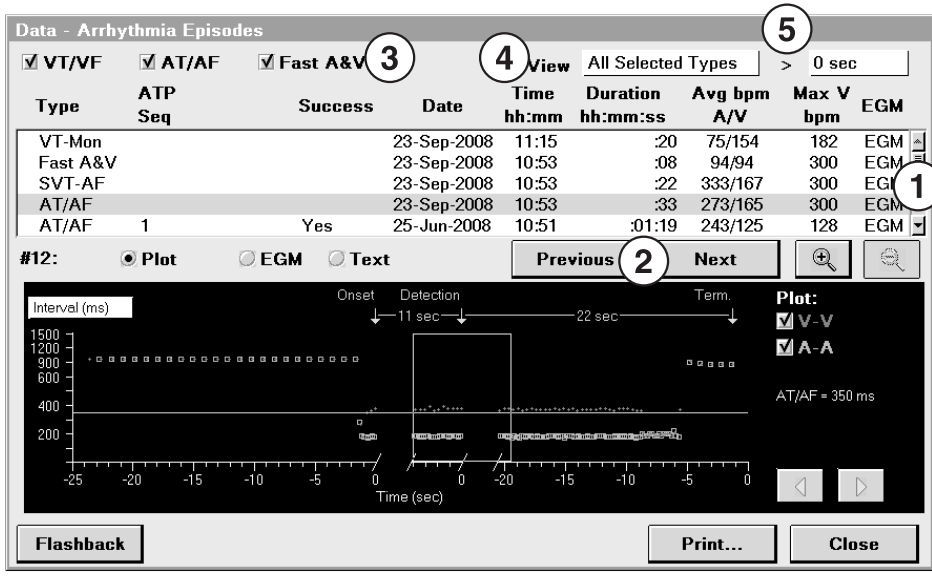
Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Arrhythmia Episodes

7.4.2 Viewing the episode log

The episode log is displayed in the upper portion of the Arrhythmia Episodes window. It provides the following summary information for the episodes currently being stored in device memory:

- 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 beats per minute
- the maximum ventricular beats per minute
- whether EGM data is available for the episode

Figure 30. Episode log



1 Use the scroll bar on the right side of the log area to scroll through the list of stored episodes.
2 Select [Next] and [Previous] to view the next or previous episode on the episode log.
3 Use the VT/VF, AT/AF, and Fast A & V check boxes to select the types of episodes you want to display.
4 Use the drop-down View filter to restrict the display to episodes with specific characteristics.
5 Use the > field to filter the list to episodes that are longer than a specific amount of time.

Avg bpm A/V – For AT/AF, VT Monitor, VT-NS, and Fast A&V episodes, the Avg bpm A/V is an average of A/V cycle length throughout the entire episode. For SVT episodes, the Avg bpm A/V is an average of the 4 beats at detection or just prior to withholding detection.

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

Notes:

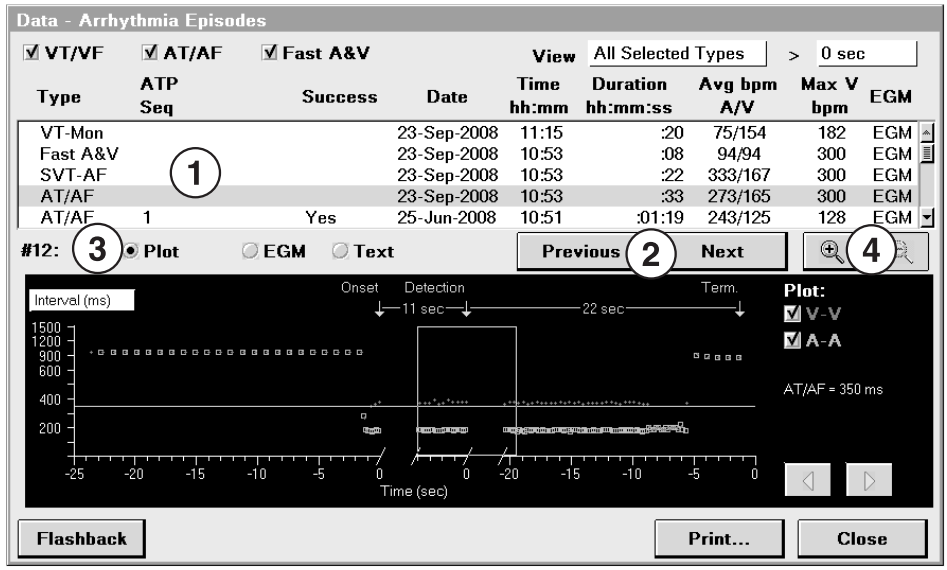
- Episodes that occur during a device session are not available to view in the episode records until an interrogation is performed. The interrogation must be performed after episode termination.
- For each episode type, when the log capacity is reached, data from the most recent episodes overwrites the oldest episode data in the log.

7.4.3 Viewing episode records

An episode record displays detailed information about the episode currently selected in the episode log. An episode record is initially displayed in the lower portion of the Arrhythmia Episodes window and can be maximized for better viewing. For a particular episode, you can display the following information:

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

Figure 31. Arrhythmia episode record



1 Select an episode record in the upper portion of the Arrhythmia Episodes window.
2 Select [Previous] and [Next] to navigate from record to record.
3 Use the Plot, EGM, and Text options to display the selected episode data in one of the available formats.
4 You can use the [+] button to maximize the plot, EGM, or text display, and the [-] button to minimize it.

Patient-Activated Symptom Log entries – If the patient has a Model 2696 InCheck Patient Assistant, you can instruct the patient to activate the device to collect data when he or she is experiencing symptoms. During patient follow-up, you can view the date, time, and average atrial and ventricular cycle lengths at the time the patient triggered data collection. This may help with diagnosis of patient symptoms when an episode is not in progress.

When the patient uses the Model 2696 InCheck Patient Assistant to activate data collection, the device stores EGM data and markers in device memory. The clinician can view the EGM and markers on the CareLink Network if it is available.

Notes:

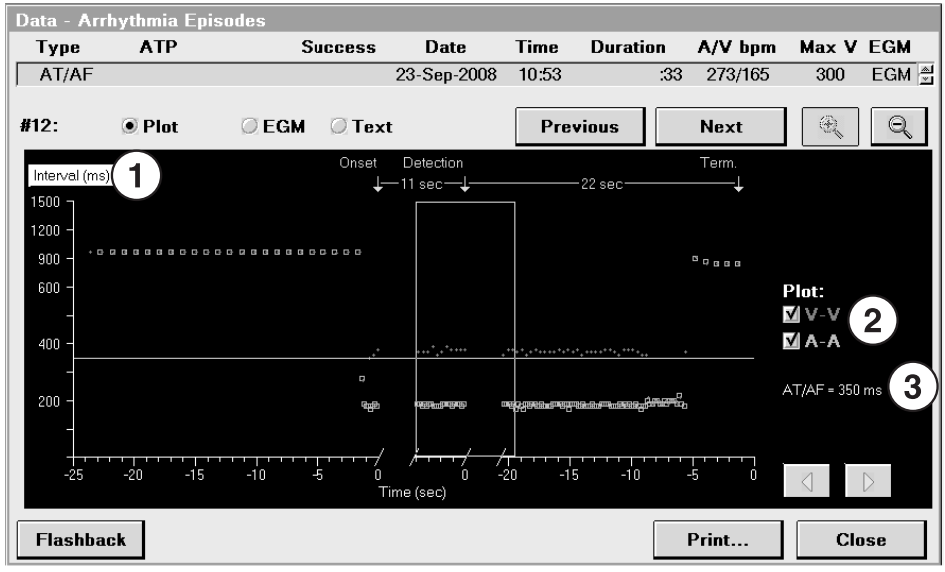
- Patient-Activated Symptom Log entries are not collected when tachyarrhythmia episodes have been detected by the device.
- If the patient uses the activator during an episode, the device records the following in the episode text: “Patient Symptom detected during episode”. However, a separate patient-activated record is not created.

7.4.3.1 Viewing the episode interval plot

When you first select an episode from the episode log, the programmer displays a graph that plots the V-V and A-A intervals versus time, and indicates the following information:

- programmed detection intervals
- point of detection or detection withheld
- point of onset for AT/AF
- points of therapy delivery

Figure 32. Episode Plot



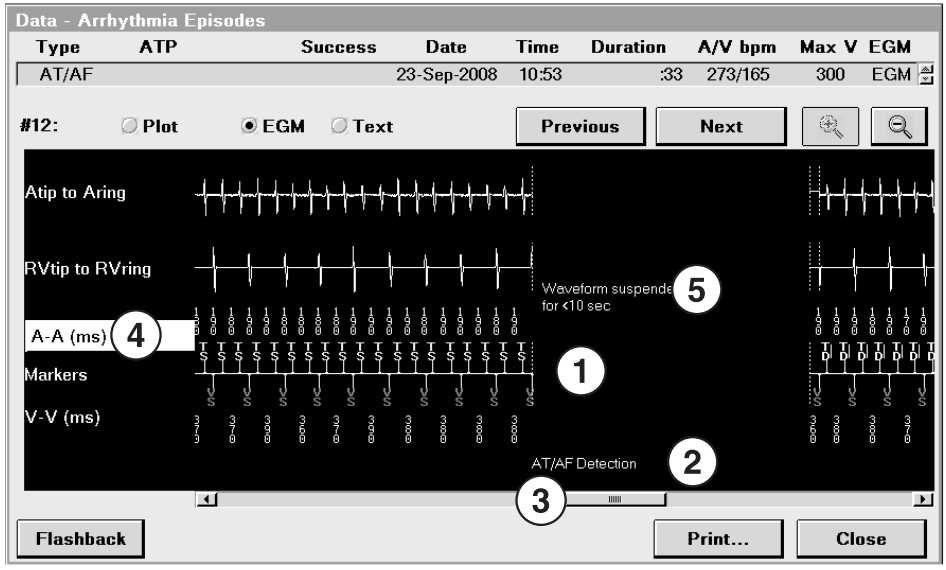
1 Use this button to switch the y-axis between interval and rate.
2 Use the Plot check boxes to display ventricular intervals, atrial intervals, or both.
3 This portion of the display shows the programmed detection intervals.

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

7.4.3.2 Viewing the episode EGM

When you select an episode from the episode log and then select the EGM option, the programmer displays the stored EGM data for the episode.

Figure 33. Episode EGM



1 The Marker Channel displays the annotated atrial and ventricular events leading up to detection.
2 The Decision Channel displays an annotation conveying the type of episode detected (here AT/AF). The EGM display must be maximized to display the Decision Channel annotations.
3 Use the horizontal scroll bar at the bottom of the screen to view all of the episode EGM data.
4 Use this button to select an option for displaying one of the atrial intervals. The EGM display must be maximized to select the atrial interval display options.
5 This annotation provides the amount of time EGM recording was suspended to conserve storage space.

EGM data storage and device memory conservation – For AT/AF episodes, the device begins to store atrial EGM data when the device detects AT/AF Onset. The device stores up to 5 s of EGM data prior to AT/AF Detection, regardless of whether a Pre-arrhythmia EGM storage option is selected. For more information about Pre-arrhythmia EGM storage, see Section 7.4.4, “How to set data collection preferences”, page 116.

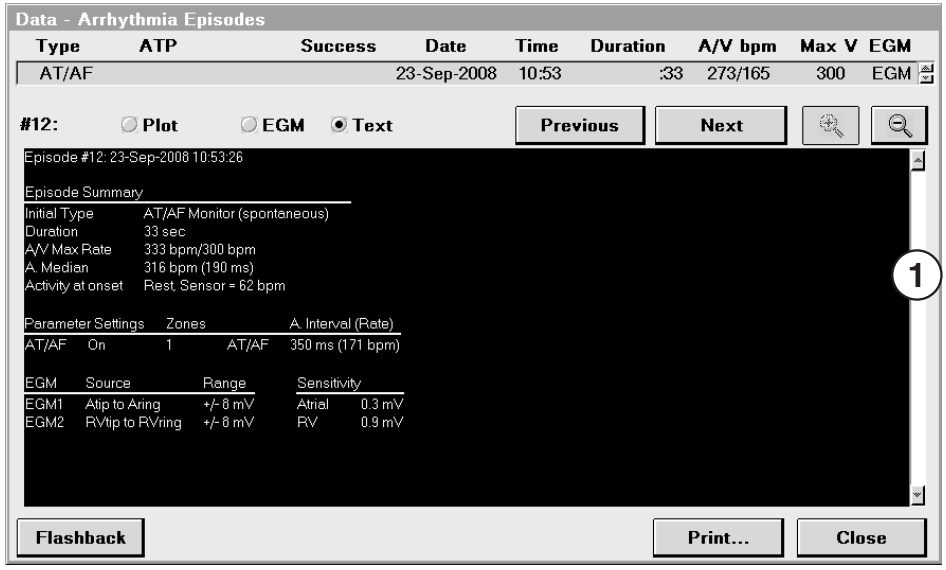
To conserve device memory, the EGM is stored only during specific parts of an episode.

Note: Long episodes may contain gaps in the EGM to save device memory.

7.4.3.3 Viewing the episode text

When you select an episode from the episode log and then select the Text option, the programmer displays a text summary of the episode.

Figure 34. Episode Text



1 Use the vertical scroll bar on the right side of the screen to scroll through all of the episode text.

7.4.4 How to set data collection preferences

Data collection is automatic and cannot be turned off. However, several preference settings that are useful for controlling the display of episode data are available on the Data Collection Setup screen. These settings also control the Live Rhythm Monitor display.

EGM source – For each EGM channel, define the source electrodes between which the device records EGM signals.

Note: 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, tachyarrhythmia interval criteria, synchronization, and therapy are not affected by your selection of EGM sources.

EGM range – For each EGM channel, select a 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.

Monitored – Select a set of 2 sources to be used for episode record storage.

Pre-arrhythmia EGM – Indicate whether you want to store EGM data collected prior to an episode. If Pre-arrhythmia EGM is programmed to On, the device stores up to 10 s of EGM

data prior to onset and detection of VT Monitor or SVT episodes. If Pre-arrhythmia EGM is programmed to Off, the episode record stores only intervals and no EGM at the beginning of each episode.

Notes:

- The Pre-arrhythmia EGM selections do not apply to AT/AF episodes. For AT/AF episodes, the device stores up to 5 s of EGM data prior to detection regardless of whether a Pre-arrhythmia EGM storage option is selected.
- 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.

Clearing data – The Clear data function clears all stored data except trend data and lifetime counters.

Note: Cleared data is not recoverable.

7.4.4.1 Programming data collection preferences

Select Params icon
- ⇒ Data Collection Setup…
  - ▷ EGM1 Source
  - ▷ EGM1 Range
  - ▷ EGM2 Source
  - ▷ EGM2 Range
  - ▷ EGM3 Source
  - ▷ EGM3 Range
  - ▷ Monitored
  - ▷ Pre-arrhythmia EGM

7.5 Viewing episode and therapy counters

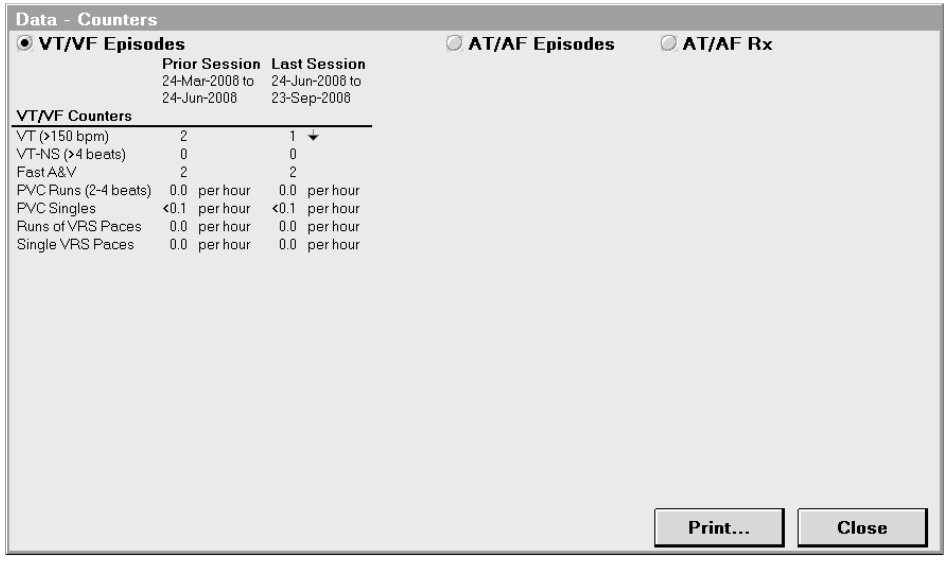
The programmer allows you to view stored data about the number of times VT/VF episodes and AT/AF episodes and therapies have occurred. The count data for ventricular episodes includes the number of Fast A&V episodes, premature ventricular contractions (PVCs), and Ventricular Rate Stabilization (VRS) paces. The count data for atrial episodes includes the number of monitored, non-sustained, treated, and pace-terminated episodes.

7.5.1 How to view the counters

Select Data icon
⇒ Clinical Diagnostics
⇒ Counters

7.5.2 VT/VF episode counters

Figure 35. VT/VF episode counters



The following count data is available for VT/VF episodes:

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.

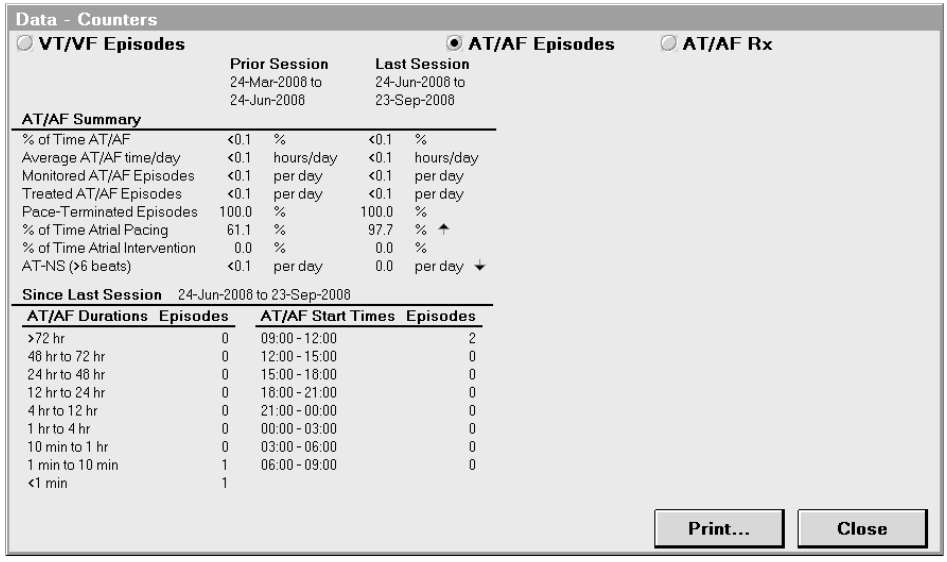
PVC Singles – The average number of single PVCs per hour. PVCs in PVC runs are not counted as PVC singles.

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.

7.5.3 AT/AF episode counters

Figure 36. AT/AF episode counters



The following count summary data is available for AT/AF episodes:

% of Time AT/AF – The percentage of total time in AT/AF. AT/AF is defined as starting from AT/AF onset.

Average AT/AF time/day – The average time in AT/AF per day. AT/AF is defined as starting from AT/AF onset.

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 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.

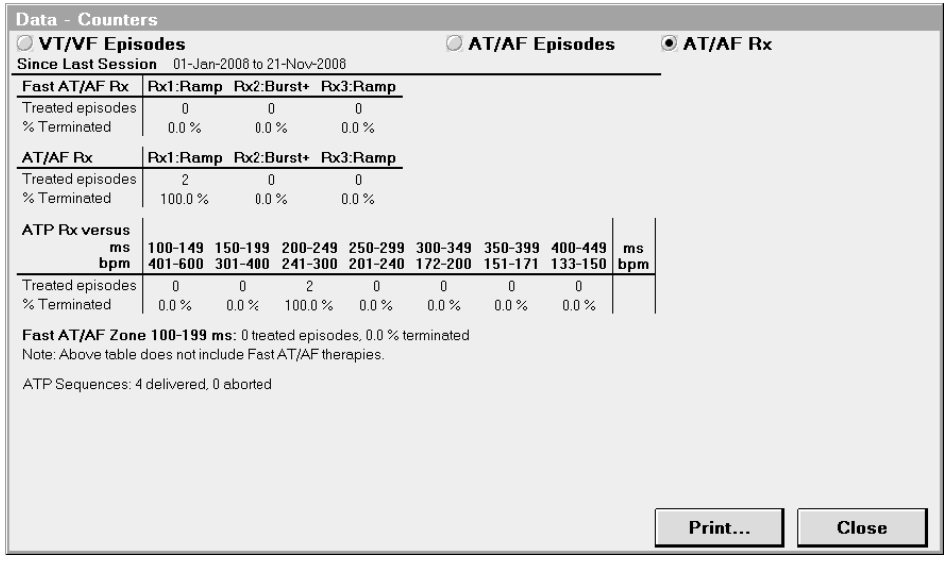
The following AT/AF Durations and Start Times information is available for AT/AF episodes:

AT/AF Durations – The number of episodes for each of a series of durations, starting with episodes lasting more than 3 days, and ending with episodes lasting less than 1 min.

AT/AF Start Times – The number of episodes falling into each of a series of 3-hour periods of the day.

7.5.4 AT/AF therapy counters

Figure 37. AT/AF therapy counters



AT/AF therapy count data is available for the period between the current interrogation and the last session.

The following data is available for AT/AF therapies:

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

AT/AF therapies – 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.

7.6 Viewing 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.

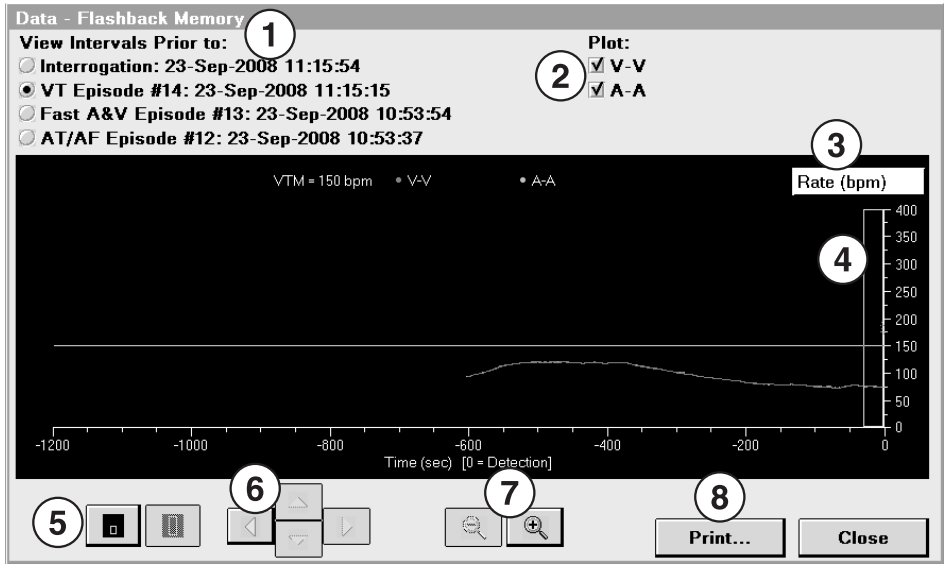
Note: When an episode is detected, Flashback Memory storage is suspended until the episode terminates.

7.6.1 How to view Flashback Memory data

Select Data icon
⇒ Clinical Diagnostics
⇒ Flashback Memory

Note: You can also display the Flashback Memory screen by selecting [Flashback] from the most recent VT, Fast A&V, or AT/AF record details screens.

Figure 38. Data – Flashback Memory screen



1 Intervals available to view
2 Plot intervals
3 Interval or Rate
4 Zoom window
5 Resize zoom window (shrink or enlarge)
6 Reposition zoom window
7 Zoom in (+); zoom out (-)
8 Print

7.7 Viewing Rate Drop Response episodes

The Rate Drop Response Episodes screen displays beat-to-beat data that is useful for analyzing rate drop response episodes and the events leading up to them. Rate Drop Response monitors the heart for significant rate drops and responds by pacing the heart at an elevated rate. For more information, see Section 8.9, “Treating syncope with Rate Drop Response”, page 198.

When Rate Drop Response is programmed on, the device records data about episodes that meet the programmed rate drop detection criteria. You can view and print data for the last 10 episodes.

List of rate drop episodes – The Rate Drop Response Episodes screen provides several facts about each episode. Type indicates the method by which the episode was detected (Drop Detection or Low Rate Detection). Date and Time indicate when the episode was detected. Detection V. Rate bpm specifies the heart rate at the moment when the episode was detected. Peak V. Rate bpm lists the peak ventricular rate before detection (for Drop Detection episodes only).

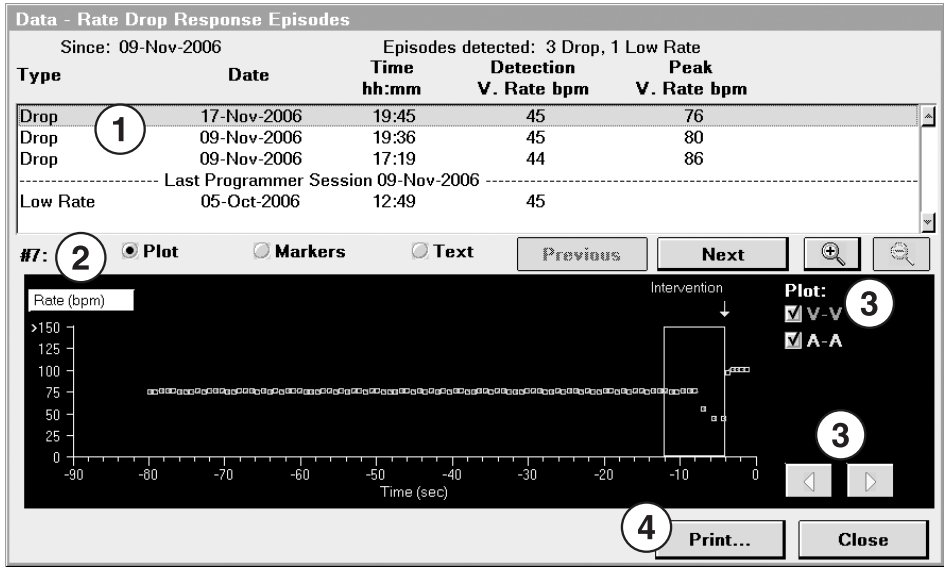
Available views – The Rate Drop Response Episodes screen allows you to select from different views of the episode. Selecting Plot shows the beat-to-beat data for the selected episode. Selecting Markers provides the data as annotated marker channels. Selecting Text allows you to review Rate Drop Response settings that were in effect at the start of the programming session.

Plot of the selected episode – The plot shows beat-to-beat data for the period before detection, the rate drop leading up to detection, and the first few beats of intervention pacing (when the device paces the heart at an elevated rate). Much of the plot depicts the period before detection; this enables you to study events that may precede rate drop episodes. The yellow box displayed over the plot marks the period for which you can view marker channel data. To view this data, select Markers. To view Marker Channel data for a different period, move the scroll bar.

7.7.1 How to view Rate Drop Response episode data

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Drop Response Episodes

Figure 39. Rate Drop Response Episodes screen showing the Plot view



1. Select a Rate Drop Response episode from the list.
2. The different views of the selected episode are displayed in this window. Select the desired view.
3. To modify or navigate the screen, you have the following options:
   - Select (+) to enlarge the window. Select (-) to reduce the size of the window.
   - Select the check boxes to show or hide plot intervals as desired.
   - Select < or > to move the yellow box to the desired area of the episode plot. Select Markers to view the corresponding Marker Channel data.
   - Slide the navigation bar back and forth to move to the desired area of the Markers view.
   - Select [Previous] and [Next] to display other episodes.
4. Select [Print…] to print reports. You can print a detailed report of the selected episode, a summary of all episodes, or both.

7.8 Using rate histograms to assess heart rates

Information about heart rates recorded between patient sessions can help you to monitor a patient's condition to assess the effectiveness of therapies. The Rate Histograms Report shows the distribution of atrial and ventricular rates recorded Prior to Last Session and Since Last Session. Rate histogram data is available on the programmer screen or as a printed report.

7.8.1 How to view and print Rate Histograms

To view or print Rate Histograms from the Data icon:

Select Data icon
⇒ Clinical Diagnostics
⇒ Rate Histograms

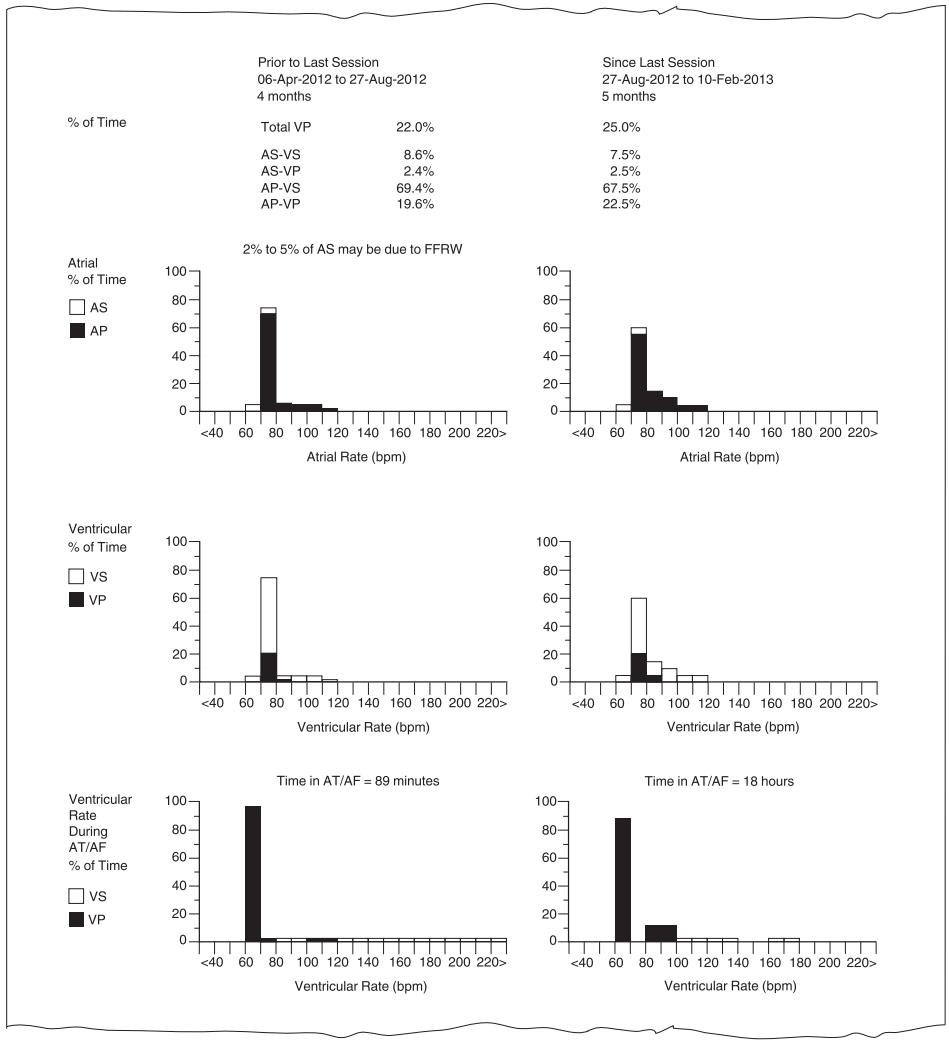
To print Rate Histograms starting from the Reports icon:

Select Reports icon
⇒ Available Reports…
⇒ Rate Histograms

7.8.2 Information provided by the Rate Histograms Report

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

Figure 40. Rate Histograms Report



The rate histogram shows 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 < to 40 range; rates faster than 220 bpm are included in the 220 to > range.

% of Time – This section shows the patient's conduction status as the percentage of the total time that the device paced or sensed during the collection period. The percentages are calculated from the daily counts of AS-VS, AS-VP, AP-VS, and AP-VP event sequences.

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). The histogram also indicates if the percentage of atrial senses that may be due to far-field R-wave (FFRW) sensing is 2% or greater. If so, the percentage is reported within one of two ranges: 2% to 5% of AS may be due to FFRW or >5% of AS may be due to FFRW. Far-field R-wave sensing may be suspected if the intervals between atrial sensed events are irregular.

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[2]. This histogram may be used to monitor the effectiveness of ventricular rate control therapy and drug titration.

7.9 Viewing detailed device and lead performance data

The device automatically measures and records device and lead performance data every day. Detailed views of this data are available from the Battery and Lead Measurements screen and the Lead Trends screen.

7.9.1 Viewing battery and lead measurement data

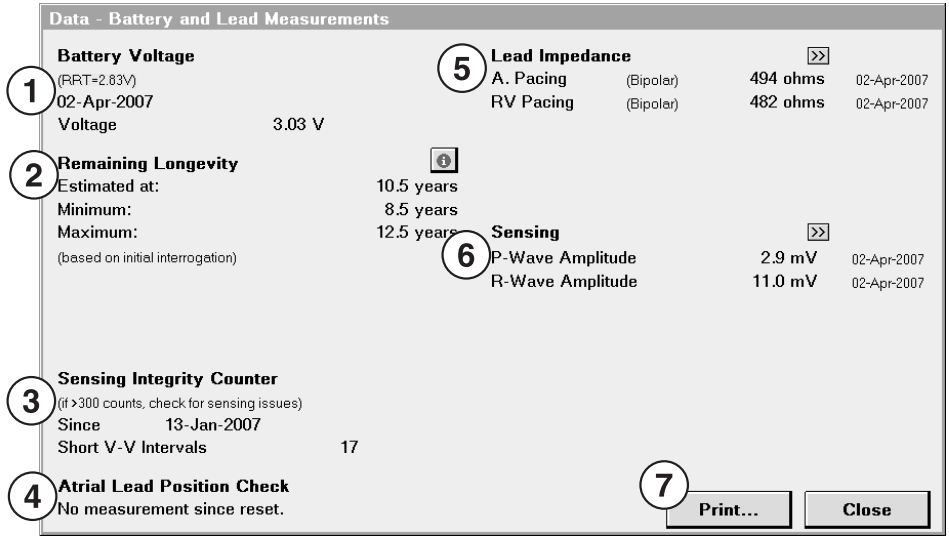
The Battery and Lead Measurements screen displays the most recent values for key measures of device and lead performance. These may include automatically measured values or those measured during manual system tests.

7.9.1.1 How to view battery and lead measurement data

Select Data icon
- ⇒ Device/Lead Diagnostics
  - ⇒ Battery and Lead Measurements

[2] The time in AT/AF is calculated from the point of AT/AF Onset. For more information, see Section 9.1, "Detecting atrial tachyarrhythmias", page 237.

Figure 41. Battery and Lead Measurements screen



1 Battery voltage and replacement indicator information
2 Longevity estimates
3 Sensing Integrity Counter
4 Result of the last Atrial Lead Position Check
5 Most recent lead impedance measurements
6 Most recent daily automatic sensing amplitude measurements
7 Select [Print…] to print a Battery and Lead Measurements Report

7.9.1.2 Battery voltage and replacement indicators

The device automatically measures the battery voltage several times a day. At midnight, the device calculates the automatic daily battery voltage by averaging the measurements taken during the previous 24 hours. The most recent automatic daily battery voltage measurement is displayed on the Battery and Lead Measurements screen.

If 3 consecutive automatic daily battery voltage measurements are less than or equal to the Recommended Replacement Time (RRT) value, the programmer displays the RRT symbol and the date when the battery reached RRT. If the programmer displays the RRT symbol, contact your Medtronic representative and schedule an appointment to replace the device.

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.[3] When the device reaches ERI, it automatically changes the pacing mode to VVI and sets the pacing rate to 65 bpm. It also changes the value of several other programmed parameters. For more information, see Section A.2, “Replacement indicators”, page 288 for Advisa DR, and Section B.2, “Replacement indicators”, page 296 for Advisa SR. After the 180-day PSP has expired, the device reaches End of Service (EOS), and the programmer displays the EOS symbol.[3]

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.

7.9.1.3 Remaining longevity estimates

Starting 2 weeks after the device is implanted, the programmer is able to estimate the remaining device longevity (the number of years until the battery reaches RRT). Longevity estimates are based on a history of battery voltage measurements made by the device since implant.

The Battery and Lead Measurements screen displays maximum, minimum, and mean values for remaining longevity. These values are based on a statistical analysis of accelerated battery discharge data. 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 the battery voltage reaches the RRT value, the Battery and Lead Measurements screen displays “Replace Device” instead of an estimate of remaining longevity. 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. See Section A.2, “Replacement indicators”, page 288 for Advisa DR, and Section B.2, “Replacement indicators”, page 296 for Advisa SR.

[3] 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 Prolonged Service Period. For an explanation of these conditions, see Section A.2, “Replacement indicators”, page 288 for Advisa DR, and Section B.2, “Replacement indicators”, page 296 for Advisa SR

7.9.1.4 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.

7.9.1.5 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 about the Atrial Lead Position Check, see Section 10.1, “Scheduling atrial therapies”, page 257.

7.9.1.6 Lead impedance and sensing amplitude measurements

The Battery and Lead Measurements screen displays recent lead impedance and sensing amplitude measurements. For lead impedance measurements, the screen displays the most recent manually performed measurements or the most recent daily automatic measurements. For sensing amplitude measurements, the screen displays the most recent daily automatic measurements. Measurements performed with the manual Sensing Test are not displayed on the Battery and Lead Measurements screen. For more information about performing manual lead impedance measurements, see Section 11.3, “Measuring lead impedance”, page 276. For more information about performing manual sensing amplitude measurements, see Section 11.4, “Performing a Sensing Test”, page 277.

You can compare the most recent measurements to the trends of daily automatic measurements by selecting the Lead Impedance [>>] button or Sensing [>>] button to view the Lead Trends screen.

7.9.2 Viewing lead impedance trends

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

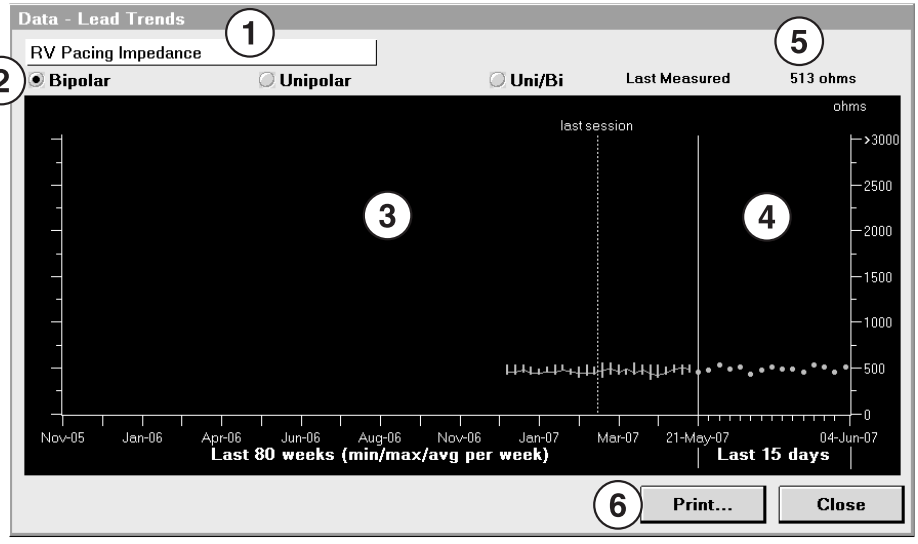
The daily automatic lead impedance measurements are displayed on the Lead Trends screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or sudden 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.

7.9.2.1 How to view lead impedance trends

Select Data icon
- ⇒ Device/Lead Diagnostics
  - ⇒ Lead Impedance Trends

Figure 42. Lead Trends screen showing the RV Pacing Impedance trend



1 Selected measurement trend
2 Selected polarity to display
3 Weekly minimum, maximum, and average values
4 Most recently measured values
5 Last measured impedance value
6 Select [Print…] to print a Lead Trends Report

7.9.3 Viewing sensing amplitude trends

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 midnight, 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 80 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.

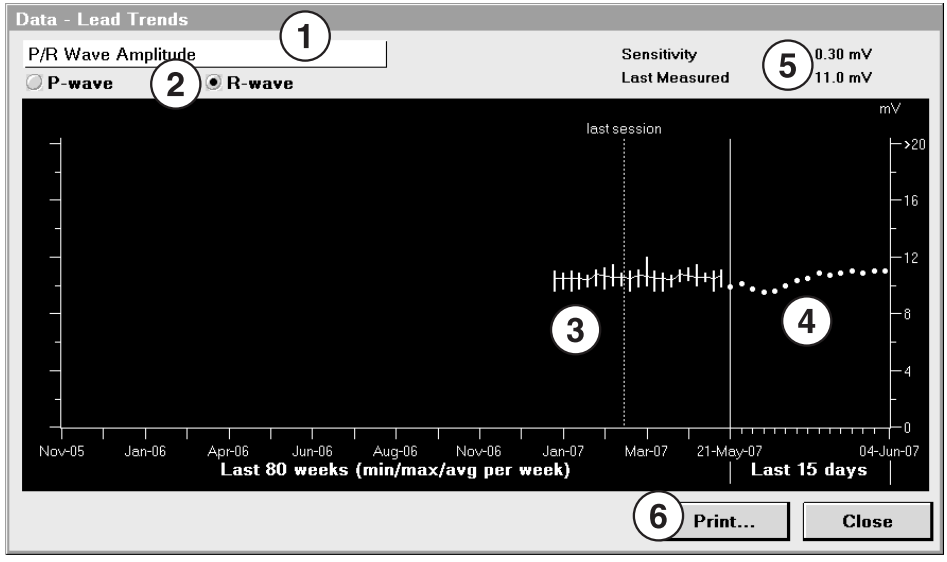
7.9.3.1 How to view sensing amplitude trends

Select Data icon

⇒ Device/Lead Diagnostics

⇒ P/R Wave Amplitude Trends

Figure 43. Lead Trends screen showing the R-wave amplitude trend



1 Selected measurement trend
2 Selected amplitude measurement type
3 Weekly minimum, maximum, and average values
4 Most recently measured values
5 Last automatic daily measurement
6 Select [Print…] to print a Lead Trends Report

7.9.4 Viewing capture threshold trends

If Capture Management 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 about Capture Management, see Section 8.5, “Managing pacing output energies with Capture Management”, page 177.

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 80 weekly summary measurements (showing minimum, maximum, and average values for each week).

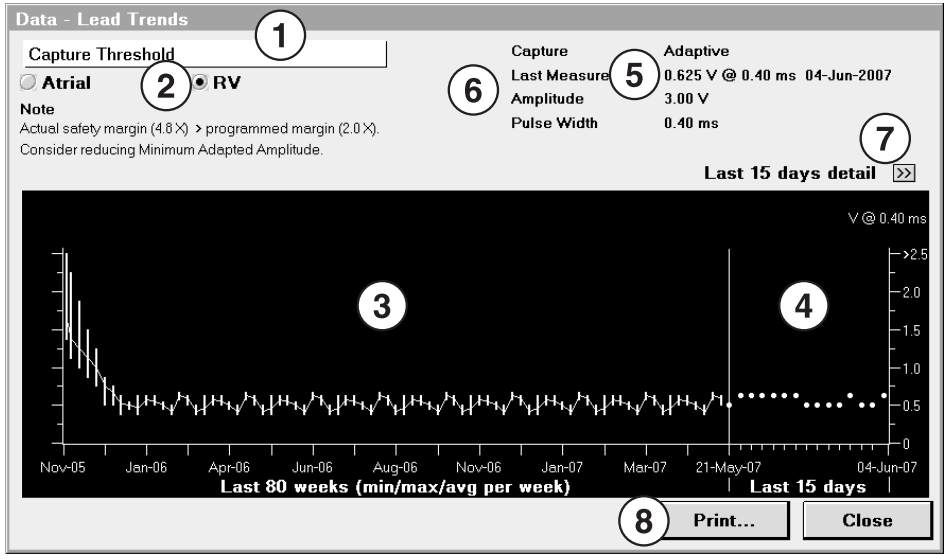
The Lead Trends screen also displays programmed values for pacing output and Capture Management parameters, the last measured threshold value, and a link to a detailed view of the last 15 days of threshold measurement data. The details screen shows daily results from the last 15 days of threshold measurements. 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 the operation of Capture Management 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.

7.9.4.1 How to view capture threshold trends

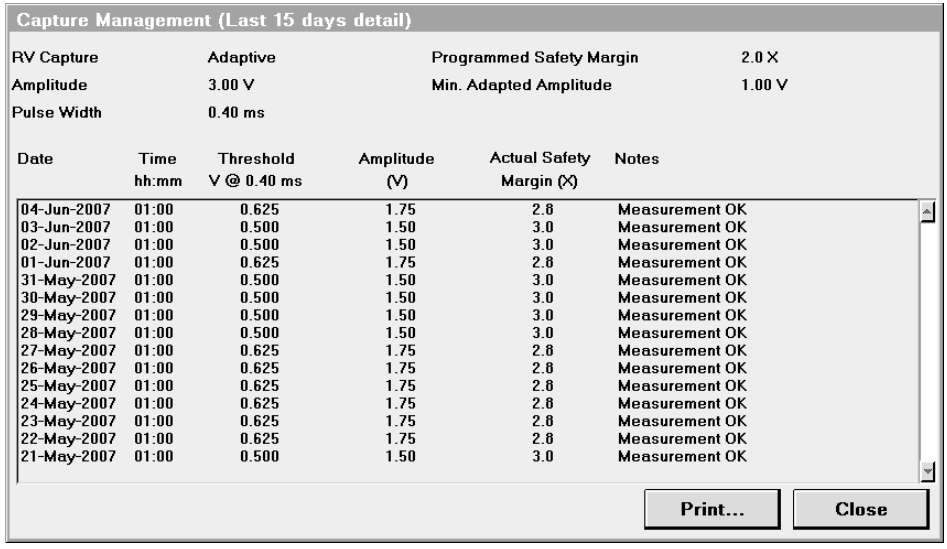
Select Data icon
⇒ Device/Lead Diagnostics
⇒ Capture Threshold Trends

Figure 44. Lead Trends screen showing the RV Capture Threshold trend



1 Selected measurement trend
2 Selected chamber to display
3 Weekly minimum, maximum, and average values
4 Most recently measured values
5 Last measured threshold value
6 Capture Management and pacing output parameter values
7 Select [>>] to view threshold measurement details from the last 15 days
8 Select [Print…] to print a Lead Trends Report

Figure 45. RV Capture Threshold trend detail



7.10 Automatic device status monitoring

The device automatically and continuously monitors for electrical reset and disabled therapy conditions. During each interrogation, the device reports detected conditions that require attention as device status indicator warnings and then displays these warnings on the programmer screen. Device status indicator warnings are displayed both as a pop-up window on the programmer screen and in the Observations box on the Quick Look II screen. A specific procedure about how to respond to the device status indicator warning for electrical reset is provided in Section 7.10.2, “How to respond to the device status indicator warning for electrical reset”, page 136.

Caution: The device status indicators are important. Please inform your Medtronic representative if any of the indicators are displayed on the programmer screen after interrogating a device.

To clear the displayed status indicator, select [Clear] in the pop-up window that displays the device status indicator warning.

7.10.1 Definitions of device status indicator warnings

Warning - Device Electrical Reset – Indicates that an electrical reset has occurred. An electrical reset can be either a full reset or a partial one. When a full reset occurs, the

programmed parameters are reset to the default electrical reset values. When a partial reset occurs, the reset does not affect any programmed parameters. For information about dual chamber device reset settings, see Appendix C, “Advisa DR device parameters”, page 301; for information about single chamber device settings, see Appendix D, “Advisa SR MRI device parameters”, page 315. Read the message accompanying the indicator and follow the screen instructions carefully. See the following section for instructions about what to do in the event of an electrical reset. If the error message does not indicate that parameters have been reprogrammed, then the reset was a partial reset and did not affect any programmed parameters.

An electrical reset is a device-activated safety feature that can reset device parameters to values that provide basic device functionality. These basic parameters are considered safe for the majority of patients. Pacing in VVI mode remains active during a reset condition. An electrical reset may occur when the device is exposed to extreme conditions, such as cold temperatures (before implant); intense, direct x-ray exposure; electrocautery; or external defibrillation. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen.

After an electrical reset, the programmer and Medtronic patient Monitor may not be able to communicate with the device. If this occurs, inform a Medtronic representative. **Immediate replacement of the device is recommended.**

SERIOUS DEVICE ERROR – Indicates an error has occurred from which the device cannot recover. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

AT/AF Therapies Disabled – Atrial therapies can be disabled for the following reasons:

- 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 10.1, “Scheduling atrial therapies”, page 257.

7.10.2 How to respond to the device status indicator warning for electrical reset

If the programmer reports that an electrical reset occurred and the device is not yet implanted, do not implant the device. Contact a Medtronic representative. If the device is implanted, perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).
2. Notify a Medtronic representative.
3. Select [Clear] in the pop-up window to clear the reset indicator. A confirmation window appears indicating that all previously interrogated data in the programmer will be cleared.
4. Select [Continue].
5. Interrogate the device.
   a. Note the time and date when counter data was last cleared because this indicates when the electrical reset occurred.
   b. Determine, if possible, what the patient was doing at the time and date the electrical reset occurred.
   c. Save your session data to disk. You should give a copy of this saved data file to your Medtronic representative; it will be helpful in determining the events leading up to the reset.
6. Verify the programmed device parameters. If a full electrical reset occurred, the primary reprogrammed values are displayed in the error message. If a full electrical reset occurred, reprogram the device parameters.

   After this type of reset, the device operates in VVI mode until it is reprogrammed. For more information about reset settings, see Appendix C, “Advisa DR device parameters”, page 301 and Appendix D, “Advisa SR MRI device parameters”, page 315.
7. Verify that the device date and time are correct. If necessary, reprogram the date and time.
8. Interrogate the device again. Check the Battery and Lead Measurements screen to verify that the battery voltage is acceptable.
9. Conduct lead impedance and pacing threshold tests as desired.

7.11 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 estimated Remaining Longevity of a device, refer to the Quick Look II screen. For information about the longevity of the device, see Section A.3, “Projected service life”, page 289 for Advisa DR, and Section B.3, “Projected service life”, page 297 for Advisa SR.

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

7.11.1 Promoting intrinsic AV conduction

Managed Ventricular Pacing (MVP) – MVP promotes AV conduction by reducing unnecessary right ventricular pacing. This primary benefit of MVP is therapeutic but it may also increase device longevity as a result of a decrease in the percentage of pacing. For more information about MVP, see Section 8.3, “Reducing unnecessary ventricular pacing with MVP mode”, page 163.

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 increase device longevity. For more information, see Section 8.2, “Providing pacing therapies”, page 152.

7.11.2 Managing pacing outputs

Capture Management – Capture Management provides the device with automatic monitoring and follow-up capabilities for managing pacing thresholds in the right ventricle and atrium. This feature is designed to monitor the pacing threshold and, optionally, to adjust the pacing outputs to maintain capture. Programming Capture Management allows the device to set the pacing amplitude just high enough to maintain capture while preserving battery energy. For more information about Capture Management, see Section 8.5, “Managing pacing output energies with Capture Management”, page 177.

Manually optimizing amplitude and pulse width – If you choose to program Capture Management 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. This decreases the pacing outputs and preserves battery energy. For more information about pacing thresholds, see Section 11.2, “Measuring pacing thresholds”, page 274.

Pacing rate – The more paced events that are delivered, the more battery 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, Conducted AF Response, and Rate Response only for patients who can receive therapeutic benefit from the feature.

7.11.3 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 10 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 up to 5 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 battery 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.

8 Configuring pacing therapies

8.1 Sensing intrinsic cardiac activity

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.

8.1.1 System solution: sensing

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 operation of some sensing features depends on lead polarities. The device operates with bipolar leads or unipolar leads. The sensing and pacing lead polarities may be configured individually in the atrium and right ventricle to be bipolar or unipolar. Several conditions account for bipolar leads operating in a unipolar configuration. Unipolar operation can result from manual programming or through automatic lead configuration, which occurs during implant detection. If Lead Monitor is programmed to Adaptive for any polarity, the device switches that polarity setting from bipolar to unipolar when the lead integrity is in doubt. For more information, refer to Section 8.6, “Configuring lead polarity”, page 189.

Note: MRI SureScan cannot be On unless A Pace Polarity and RV Pace Polarity are set to Bipolar.

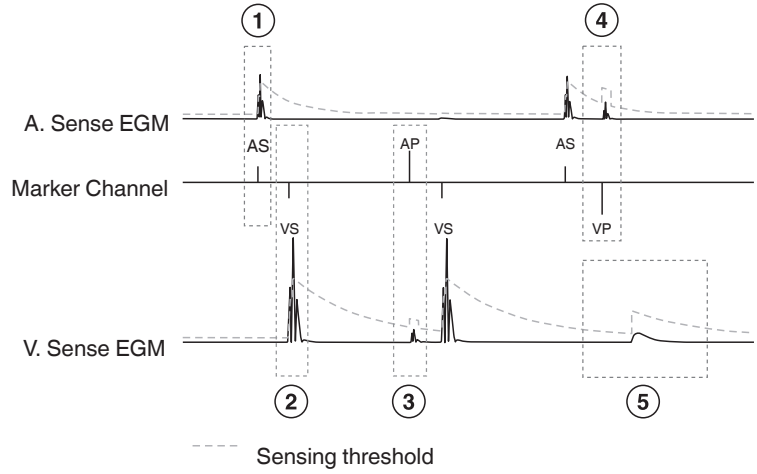
8.1.2 Operation of sensing thresholds

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. For information about sensing with unipolar leads, refer to Section 8.1.2.2.

8.1.2.1 Bipolar sensing

The device automatically adjusts the sensing threshold for a lead that is configured for bipolar sensing. The 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 46.

Figure 46. Adjustment of sensing thresholds with bipolar sensing



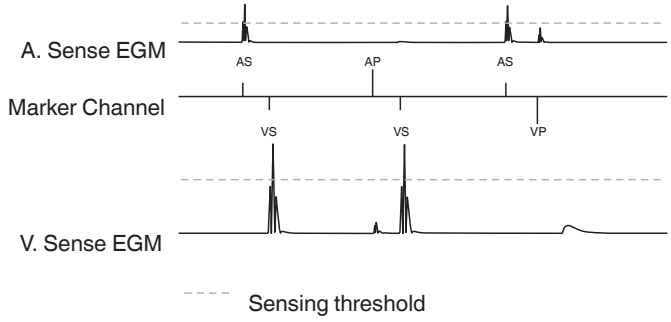
1 After an atrial sensed event, the device is temporarily less sensitive to atrial events.
2 After a ventricular sensed event, the device is temporarily less sensitive to ventricular events.
3 After an atrial paced event, the device is temporarily less sensitive to ventricular events, but the sensitivity 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.

8.1.2.2 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 47.

Figure 47. Fixed sensing thresholds with unipolar sensing

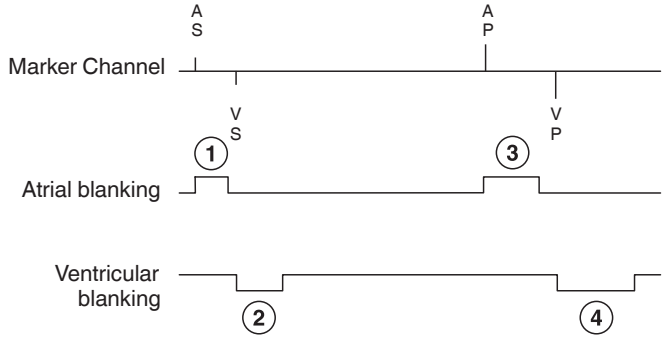


8.1.3 Operation of blanking periods

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 48. 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 10 are nonprogrammable.

Table 10. 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.

8.1.4 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. Refer to Section 8.1.4.1 and Figure 49 for information about PVAB operation if the atrial lead is configured for bipolar sensing. Refer to Section 8.1.4.2 and Figure 50 if the atrial lead is configured for unipolar sensing.

8.1.4.1 PVAB operation with bipolar atrial sensing

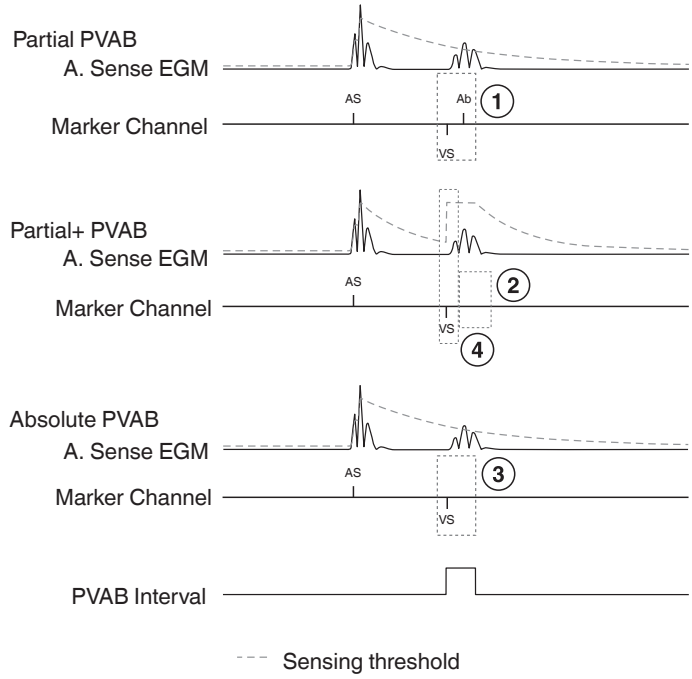
Partial PVAB – When the Partial PVAB method is used, atrial events sensed during the programmed PVAB interval are not used by the bradycardia pacing features but are used by the tachyarrhythmia detection features.

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, but 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 49. 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.

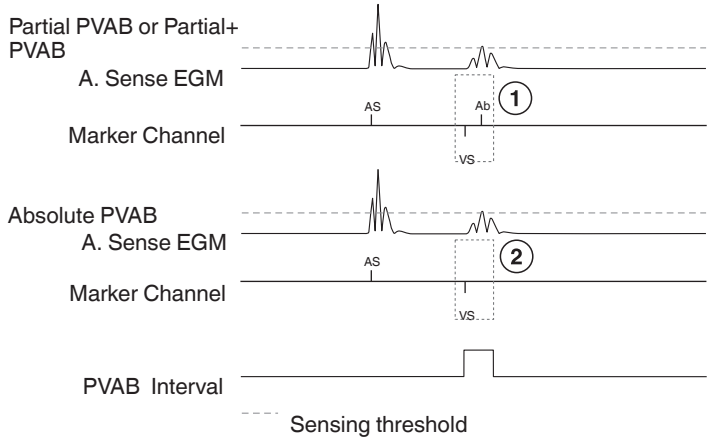
8.1.4.2 PVAB operation with unipolar atrial sensing

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 50. 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.

8.1.5 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.

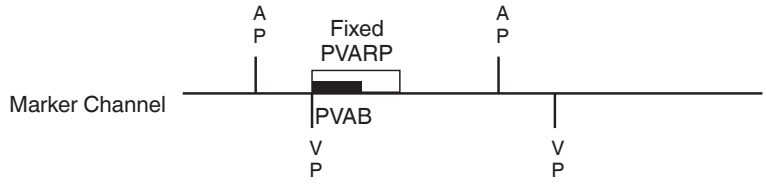
The availability of refractory periods depends on the programmed pacing mode. The Post Ventricular Atrial Refractory Period (PVARP) is available in dual chamber pacing modes, and the Atrial Refractory Period is available in atrial pacing modes.

8.1.5.1 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 51. 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 8.8, "Adjusting PVARP to changes in the patient's heart rate", page 195.

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

8.1.5.2 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.

8.1.6 Programming considerations for sensing

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.

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 A. 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 sensing threshold, set by reprogramming the A. 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 8.12, “Preventing competitive atrial pacing”, page 209.

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.

8.1.7 Programming sensing

8.1.7.1 Programming sensitivities, polarities, and blanking periods

Select Params icon
- ▷ A. Sensitivity
- ▷ RV Sensitivity
  - ⇒ Atrial Sense Polarity…
    - ▷ Atrial Pace Polarity…
    - ▷ Atrial Sense Polarity…
    - ▷ RV Pace Polarity…
    - ▷ RV Sense Polarity…
    - ⇒ Blanking…
      - ▷ PVAB Interval
      - ▷ PVAB Method
      - ▷ A. Blank Post AP
      - ▷ A. Blank Post AS
      - ▷ V. Blank Post VP
      - ▷ V. Blank Post VS

8.1.7.2 Programming refractory periods

Select Params icon
- ⇒ PVARP…
  - ▷ PVARP (or A. Refractory)
  - ▷ Minimum PVARP

8.1.8 Evaluation of sensing

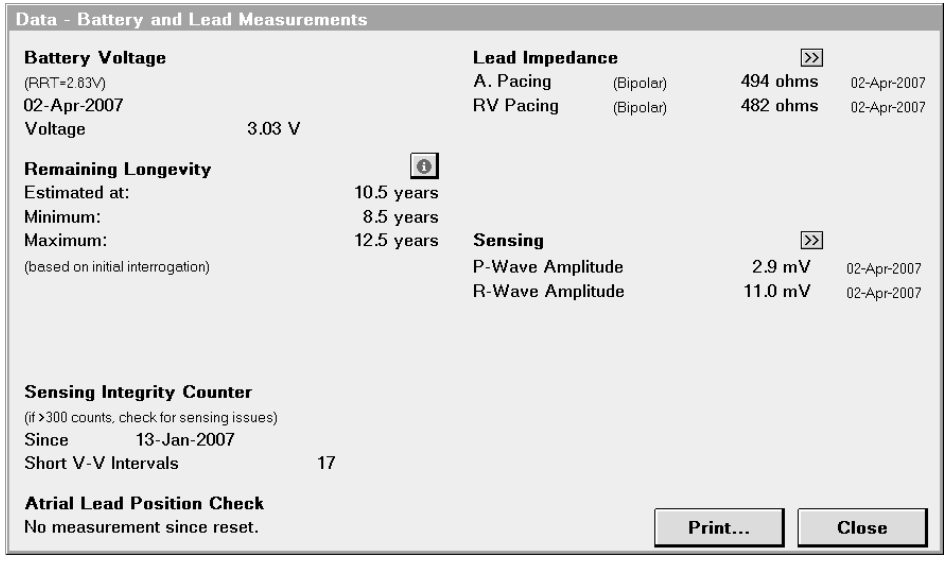
8.1.8.1 Using the Sensing Test to evaluate sensing

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, refer to Section 11.4, “Performing a Sensing Test”, page 277.

8.1.8.2 Viewing the Sensing Integrity Counter

Select Data icon
- ⇒ Device/Lead Diagnostics
  - ⇒ Battery and Lead Measurements

Figure 52. Battery and Lead Measurements screen



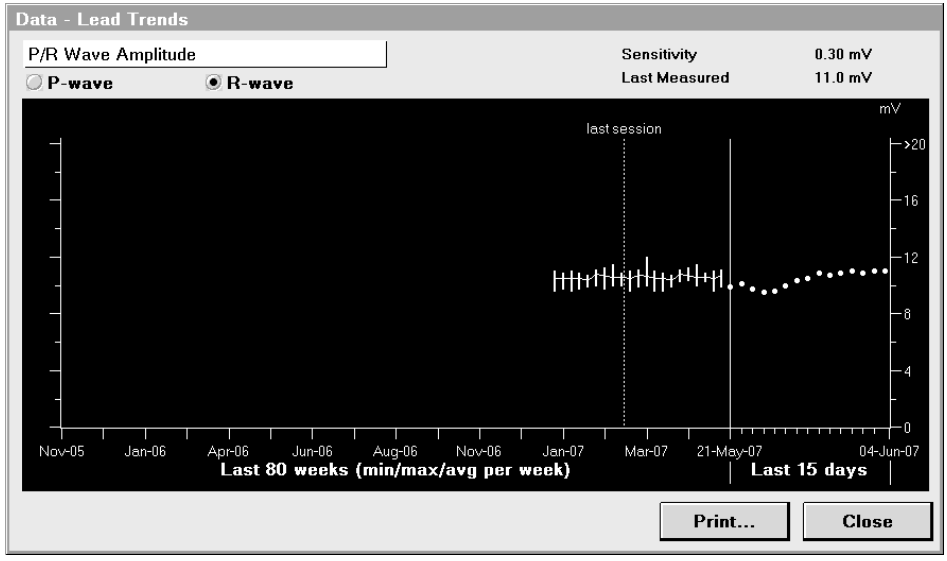
The Sensing Integrity Counter records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate oversensing, lead fracture, or a loose setscrew. If the Sensing Integrity Counter reports more than 300 short ventricular intervals,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

8.1.8.3 Viewing P-wave and R-wave amplitude trends

Select Data icon
- ⇒ Device/Lead Diagnostics
  - ⇒ P/R Wave Amplitude Trends

Figure 53. R-wave Amplitude trend



Every day at 2:15 AM, 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 midnight no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

8.2 Providing pacing therapies

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.

8.2.1 System solution: pacing therapies

The system provides dual chamber and single chamber pacing modes to 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.

8.2.2 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 8.5, “Managing pacing output energies with Capture Management”, page 177.

The device provides sensing in both the atrium and right ventricle. Refer to Section 8.1, “Sensing intrinsic cardiac activity”, page 140, for information about sensing thresholds, lead polarities, blanking periods, and refractory periods.

8.2.3 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.

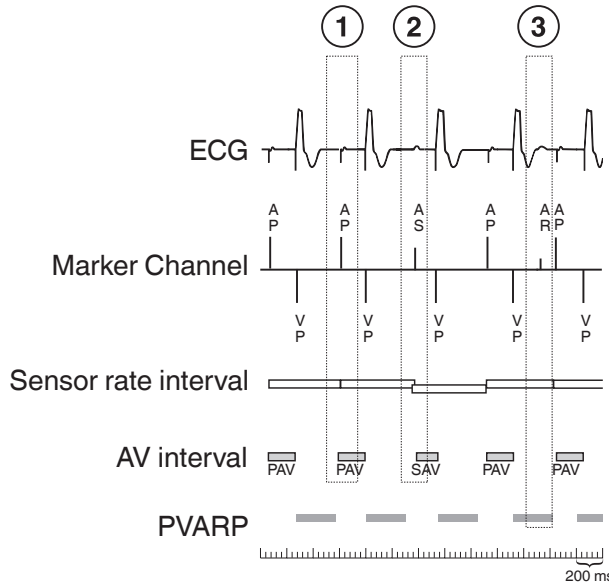
8.2.3.1 AAIR<=>DDDR and AAI<=>DDD modes

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 8.3, “Reducing unnecessary ventricular pacing with MVP mode”, page 163.

8.2.3.2 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 54). 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, does not inhibit atrial pacing, and is not tracked. For more information, see Section 8.8, “Adjusting PVARP to changes in the patient’s heart rate”, page 195.

Figure 54. Operation of dual chamber pacing in DDDR

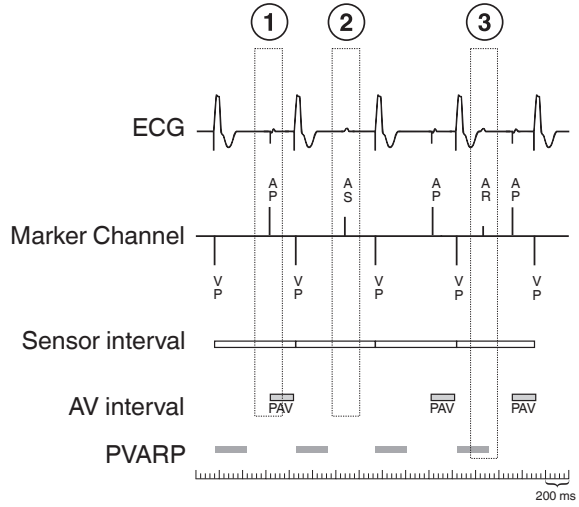


1 An atrial paced event starts a PAV interval.
2 An atrial sensed event starts an SAV interval.
3 An atrial sensed event during PVARP is not tracked.

8.2.3.3 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 55). 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 8.8, “Adjusting PVARP to changes in the patient’s heart rate”, page 195.

Figure 55. 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.

8.2.3.4 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.

8.2.3.5 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.

8.2.4 Operation of single chamber pacing

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

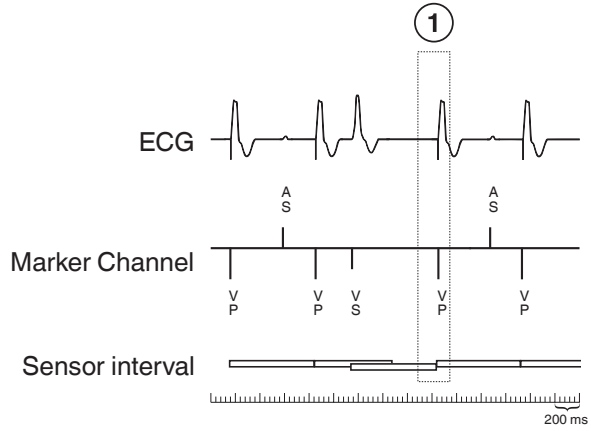
8.2.4.1 AAIR<=>DDDR and AAI<=>DDD modes

For information about the AAIR<=>DDDR and AAI<=>DDD modes (MVP modes), see Section 8.3, “Reducing unnecessary ventricular pacing with MVP mode”, page 163.

8.2.4.2 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 56). In VVIR and VVI modes, the device continues sensing atrial events for tachyarrhythmia detection purposes.

Figure 56. Operation of single chamber ventricular pacing in VVIR



1 A ventricular paced event occurs when no intrinsic ventricular event is sensed.

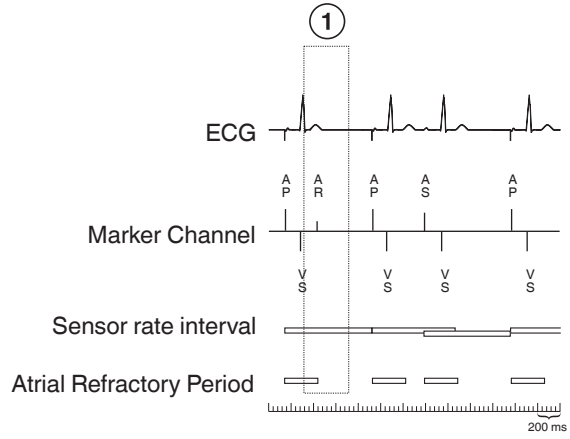
8.2.4.3 AAIR and AAI modes

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 57).

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. 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 57. 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.

8.2.4.4 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.

8.2.4.5 OVO mode (bradycardia pacing off)

The OVO mode does not deliver ventricular pacing, regardless of the intrinsic rate. The OVO mode 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.

8.2.4.6 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.

8.2.5 Programming considerations for pacing therapies

8.2.5.1 Pacing mode selection

TherapyGuide – It is suggested that you use TherapyGuide to determine the pacing mode for a particular patient. For more information, see Section 4.8, “Using TherapyGuide to select parameter values”, page 46.

8.2.5.2 Programming considerations for dual chamber pacing

SAV and PAV intervals – The SAV interval is usually programmed 30 ms to 50 ms shorter than the PAV interval. This programming 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 8.2.8, “Tracking rapid atrial rates”, page 160.

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 8.2.8, “Tracking rapid atrial rates”, page 160). 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.

8.2.6 Programming pacing therapies

Select Params icon
- ▷ Mode
- ▷ Lower Rate
- ▷ Upper Track
- ▷ Upper Sensor
- ▷ Atrial Amplitude
- ▷ Atrial Pulse Width
- ▷ RV Amplitude
- ▷ RV Pulse Width
  - ⇒ Paced AV…
    - ▷ Paced AV
    - ▷ Sensed AV

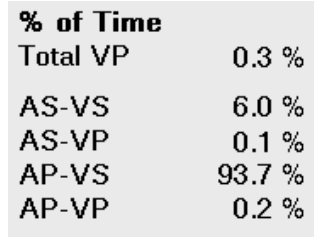
8.2.7 Evaluation of pacing therapies

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

Select Data icon
- ⇒ Quick Look II

Percentage of Time (% of Time) – For single chamber modes, the % of Time section reports the patient's pacing and sensing as the percentage of the total time during the reporting period. For dual chamber modes, the % of Time section reports the percentage for each of the possible AV sequence combinations (AS-VS, AS-VP, AP-VS, AP-VP).

Figure 58. Pacing percentages on the Quick Look II screen



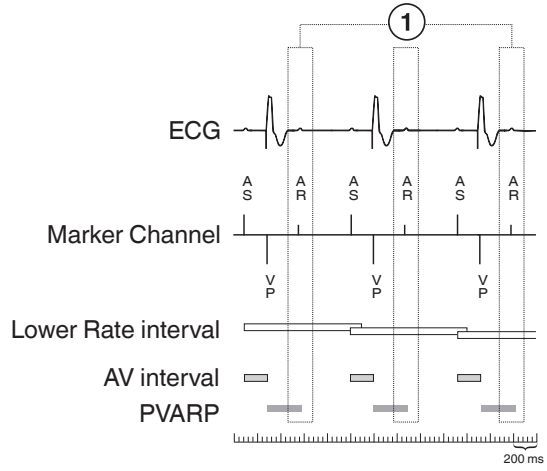
8.2.8 Tracking rapid atrial rates

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 8.2.8.1.

8.2.8.1 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 59). 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 59. 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 about PVARP, see Section 8.8, “Adjusting PVARP to changes in the patient’s heart rate”, page 195. 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.

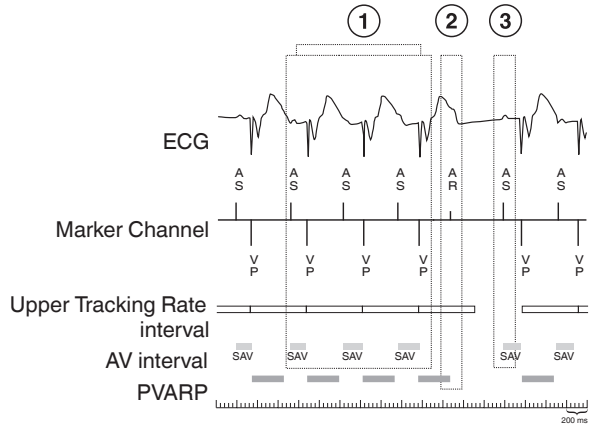
8.2.8.2 Upper Tracking Rate

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 60). 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 60. 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.

8.3 Reducing unnecessary ventricular pacing with MVP mode

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.[4,5,6]

One way to reduce unnecessary ventricular pacing is by programming longer AV intervals. However, the resulting level of ventricular pacing may still be considered too great. In addition, ventricular pacing delivered with longer AV intervals may be less hemodynamically effective, resulting in patient symptoms.

Another way to reduce unnecessary ventricular pacing is to program a pacing mode like AAI or AAIR that does not provide any ventricular pacing. However, such modes are not acceptable for patients who require ventricular pacing during conditions like AV block or atrial fibrillation with a slow ventricular response.

8.3.1 System solution: MVP mode

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 the DDD(R) mode with the ability to switch back to the AAI(R) mode when AV conduction resumes
- Backup ventricular support for transient loss of AV conduction

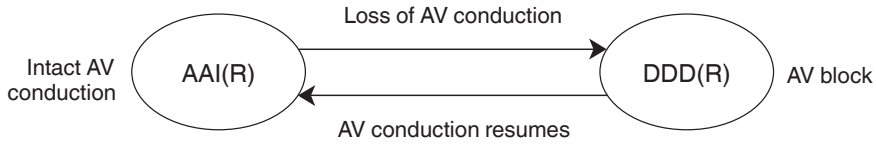
[4] Sweeney M, Hellkamp A, Ellenbogen K, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. *Circulation*. 2003;107:2932-2937.

[5] 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.

[6] 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.

8.3.2 Operation of MVP mode

Figure 61. Overview of MVP mode



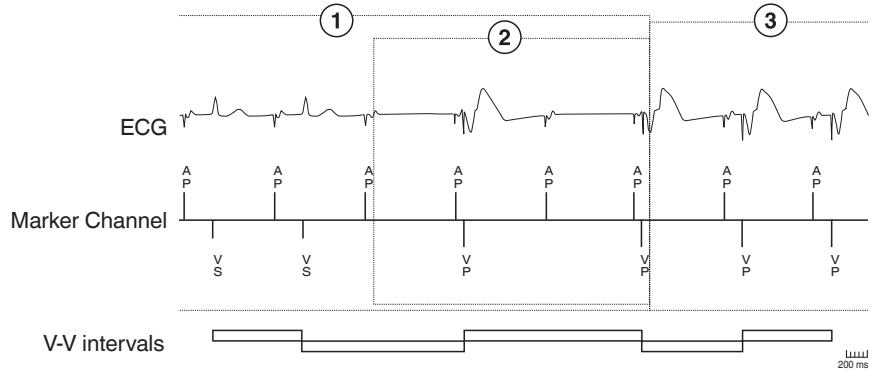
8.3.2.1 Intact AV conduction

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

8.3.2.2 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 62. Switching from AAIR mode to DDDR mode



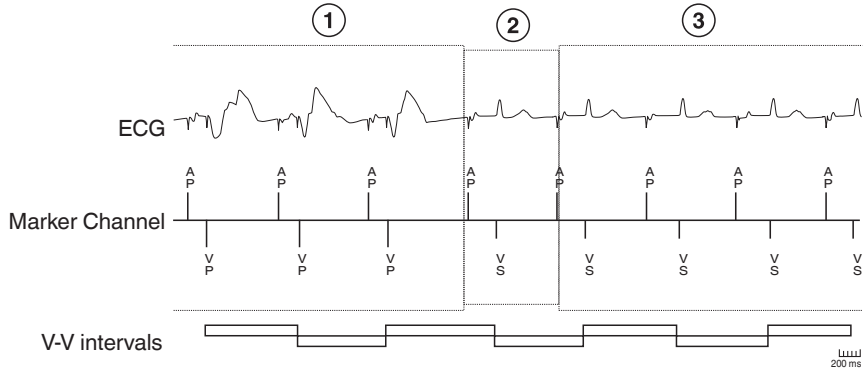
1 The device operates in AAIR mode.
2 At the onset of AV block, the device supplies ventricular backup pacing pulses.
3 The device switches to DDDR mode.

8.3.2.3 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 63. Switching from DDDR mode to AAIR mode after AV conduction resumes

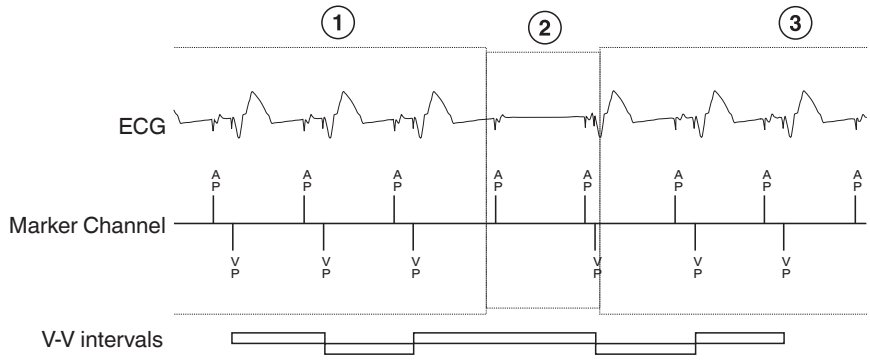


1 The device operates in DDDR mode.
2 The device performs an AV conduction check. AV conduction is detected.
3 The device operates in AAIR mode.

8.3.2.4 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 64. 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.

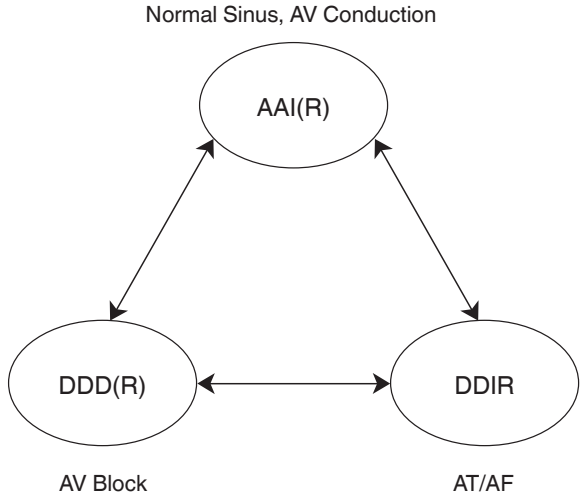
8.3.2.5 Transient loss of conduction

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

8.3.2.6 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 65. Operation of MVP mode and Mode Switch



Atrial Refractory Period – When the MVP feature is operating in the AAIR mode or the 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 the AAIR mode or the 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.

8.3.3 Programming considerations for MVP mode

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. See Figure 62 and Figure 64.

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 Figure 64. 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.

Operation immediately after implant – The device is shipped in the MVP mode, initially operating in the DDD mode. Approximately 30 min after implant, the device checks for AV conduction and switches to the AAIR mode or the AAI mode if the next A-A interval includes a sensed ventricular beat. See Section 8.3.2.3 for more information.

8.3.4 Programming MVP mode

Select Params icon

▷ Mode <AAIR<=>DDDR, AAI<=>DDD>

8.3.5 Evaluation of MVP mode

The programmer screen status bar, the Quick Look II screen, the Rate Histograms Report, and the Cardiac Compass Report may help to assess atrial and ventricular pacing and MVP performance.

8.3.5.1 Status bar

In AAIR<=>DDDR mode, the status bar displays either AAIR+ or DDDR as the current pacing mode. In AAI<=>DDD mode, it displays either AAI+ or DDD. The atrial mode is followed by a + symbol to indicate that an MVP mode is operational.

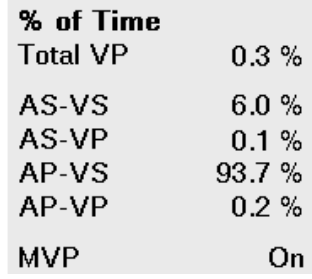
Figure 66. Pacing mode on the status bar

8.3.5.2 Quick Look II screen

Select Data icon
⇒ Quick Look II

The Quick Look II screen shows the percentages of atrial and ventricular pacing since the last follow-up appointment. The Quick Look II screen also reports if 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.”

Figure 67. Pacing percentages and MVP mode status on the Quick Look II screen



8.3.5.3 Cardiac Compass Report

You can view or print Cardiac Compass Trends starting from the Data icon:

Select Data icon
⇒ Clinical Diagnostics
⇒ Cardiac Compass Trends

8.3.5.4 Rate Histograms Report

To view or print Rate Histograms from the Data icon:

Select Data icon
⇒ Clinical Diagnostics
⇒ Rate Histograms

8.4 Providing rate-responsive pacing

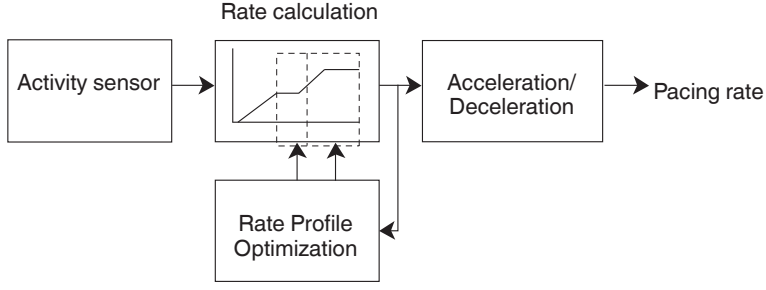
Some patients exhibit heart rates that do not adapt to changes in their physical activity. Their symptoms might be shortness of breath, fatigue, or dizziness. This group includes patients with chronotropic incompetence and patients with chronic or paroxysmal AF.

8.4.1 System solution: Rate Response

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.

8.4.2 Operation of Rate Response

Figure 68. 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.

8.4.2.1 Activity sensing

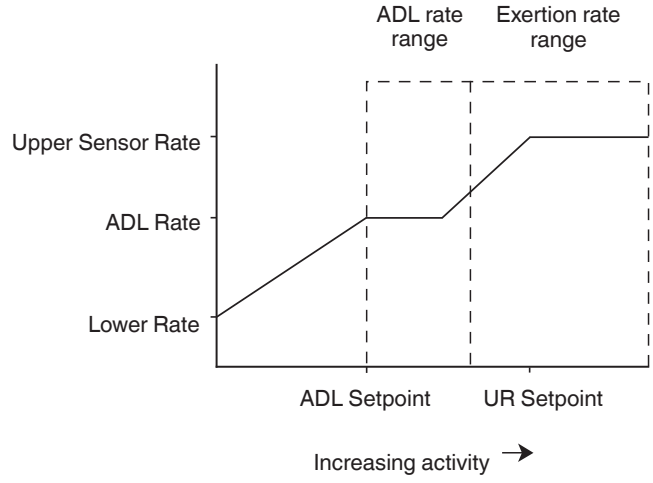
The activity sensor is an accelerometer in the device that detects the patient's body movements. Because activity detection varies from patient to patient, the sensitivity to motion can be adjusted by reprogramming the Activity Threshold parameter. If the Activity Threshold is lowered, smaller body movements 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.

8.4.2.2 Rate calculation

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

Figure 69. Rate curve



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.

8.4.2.3 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 either 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.

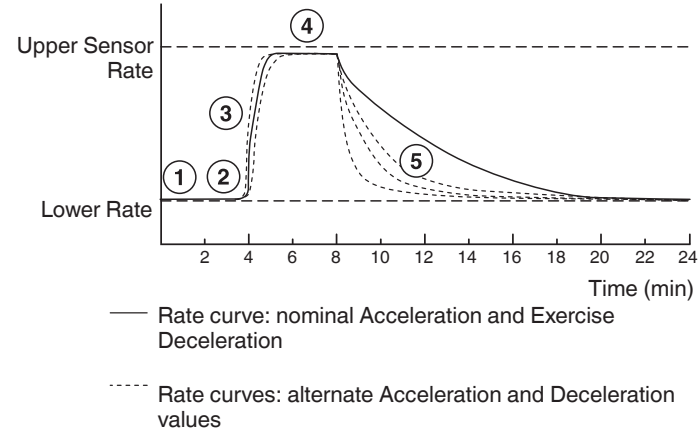
Note: Because the device is automatically changing the setpoint values, if you manually program the setpoint values, Rate Profile Optimization is disabled.

8.4.2.4 Activity Acceleration and Activity Deceleration

The Activity Acceleration parameter and the Activity Deceleration parameter 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 70, changing the values of the Activity Acceleration and the Activity Deceleration parameters affects the pacing rate during and after exertion.

Figure 70. 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.

8.4.2.5 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 30 minutes after implant. The device detects implant when the leads are attached.

8.4.2.6 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.

8.4.3 Programming considerations for Rate Response

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 parameter can 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 parameter can 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 the Lower Rate, the ADL Rate, and the Upper Sensor Rate parameters are appropriate for the patient.

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

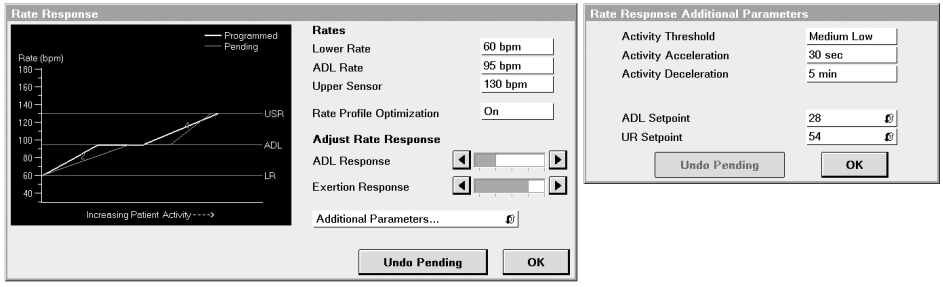
Adjust the ADL Response parameter to prescribe how quickly the patient reaches the ADL Rate, and adjust the Exertion Response parameter to prescribe how quickly the patient reaches the Upper Sensor Rate. In both cases, a lower value decreases the rate responsiveness and a higher value increases the rate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

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

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

8.4.4 Programming Rate Response

Figure 71. Rate Response parameters screens



Select Params icon
- ⇒ Rate Response…
  - ▷ Lower Rate
  - ▷ ADL Rate
  - ▷ Upper Sensor
  - ▷ Rate Profile Optimization
  - ▷ ADL Response
  - ▷ Exertion Response
  - ⇒ Additional Parameters…
    - ▷ Activity Threshold
    - ▷ Activity Acceleration
    - ▷ Activity Deceleration
    - ▷ ADL Setpoint
    - ▷ UR Setpoint

8.4.5 Evaluation of Rate Response

8.4.5.1 Rate Histograms Report

To view or print Rate Histograms from the Data icon:

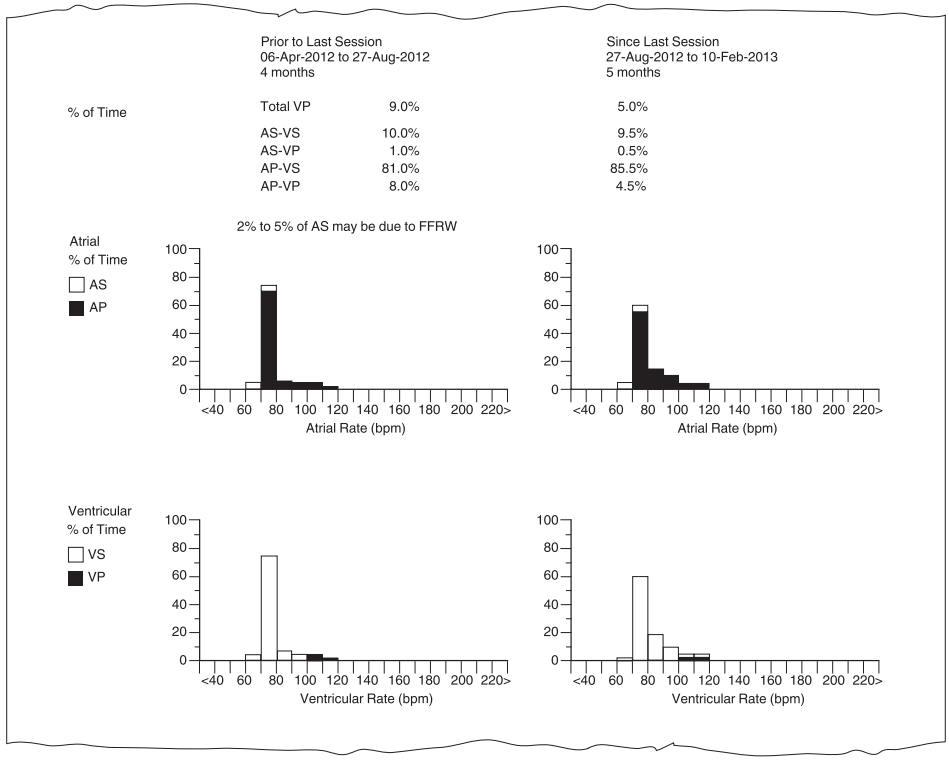
Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Histograms

The Rate Histograms Report provides information about how Rate Response has been performing since the previous patient session.

In Figure 72, you can see how the histograms changed after Rate Response was programmed to be more aggressive.

Note that the percentage of atrial pacing has shifted from the lower rates to the higher rates.

Figure 72. Rate Histograms Report



8.4.5.2 Flashback Memory

Select Data icon

⇒ Clinical Diagnostics

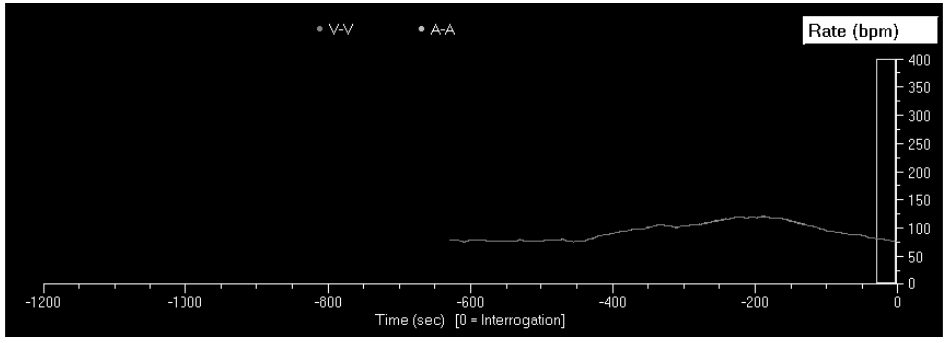
⇒ Flashback Memory

Flashback Memory provides a rate trend based on the initial interrogation. The rate trend shows how Rate Response was operating before the patient session.

1. View Flashback Memory.
2. Select View Intervals Prior to: Interrogation.
3. Set the plot display method to Rate.

Note: To see an updated rate trend without ending the patient session, instruct the patient to complete a hall walk, and then reinterrogate the device.

Figure 73. Rate trend in Flashback Memory



8.5 Managing pacing output energies with 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.

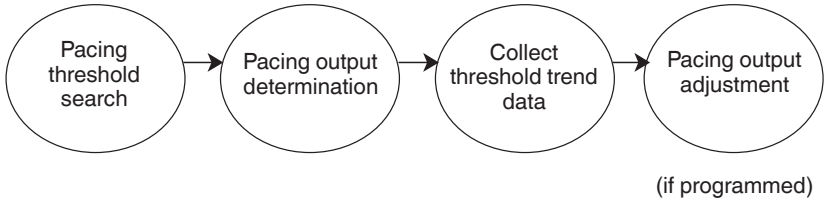
8.5.1 System solution: Capture Management

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.

8.5.2 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.

Figure 74. Overview of Capture Management



8.5.2.1 Manual adjustment of pacing outputs

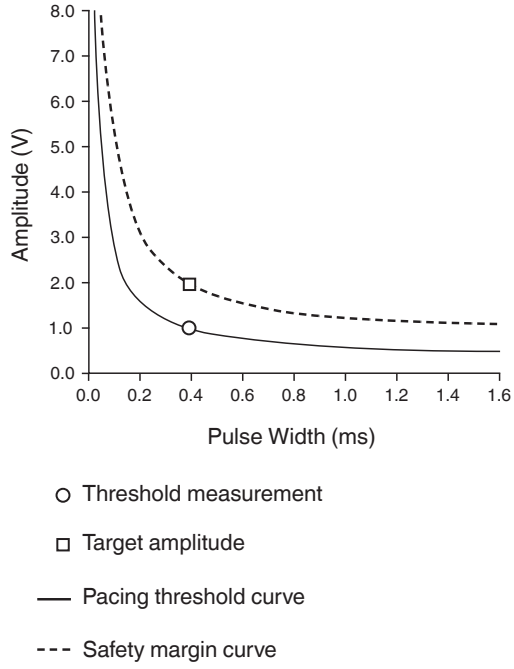
You have the option to program pacing outputs manually instead of using automatic Capture Management. The pacing safety margins should be checked if Capture Management is programmed to the Monitor setting. Threshold data that is collected during pacing threshold searches can make it easier for you to select values for pacing output parameters. For more information about manual programming, refer to Section 8.2, “Providing pacing therapies”, page 152.

8.5.2.2 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.

Both a threshold curve and a safety margin curve are shown in Figure 75. The threshold curve consists of combinations of amplitude and pulse width settings. Pacing output settings on or above the curve result in capture, whereas settings below the curve result in loss of capture. The safety margin curve consists of pacing output settings, each of which has a target amplitude that is equal to a threshold amplitude with a safety margin applied.

Figure 75. Threshold and safety margin curves



8.5.3 Operation of the Atrial Capture Management feature

Atrial Capture Management (ACM) is available when the device is operating in the DDDR mode, DDD mode, and the MVP modes (AAIR<=>DDDR and AAI<=>DDD). If ACM is programmed to the Monitor or Adaptive setting, the device conducts a pacing threshold search to determine the atrial pacing threshold. If ACM is programmed to the Adaptive setting, 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.

8.5.3.1 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.

8.5.3.2 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.

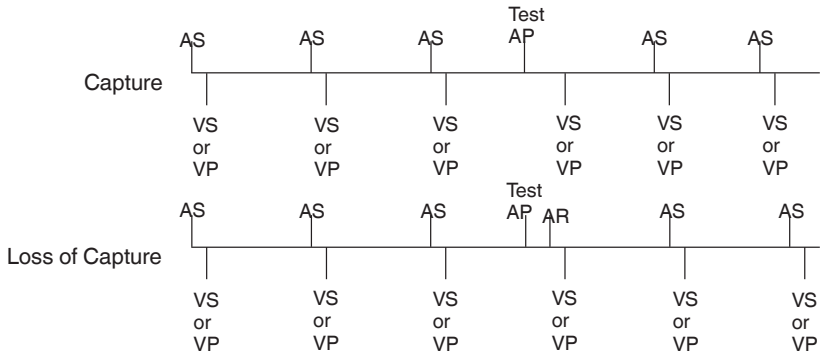
If the right atrium responds to a test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test 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 8.5.3.4.

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 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 76, this event is indicated by an AR marker.

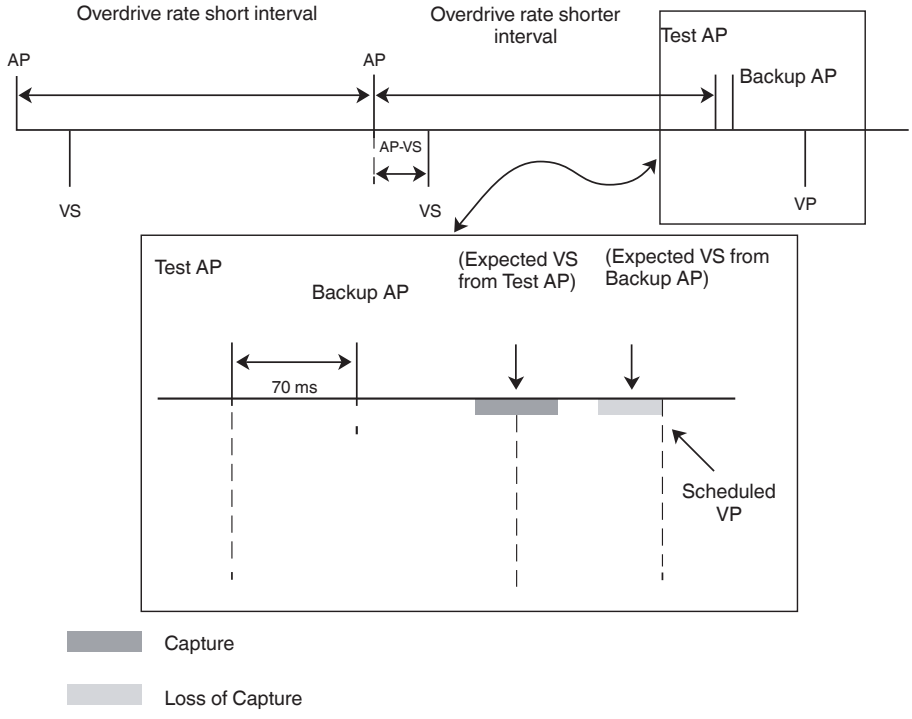
Figure 76. Atrial Chamber Reset test method



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 77. 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 77. AV Conduction test method



8.5.3.3 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 8.5.2.2.

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.

8.5.3.4 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. When the pacing threshold test is suspended, 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 8.5.7.

8.5.4 Operation of the Right Ventricular Capture Management feature

Right Ventricular Capture Management (RVCM) is available when the device is operating in the following modes: DDDR, DDD, DDIR, DDI, the MVP modes (AAIR<=>DDDR and AAI<=>DDD), VVIR, or VVI. If RVCM is programmed to the Monitor or Adaptive setting, the device conducts a pacing threshold search to determine the RV pacing threshold. If RVCM is programmed to the Adaptive setting, 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.

8.5.4.1 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 the AAIR<=>DDDR mode to the DDDR mode or from the AAI<=>DDD mode to the DDD mode.

8.5.4.2 Searching for and determining the RV pacing threshold

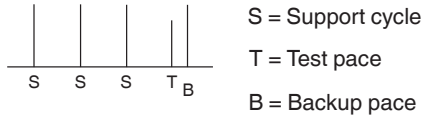
The device conducts a pacing threshold search to determine the RV pacing amplitude threshold at a fixed pulse width of 0.4 ms. RVCM varies the amplitude of test paces to find the lowest amplitude that consistently captures the right ventricular myocardium. The device evaluates capture by detecting the 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 8.5.4.4.

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 78). 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 78. RVCM test sequence



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.

8.5.4.3 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 8.5.2.2.

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 RV 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.

8.5.4.4 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. On the following day, 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 8.5.7.

8.5.5 Programming considerations for Capture Management

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.

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 low threshold measurement 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.

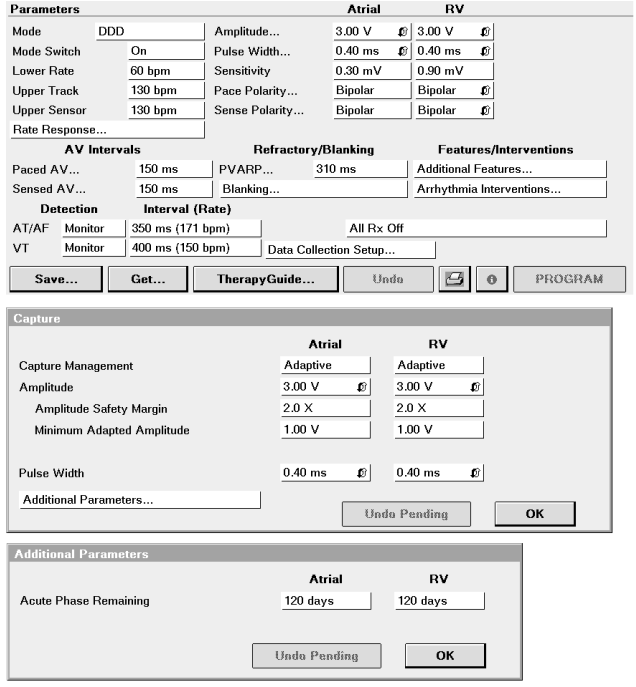
High threshold measurements with RVCM – In rare instances, the device may not detect the waveform created by the contracting myocardium immediately following a pacing pulse. In such instances, a high threshold measurement may result.

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

8.5.6 Programming the Capture Management feature

For information about programming amplitude and pulse width parameters manually, refer to Section 8.2, “Providing pacing therapies”, page 152.

Figure 79. Pacing and Capture Management parameters



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.

Select Params icon
- ⇒ Atrial Amplitude…
  - ▷ Atrial Capture Management
  - ▷ Atrial Amplitude Safety Margin
  - ▷ Atrial Minimum Adapted Amplitude
  - ▷ RV Capture Management
  - ▷ RV Amplitude Safety Margin
  - ▷ RV Minimum Adapted Amplitude
  - ⇒ Additional Parameters…
    - ▷ Acute Phase Remaining
    - ▷ Acute Phase Completed (read only)

8.5.7 Evaluation of the Capture Management feature

8.5.7.1 Quick Look II

Select Data icon
- ⇒ 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.

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

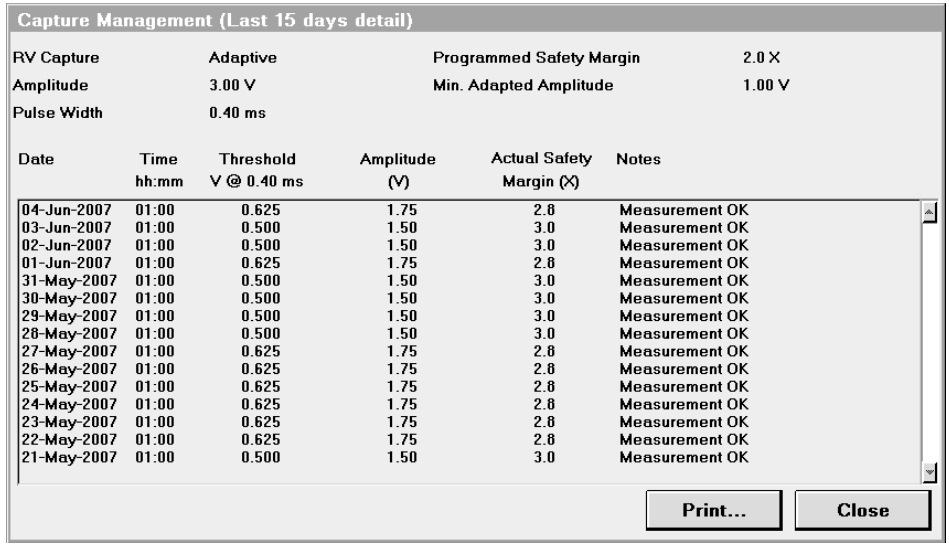
8.5.7.2 Capture Threshold trends

Select Data icon
- ⇒ Device/Lead Diagnostics
  - ⇒ Capture Threshold Trends

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 days of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week).

From the Capture Threshold trend, you can select the Last 15 days detail [>>] button to view details about the daily capture threshold searches. The details screen shows daily results from the last 15 days of threshold measurements, including dates, times, threshold measurements, pacing pulse width and amplitude values. Notes describe the results of each pacing threshold search.

Figure 80. RV Capture Threshold detail



Date	Time hh:mm	Threshold V @ 0.40 ms	Amplitude (V)	Actual Safety Margin (X)	Notes
04-Jun-2007	01:00	0.625	1.75	2.8	Measurement OK
03-Jun-2007	01:00	0.500	1.50	3.0	Measurement OK
02-Jun-2007	01:00	0.500	1.50	3.0	Measurement OK
01-Jun-2007	01:00	0.625	1.75	2.8	Measurement OK
31-May-2007	01:00	0.500	1.50	3.0	Measurement OK
30-May-2007	01:00	0.500	1.50	3.0	Measurement OK
29-May-2007	01:00	0.500	1.50	3.0	Measurement OK
28-May-2007	01:00	0.500	1.50	3.0	Measurement OK
27-May-2007	01:00	0.625	1.75	2.8	Measurement OK
26-May-2007	01:00	0.625	1.75	2.8	Measurement OK
25-May-2007	01:00	0.625	1.75	2.8	Measurement OK
24-May-2007	01:00	0.625	1.75	2.8	Measurement OK
23-May-2007	01:00	0.625	1.75	2.8	Measurement OK
22-May-2007	01:00	0.625	1.75	2.8	Measurement OK
21-May-2007	01:00	0.500	1.50	3.0	Measurement OK

8.6 Configuring lead polarity

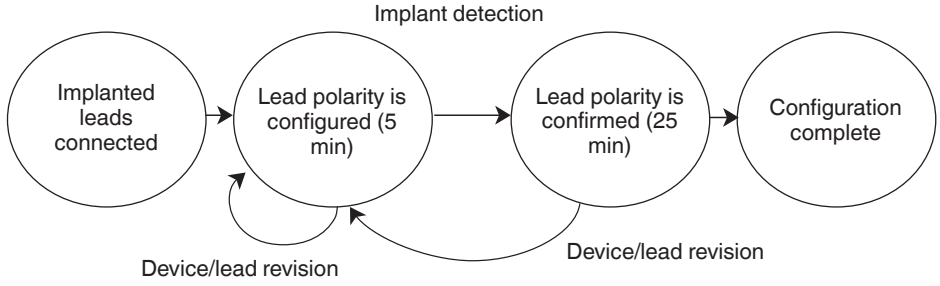
When leads are connected to the device at implant, a mechanism should detect when implant occurs and detect what kind of leads are attached. That same mechanism should maintain pacing even after one of the electrodes fails (with the switch to unipolar pacing).

8.6.1 System solution: Automatic Polarity Configuration and Lead Monitor

The Automatic Polarity Configuration feature automatically configures the pacing and sensing lead polarities during the Implant Detection process. Post-implant, the Lead Monitor feature monitors the leads for trends that may indicate lead system failures. If the performance of a particular lead is diminished, Lead Monitor switches the polarity of that lead from bipolar to unipolar.

8.6.2 Operation of Automatic Polarity Configuration

Figure 81. Automatic polarity configuration process



Implant Detection is a 30 min period, beginning when the device is placed in the surgical pocket. 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. Any lead or device revision restarts the 30 min process. When lead configuration is complete, the device configuration is set to bipolar for bipolar leads and to unipolar for unipolar leads.

Note: Implant Detection will run only if the Atrial and RV leads are inserted. Plugged ports (Atrial and RV), with out-of-range impedance, will prevent Implant Detection from completing.

Lead polarity can also be set manually at any time during the automatic configuration process. For more information on programming lead polarity, see Section 8.6.5.

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

8.6.3 Operation of 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.

You can set the range of impedance values that the device classifies as normal for a stable lead. You can also program Lead Monitor to Adaptive, which automatically switches bipolar pacing and sensing to unipolar when lead integrity is in doubt, or to Monitor Only, which monitors impedance values but does not switch bipolar pacing and sensing to unipolar when lead integrity is in doubt. 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, investigate possible lead system failures. Lead system failures can prevent adequate sensing or full pacing support.

For information about the lead impedance range, see Section 1.7, “MRI conditions for use”, page 18. Refer to the Medtronic MRI Technical Manual for additional information about lead impedance measurements.

8.6.4 Programming considerations for lead polarity

MRI SureScan and lead polarity – MRI SureScan cannot be On unless A 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. AT/AF Detection must also be set to Monitor when the Atrial Lead Monitor is set to Adaptive, because there is potential for the device to switch to a 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.

8.6.5 Programming lead polarity

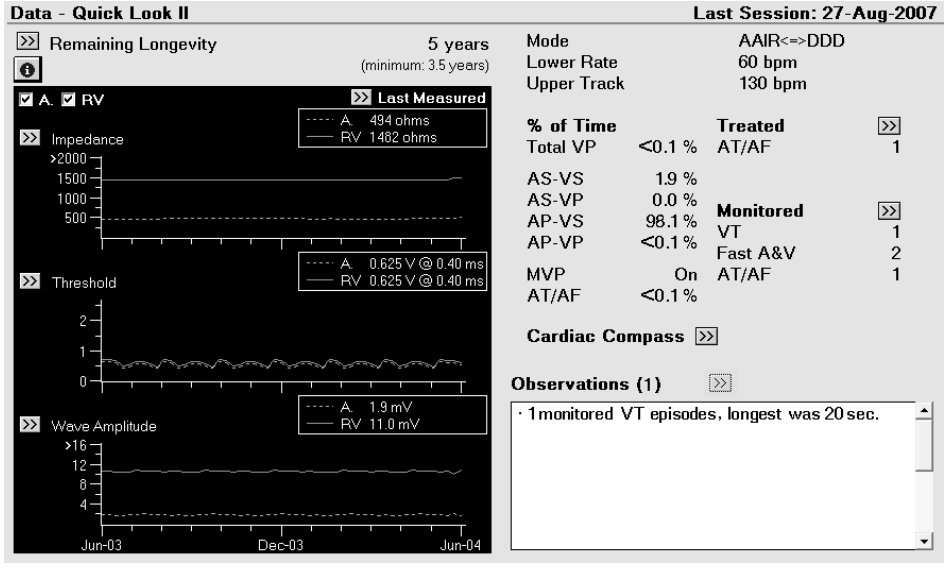
Select Params icon
- ⇒ Pace Polarity…
  - ▷ Atrial Pace Polarity
  - ▷ RV Pace Polarity
  - ▷ Atrial Sense Polarity
  - ▷ RV Sense Polarity
  - ▷ Atrial Lead Monitor
  - ▷ Atrial Min Limit
  - ▷ Atrial Max Limit
  - ▷ RV Lead Monitor
  - ▷ RV Min Limit
  - ▷ RV Max Limit

8.6.6 Evaluation of lead polarity

Select Data icon
- ⇒ Quick Look II

The Quick Look II screen provides a lead impedance trend chart. If trends indicate possible lead system failures, a lead warning message provides further information, including impedance values and the date and time of the event. The messages are displayed in the Observations area. The screen also shows the current lead status.

Figure 82. Quick Look II screen



8.7 Adapting the AV interval during rate changes

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.

8.7.1 System solution: Rate Adaptive AV

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

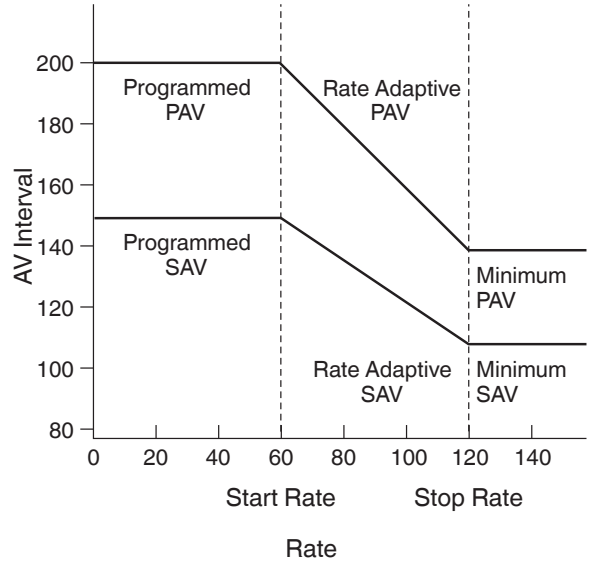
8.7.2 Operation of the Rate Adaptive AV feature

The Rate Adaptive AV feature is available when the device is programmed to the DDDR, DDIR, DDD, DDI, AAIR<=>DDDR, or AAI<=>DDD mode.

Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), Rate Adaptive AV functions only when MVP is operating in the DDDR or DDD 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 83.

Figure 83. 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 Minimum PAV intervals and Minimum SAV intervals are applied.

8.7.3 Programming considerations for Rate Adaptive AV

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 pressing the information icon at the bottom of the screen. If you select a new value for a parameter that affects dynamic 2:1 block rate (for example, Sensed AV or PVARP), press the information icon to see the recalculated rate.

8.7.4 Programming the Rate Adaptive AV feature

Note: The TherapyGuide feature suggests parameter values based on information entered about the patient's clinical conditions. Parameter values for this feature are included. For more information, see Section 4.8, "Using TherapyGuide to select parameter values", page 46.

Select Params icon
- ⇒ Paced AV…
  - ▷ Rate Adaptive AV <On>
  - ▷ Start Rate
  - ▷ Stop Rate
  - ▷ Minimum Paced AV
  - ▷ Minimum Sensed AV

8.8 Adjusting PVARP to changes in the patient's heart rate

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 related information, refer to Section 8.1, "Sensing intrinsic cardiac activity", page 140, and Section 8.2, "Providing pacing therapies", page 152.

8.8.1 System solution: Auto PVARP

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

8.8.2 Operation of the Auto PVARP feature

The Auto PVARP feature is available when the device is programmed to the DDDR, DDD, DDIR, DDI, AAIR<=>DDDR, or AAI<=>DDD mode.

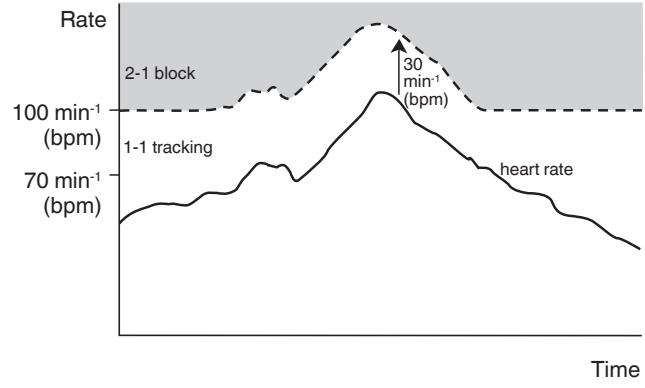
Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), Auto PVARP functions only when MVP is operating in the DDDR or DDD mode.

In a tracking mode (DDDR or DDD), Auto PVARP 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 on, the Sensed AV (SAV) interval is shortened to help maintain 1:1 tracking.

For information about Rate Adaptive AV, refer to Section 8.7, “Adapting the AV interval during rate changes”, page 193.

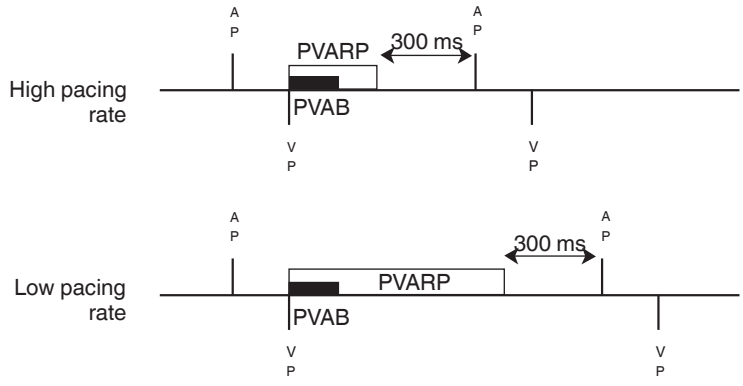
Figure 84. Operation of Auto PVARP in the DDDR or DDD mode



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 PVAB (Post-Ventricular Atrial Blanking) interval.

Figure 85. Operation of Auto PVARP in the DDIR or DDI mode



8.8.3 Programming considerations for Auto 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 about Rate Adaptive AV, see Section 8.7, “Adapting the AV interval during rate changes”, page 193.

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 pressing the information icon button at the bottom of the 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.

8.8.4 Programming Auto PVARP

Select Params icon
⇒ PVARP…
▷ PVARP <Auto>
▷ Minimum PVARP

8.9 Treating syncope with Rate Drop Response

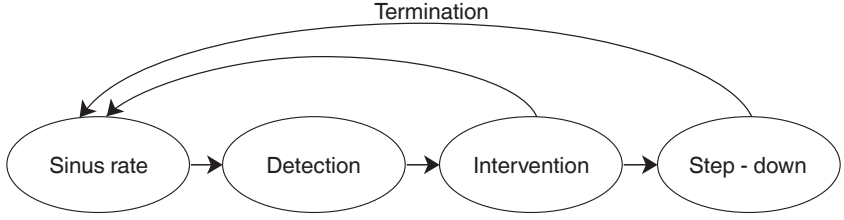
Patients with carotid sinus syndrome or vasovagal syncope may lose consciousness or experience related symptoms after significant drops in heart rate. When syncope is caused primarily by cardioinhibition and when permanent AF is not present, pacing at an elevated rate may prevent syncope and related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

8.9.1 System solution: Rate Drop Response

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

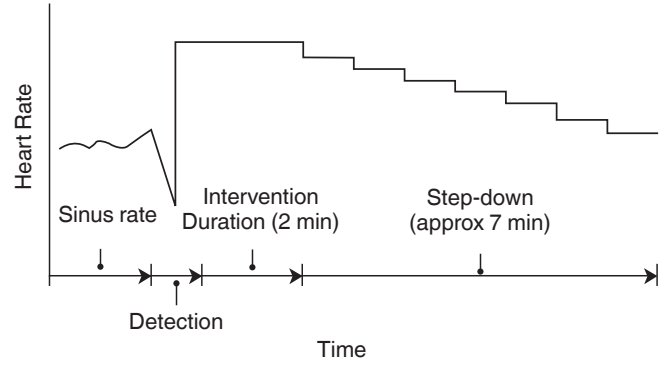
8.9.2 Operation of Rate Drop Response

Figure 86. 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 87. Rate Drop Response Rate and Time



As shown in Figure 87, Rate Drop Response typically operates over several minutes, and most of this time involves the step-down phase.

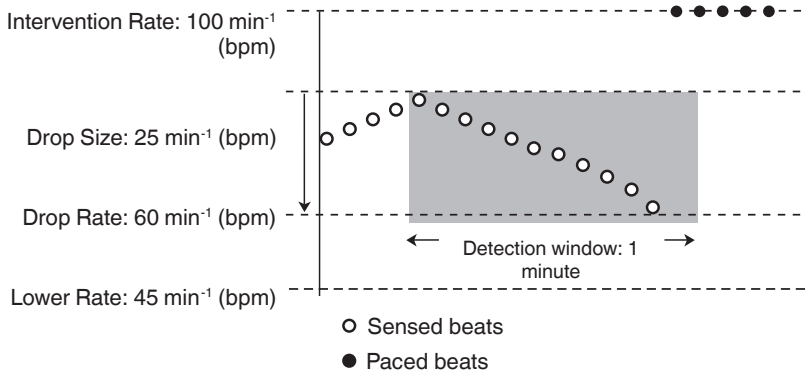
Rate Drop Response is available in MVP (AAI<=>DDD), DDD, and DDI modes. For the MVP mode, the device operates in DDD mode during Rate Drop Response interventions. Rate Drop Response does not operate during tachyarrhythmias, Mode Switch episodes, and Capture Management pacing threshold searches.

8.9.2.1 Detection

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

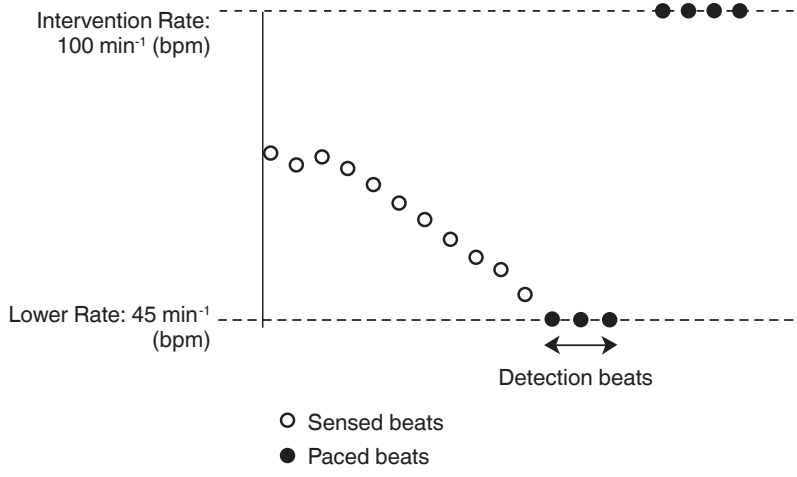
- Drop Detection
- Low Rate Detection

Figure 88. 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, the Drop Rate, and the Detection Window parameters, respectively.

Figure 89. 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 the programmed Drop Detection criteria and continues to drop, the heart is eventually paced at the Lower Rate. If this situation continues for the programmed number of detection beats, the device intervenes.

8.9.2.2 Intervention and step-down

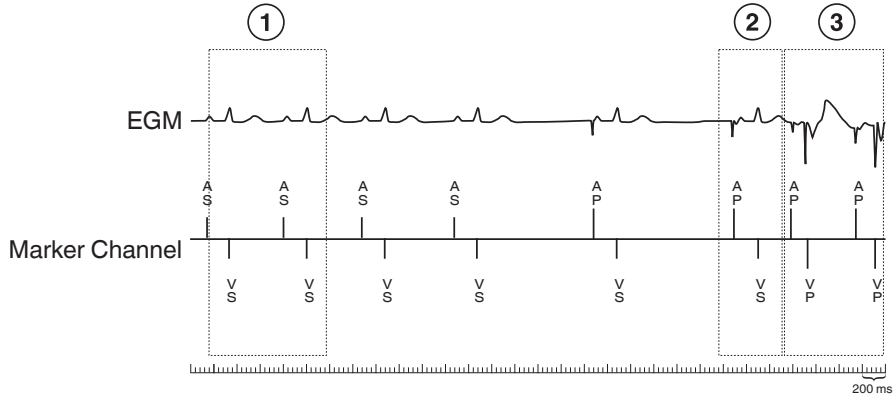
When a rate drop is detected, the device paces the heart at the programmed Intervention Rate for the programmed Intervention Duration. After the Intervention Duration is complete, the device reduces the pacing rate by 5 bpm steps per minute. This step-down process continues until the sinus rate or the 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 90 for an example of the device detecting a rate drop and starting to pace the heart at the programmed Intervention Rate.

Figure 90. Example of detection and intervention



1 Normal sinus rhythm
2 Rate drop detected
3 Intervention pacing started

8.9.3 Programming considerations for Rate Drop Response

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 about the Sleep feature, see Section 8.11, "Providing a slower pacing rate during periods of sleep", page 206.

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

8.9.4 Programming Rate Drop Response

Note: 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, see Section 4.8, "Using TherapyGuide to select parameter values", page 46.

Select Params icon
- ⇒ Additional Features…
  - ⇒ Rate Drop Response…
    - ▷ Rate Drop Response <On>
    - ▷ Mode
    - ▷ Lower Rate
    - ▷ Detection Type
    - ▷ Drop Size
    - ▷ Drop Rate
    - ▷ Detection Window
    - ▷ Detection Beats
    - ▷ Intervention Rate
    - ▷ Intervention Duration

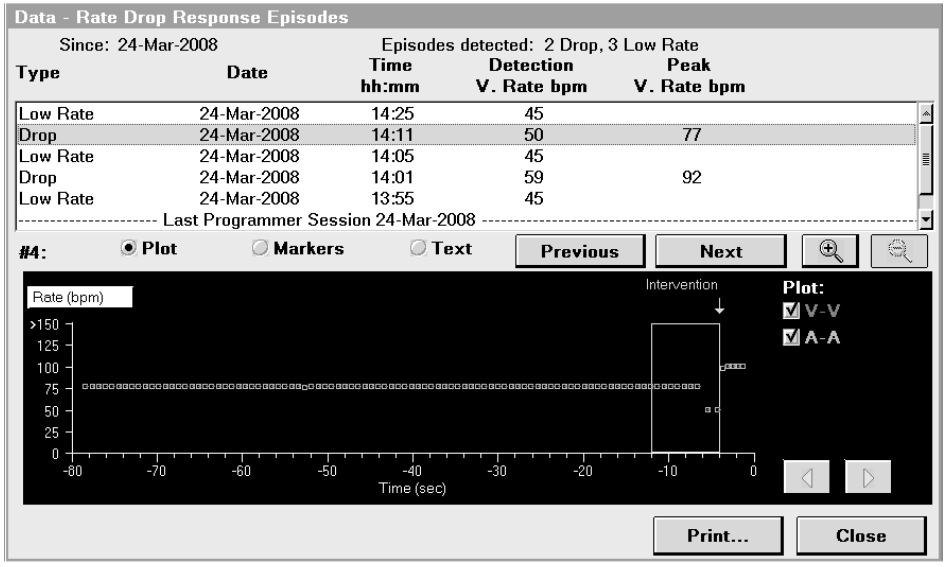
8.9.5 Evaluation of Rate Drop Response

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.

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Drop Response Episodes

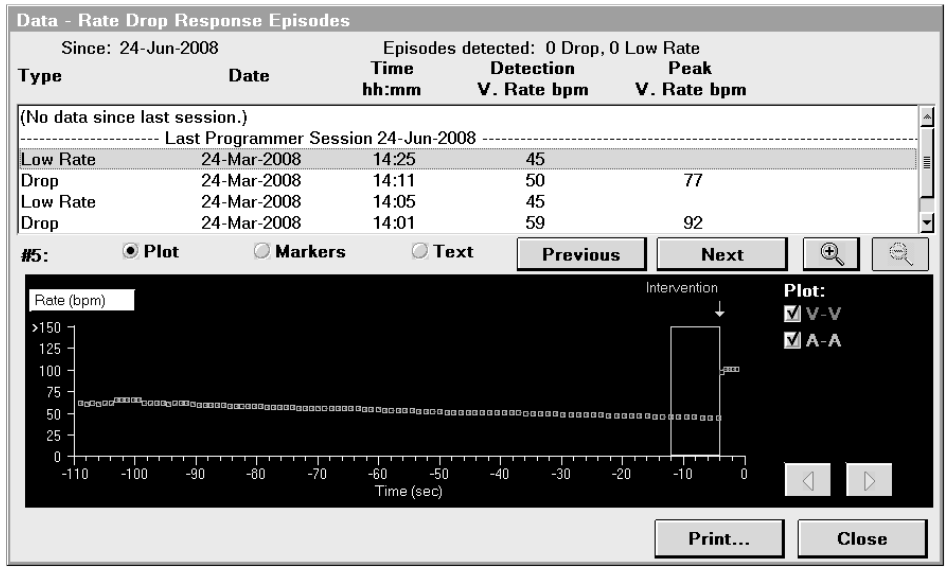
A sudden rate drop episode that is detected by the Drop Detection method is shown in Figure 91.

Figure 91. Drop Episode



A more gradual rate drop episode that is detected by the Low Rate Detection method is shown in Figure 92.

Figure 92. Low Rate Episode



8.10 Promoting the intrinsic rate during periods of inactivity

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

8.10.1 System solution: Rate Hysteresis

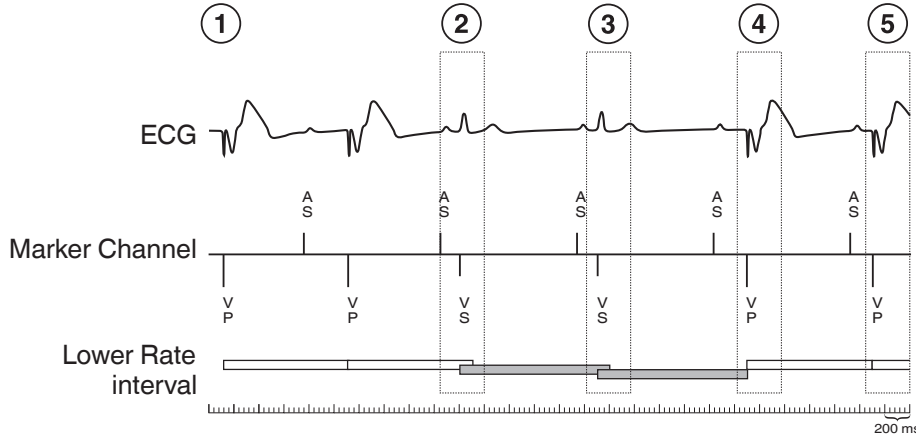
Rate Hysteresis allows intrinsic rhythms to occur below the programmed Lower Rate.

8.10.2 Operation of Rate Hysteresis

Rate Hysteresis is available when the device is operating in the VVI or AAI mode.

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 93. 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.

8.10.3 Programming considerations for 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.

8.10.4 Programming Rate Hysteresis

Select Params icon
- ⇒ Additional Features…
  - ▷ Rate Hysteresis

8.10.5 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.

8.10.5.1 Viewing the Ventricular Rate Histogram Report

To view or print Rate Histograms from the Data icon:

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Histograms

8.11 Providing a slower pacing rate during periods of sleep

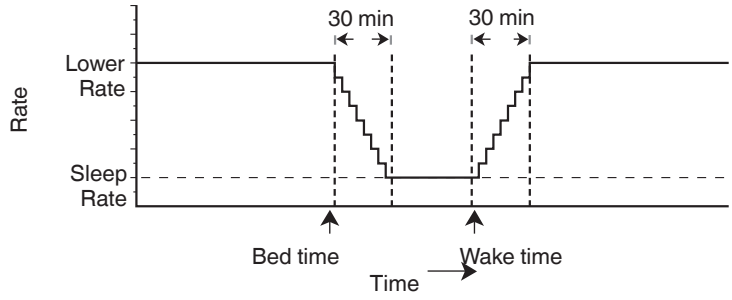
Some patients have difficulty sleeping when they are paced at a rate that is intended for times when they are normally awake.

8.11.1 System solution: Sleep feature

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

8.11.2 Operation of the Sleep feature

Figure 94. 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 about Mode Switch, see Section 8.16, “Preventing rapid ventricular pacing during atrial tachyarrhythmias”, page 217.

8.11.3 Programming considerations for the Sleep feature

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.

To ensure that the Bed Time and Wake Time parameters are accurate, keep the device set to the correct time. The Sleep feature uses the device clock.

8.11.3.1 How to set the device clock

Select Params icon
- ⇒ Data Collection Setup…
  - ⇒ Device Date/Time…

8.11.4 Programming the Sleep feature

Select Params icon
- ⇒ Additional Features…
  - ⇒ Sleep…
    - ▷ Sleep <On>
    - ▷ Sleep Rate
    - ▷ Bed Time
    - ▷ Wake Time

8.11.5 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.

The Cardiac Compass Report shows the average ventricular rate during the day and night, which should indicate that the device is allowing a slower heart rate at night.

8.11.5.1 Viewing or printing Ventricular Rate Histograms

To view or print Rate Histograms from the Data icon:

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Histograms

8.11.5.2 Viewing or printing the Cardiac Compass Trends Report

You can print the Cardiac Compass Trends report starting from the Reports icon:

Select Reports icon
- ⇒ Available Reports…
  - ⇒ Cardiac Compass Trends

8.12 Preventing competitive atrial pacing

An atrial tachycardia may be initiated if an atrial paced event occurs within the vulnerable period of the atrium. This can happen if 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.

8.12.1 System solution: NCAP

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

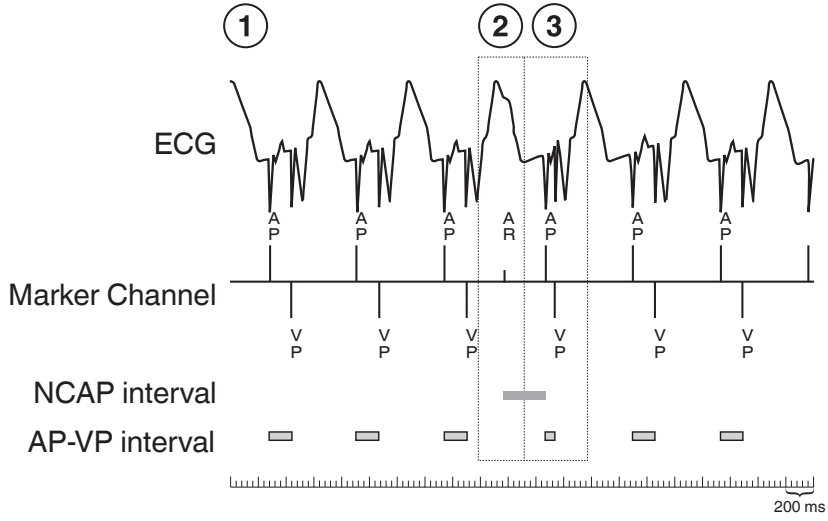
8.12.2 Operation of NCAP

NCAP is available when the device is operating in the DDDR, DDD, DDIR, DDI or the MVP modes (AAIR<=>DDDR and AAI<=>DDD).

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 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 95. 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.

8.12.3 Programming NCAP

Select Params icon
- ⇒ Additional Features…
  - ▷ Non-Comp Atrial Pacing <On>
  - ▷ NCAP Interval

8.12.4 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 95).

8.13 Interrupting pacemaker-mediated tachycardias

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.

8.13.1 System solution: PMT Intervention

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

8.13.2 Operation of PMT Intervention

PMT Intervention is available when the device is programmed to the DDDR, DDD, AAIR<=>DDDR, or AAI<=>DDD mode.

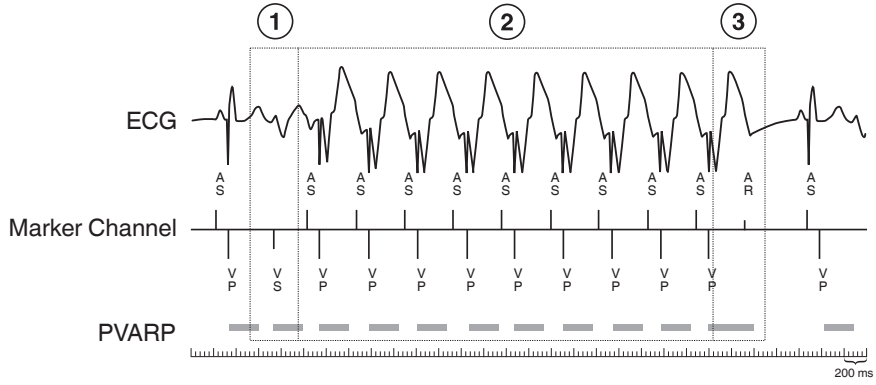
Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), PMT Intervention functions only when MVP is operating in the DDDR or DDD mode.

The device defines a PMT as 8 consecutive VP-AS intervals occurring at less than 400 ms. When the device detects a PMT, the PMT Intervention feature forces a 400 ms PVARP after the ninth paced ventricular event. 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.

PMT Intervention is suspended for 90 s following the extended PVARP in order to prevent unnecessary intervention in the presence of fast intrinsic atrial rates. The PMT detection criteria can be met during normal elevated sinus rates, resulting in 1 dropped beat (not tracked) every 90 s.

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 96. PMT Intervention extends the PVARP



1 Retrograde conduction following a PVC is detected as an atrial sensed event.
2 PMT occurs.
3 PMT is detected and PVARP lengthens to terminate the PMT.

8.13.3 Programming PMT Intervention

Select Params icon
⇒ Additional Features…
▷ PMT Intervention

8.14 Managing retrograde conduction using PVC Response

Retrograde conduction following a premature ventricular contraction (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.

8.14.1 System solution: PVC Response

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

8.14.2 Operation of the PVC Response feature

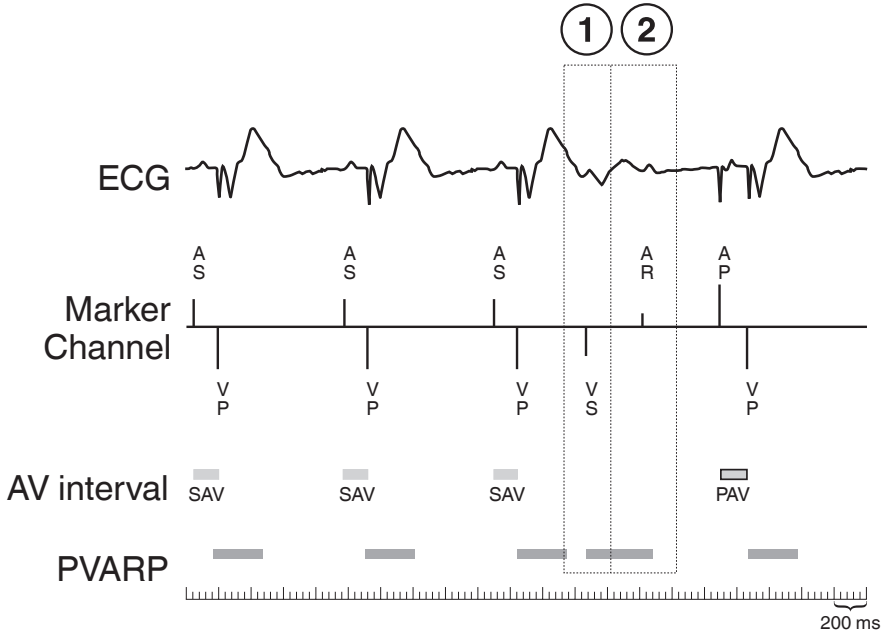
The PVC Response feature is available when the device is programmed to the DDDR, DDD, DDIR, DDI, AAIR<=>DDDR, or AAI<=>DDD mode.

Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), PVC Response functions only when MVP is operating in the DDDR or DDD 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 and 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, or evaluate the atrial and ventricular lead performance or positions, or consider drug therapy to reduce retrograde conduction.

Figure 97. 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.

8.14.3 Programming PVC Response

Select Params icon
⇒ Additional Features…
▷ PVC Response

8.15 Reducing inappropriate ventricular inhibition using VSP

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.

8.15.1 System solution: VSP

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

8.15.2 Operation of VSP

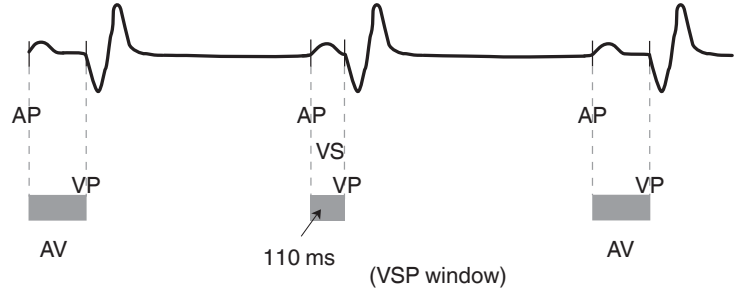
VSP is available when the device is programmed to the DDDR, DDD, DDIR, DDI, AAIR<=>DDDR, or AAI<=>DDD mode.

Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), VSP functions only when MVP is operating in the DDDR or DDD 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 98. 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.

In modern devices, crosstalk is rare. Situations in which the device is likely to deliver VSP include atrial undersensing or PVCs occurring in the VSP window.

8.15.3 Programming considerations for VSP

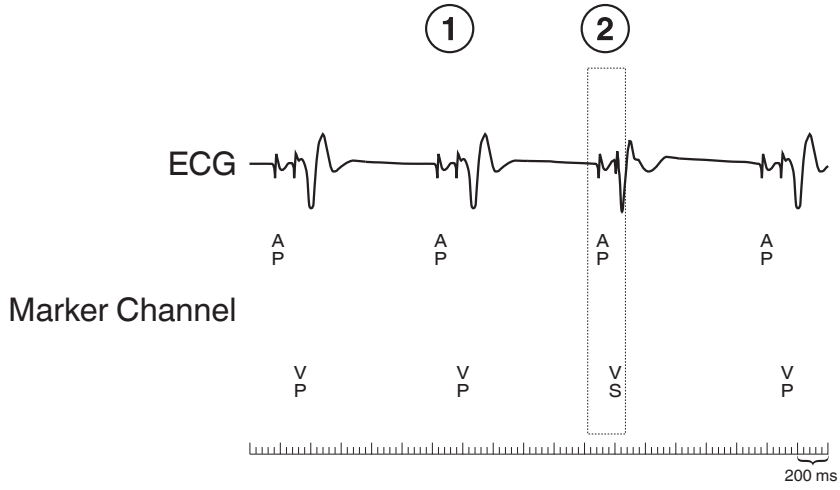
Caution: Do not program VSP to Off if the patient is pacemaker-dependent because ventricular support may not be provided during crosstalk.

8.15.4 Programming VSP

Select Params icon
- ⇒ Additional Features…
  - ▷ V. Safety Pacing

8.15.5 Evaluation of VSP

Figure 99. 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.

8.16 Preventing rapid ventricular pacing during atrial tachyarrhythmias

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.

8.16.1 System solution: Mode Switch

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.

8.16.2 Operation of Mode Switch

Figure 100. Overview of Mode Switch operation

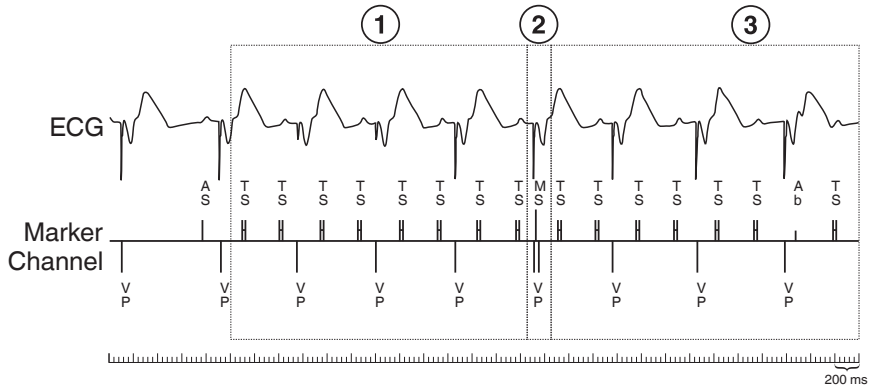
Mode Switch is available when the device is operating in the DDDR, DDD, or MVP (AAIR<=>DDDR or AAI<=>DDD) modes.

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 about atrial tachyarrhythmia detection, see Section 9.1, “Detecting atrial tachyarrhythmias”, page 237.

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 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 101. 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.

8.16.2.1 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, refer to Section 8.3, "Reducing unnecessary ventricular pacing with MVP mode", page 163.

8.16.3 Programming considerations for 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 about PMOP, refer to Section 8.17, “Using atrial intervention pacing to counteract atrial tachyarrhythmias”, page 221.

8.16.4 Programming Mode Switch

Select Params icon
▷ Mode Switch

8.16.4.1 Programming the Atrial Interval (Rate)

Select Params icon
▷ AT/AF Interval (Rate)

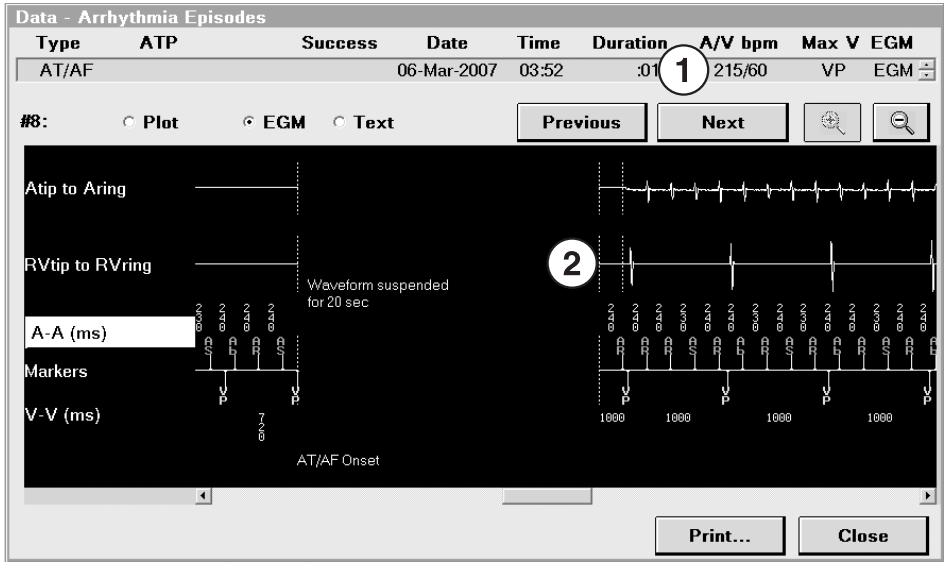
8.16.5 Evaluation of Mode Switch performance

8.16.5.1 EGM strip

Select Data icon
⇒ Clinical Diagnostics
⇒ Arrhythmia Episodes

Select an AT/AF episode from the Arrhythmia Episodes log. 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.

Figure 102. Evaluating Mode Switch operation during an AT/AF episode



1 The low average ventricular rate and the difference between the average atrial and ventricular rates suggest that the device is not operating in a tracking mode.
2 The stored EGM shows that the device is not tracking the atrial rate when pacing the ventricle.

8.16.5.2 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.

8.17 Using atrial intervention pacing to counteract atrial tachyarrhythmias

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) resulting in long sinus pauses and ectopic beats originating 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.

8.17.1 System solution: atrial intervention pacing features

The system provides overdrive pacing techniques that are designed to counteract mechanisms that can potentially initiate atrial tachyarrhythmias.

The Atrial Rate Stabilization (ARS) feature 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).

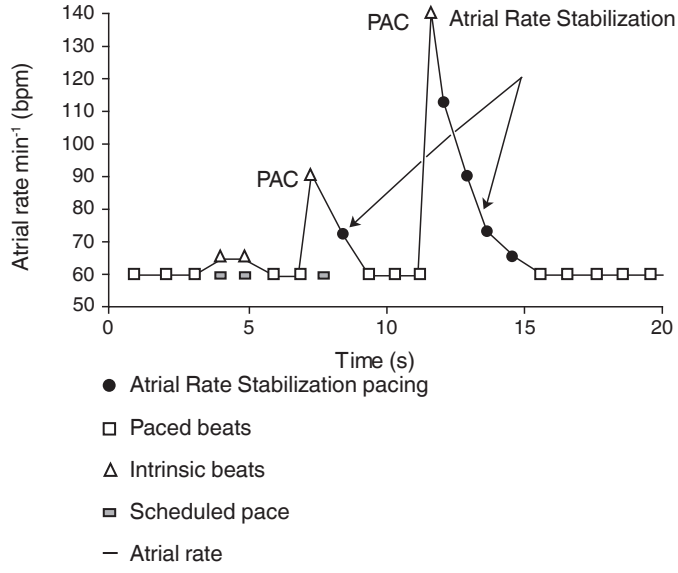
The Atrial Preference Pacing (APP) feature is designed to maintain a consistent activation sequence by providing continuous pacing that is closely matched to the intrinsic sinus rate.

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

8.17.2 Operation of ARS

Atrial Rate Stabilization (ARS) is available when the device is operating in the DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode.

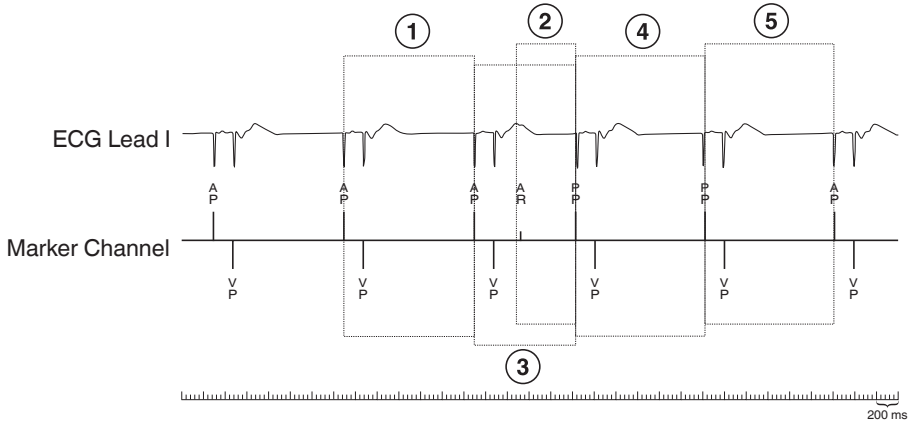
Figure 103. Atrial Rate Stabilization (ARS)



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, 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 with PP (proactive pace).

Figure 104. 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.

8.17.3 Programming considerations for ARS

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.

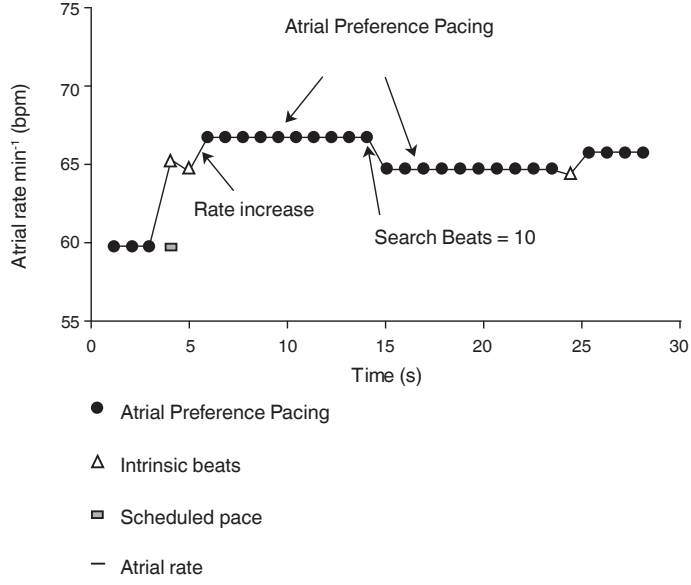
8.17.4 Programming ARS

Select Params icon
- ⇒ Arrhythmia Interventions…
  - ▷ A. Rate Stabilization <On>
  - ⇒ Additional A Settings…
    - ▷ Maximum Rate
    - ▷ Interval Percentage Increment

8.17.5 Operation of APP

Atrial Preference Pacing (APP) is available when the device is operating in the DDDR, DDD, AAIR, AAI, or MVP (AAIR<=>DDDR or AAI<=>DDD) mode.

Figure 105. Atrial Preference Pacing (APP)

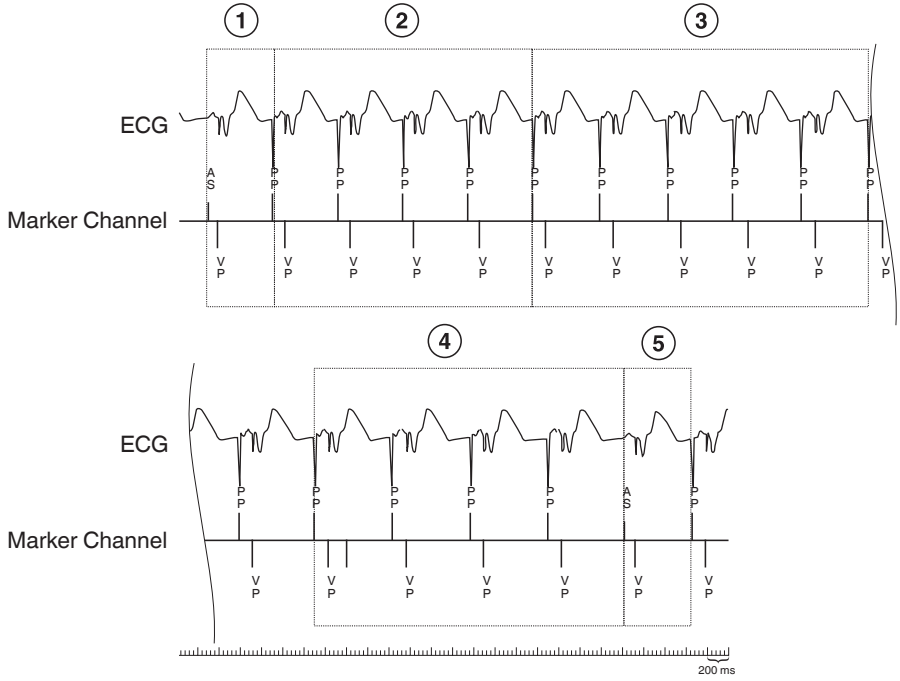


APP is a programmable feature that is designed to maximize atrial overdrive pacing when the patient is not experiencing an atrial tachyarrhythmia. The device responds to changes in the atrial rate by accelerating the pacing rate until reaching a steady paced rhythm that is slightly faster than the intrinsic 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, 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 with PP (proactive pace).

Figure 106. 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.

8.17.6 Programming considerations for APP

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

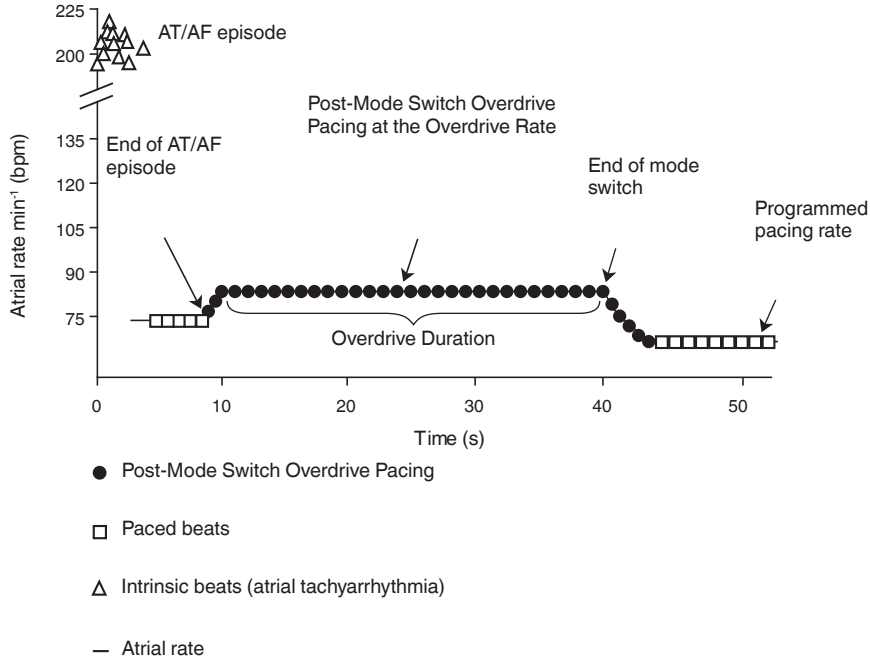
8.17.7 Programming APP

Select Params icon
- ⇒ Arrhythmia Interventions…
  - ▷ A. Preference Pacing <On>
  - ⇒ Additional A Settings…
    - ▷ Maximum Rate
    - ▷ Interval Decrement
    - ▷ Search Beats

8.17.8 Operation of PMOP

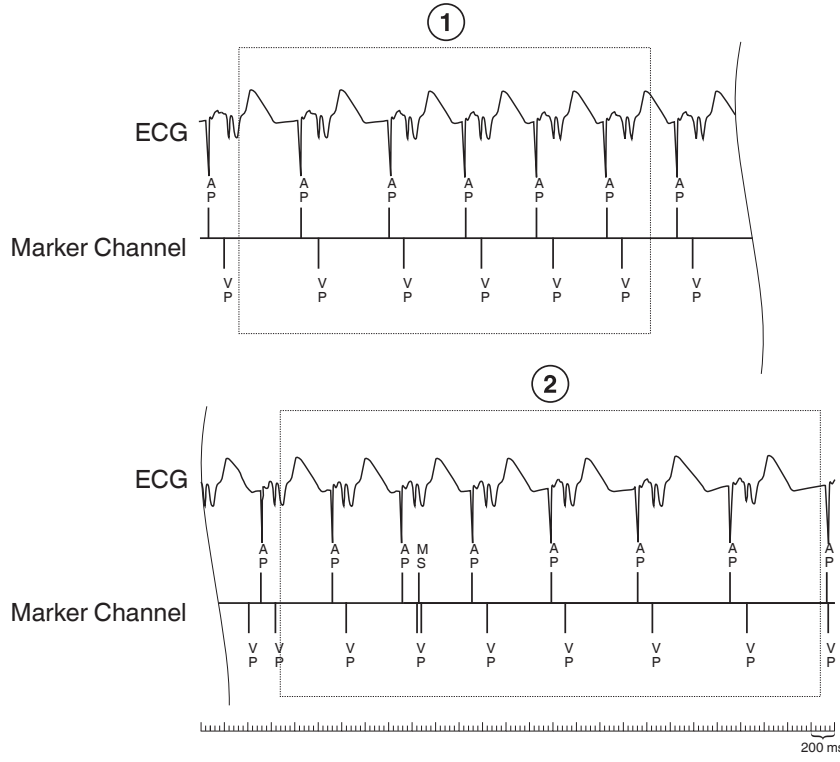
Post Mode Switch Overdrive Pacing (PMOP) is available when the pacing mode is programmed to DDDR, DDD or MVP (AAIR<=>DDDR or AAI<=>DDD) mode.

Figure 107. 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 108. 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 about mode switch, see Section 8.16, “Preventing rapid ventricular pacing during atrial tachyarrhythmias”, page 217.

8.17.9 Programming considerations for PMOP

Potential right ventricular pacing increase – Since the device remains in DDIR mode during PMOP operation, programming PMOP to 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 programmed to On.

8.17.10 Programming PMOP

Select Params icon
- ⇒ Arrhythmia Interventions…
  - ▷ Post Mode Switch <On>
  - ▷ Overdrive Rate
  - ▷ Overdrive Duration

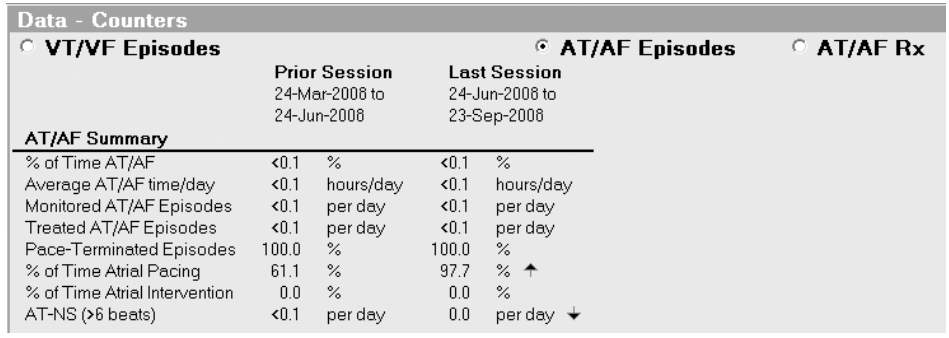
8.17.11 Evaluation of atrial intervention pacing

The device collects and stores AT/AF episode summary data that includes the total percentage of time that the device provided atrial intervention pacing. You can view the AT/AF summary data on the programmer screen and print the data in report form. For more information, see Section 7.5, “Viewing episode and therapy counters”, page 117.

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Counters
    - ⇒ AT/AF Episodes

The % of Time Atrial Intervention line in the AT/AF Summary section of the Data-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.

Figure 109. Example of the AT/AF Summary section of the Data-Counters screen



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

8.18 Smoothing the ventricular rate during conducted AF

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.

8.18.1 System solution: Conducted AF Response

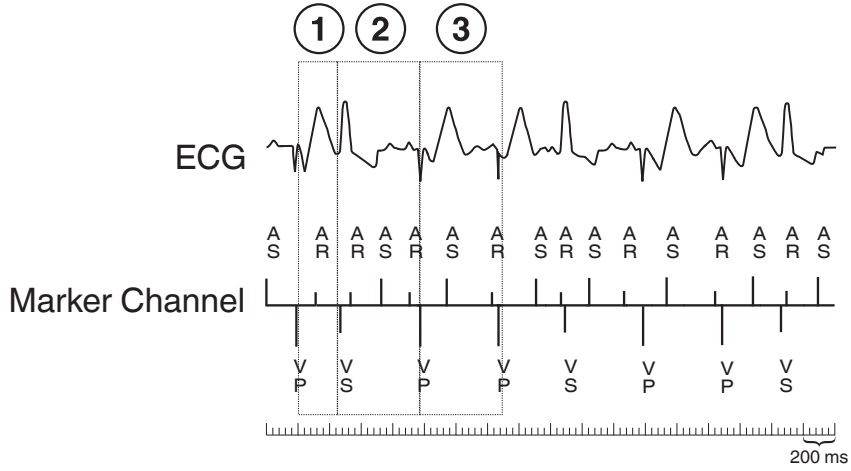
The Conducted AF Response feature helps promote a regular ventricular rate during conducted AT/AF episodes.

8.18.2 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.

Conducted AF Response operates only in nontracking (DDIR and VVIR) modes. It is typically applied during a mode switch brought about by the onset of an atrial tachyarrhythmia.

Figure 110. Operation of Conducted AF Response



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

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

8.18.3 Programming considerations for Conducted AF Response

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.

8.18.4 Programming Conducted AF Response

Select Params icon
- ⇒ Arrhythmia Interventions…
  - ▷ Conducted AF Response <On>
  - ⇒ Additional V Settings…
    - ▷ Response Level
    - ▷ Maximum Rate

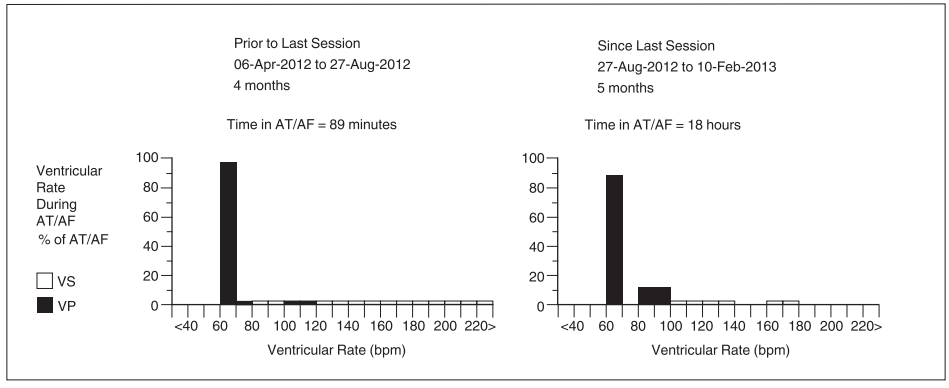
8.18.5 Evaluation of Conducted AF Response

The device reports ventricular rates during AT/AF episodes in the Rate Histogram and Cardiac Compass Trends reports. This information may help you decide which Response Level and Maximum Rate values to select for Conducted AF Response.

To view or print Rate Histograms from the Data icon:

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Cardiac Compass Trends

Figure 111. Rate Histogram Report

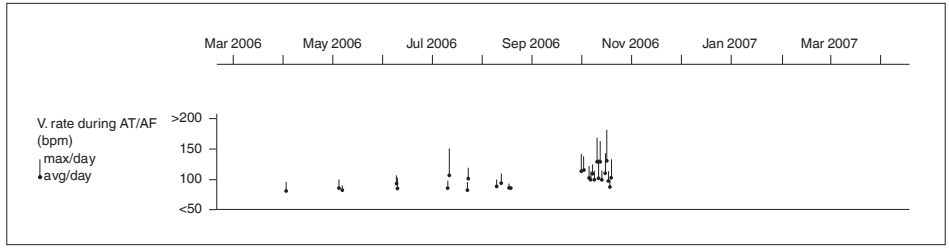


This report shows the distribution of ventricular rates during AT/AF episodes. For more information, see Section 7.8, “Using rate histograms to assess heart rates”, page 124.

To view or print Cardiac Compass Trends from the Data icon:

Select Data icon
⇒ Clinical Diagnostics
⇒ Cardiac Compass Trends

Figure 112. Cardiac Compass Trends Report



This report shows the ventricular rate during AT/AF episodes, providing maximum and average rates for each episode. For more information, see Section 7.3, “Viewing long-term clinical trends with the Cardiac Compass Report”, page 106.

8.19 Responding to PVCs using Ventricular Rate Stabilization

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

8.19.1 System solution: Ventricular Rate Stabilization

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.

8.19.2 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:

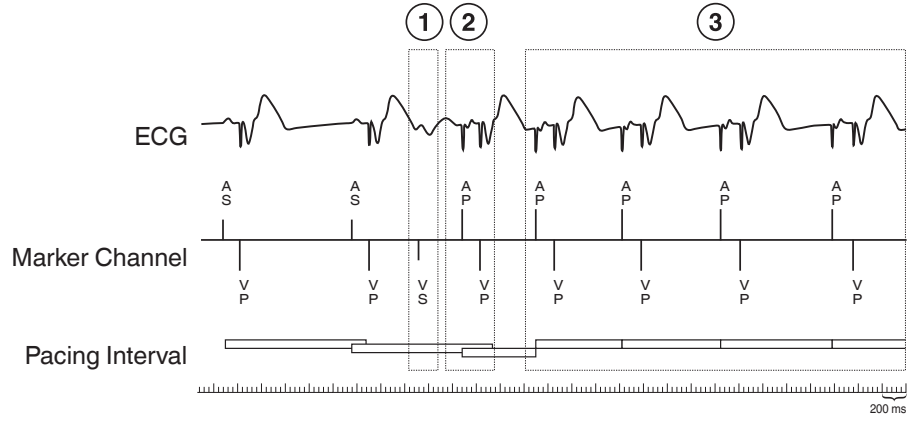
- Maximum Rate sets a limit on the minimum pacing interval.
- Interval Increment increases the pacing interval length with each successive ventricular sense or ventricular pace.

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 device is programmed to the DDDR, DDD, DDIR, DDI, VVIR, VVI, AAIR<=>DDDR, or AAI<=>DDD mode.

Note: In an MVP mode (AAIR<=>DDDR or AAI<=>DDD), VRS functions only when MVP is operating in DDDR or DDD mode.

Figure 113. 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.

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.

8.19.3 Programming considerations for VRS

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.

8.19.4 Programming VRS

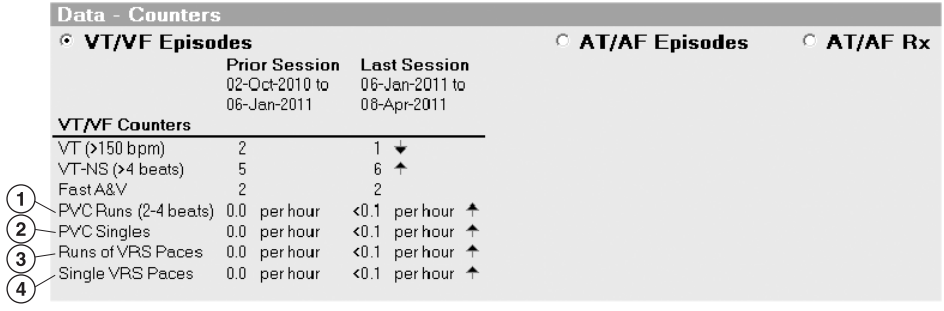
Select Params icon
- ⇒ Arrhythmia Interventions…
  - ⇒ V. Rate Stabilization <On>
    - ⇒ Additional V Settings…
      - ▷ Maximum Rate
      - ▷ Interval Increment

8.19.5 Evaluation of VRS performance

The device collects and stores counter data that includes information about the frequency of PVCs and VRS operation. You can view the stored data on the programmer screen and print the data.

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Counters
    - ⇒ VT/VF Episodes

Figure 114. Example of PVC and VRS counter data



1 PVC Runs counter reports instances of PVCs in which 2 to 4 premature ventricular events occur consecutively.
2 PVC Singles counter reports instances of premature events that occur separately.
3 Runs of VRS Paces counter reports instances of VRS pacing pulses per hour in which 2 or more consecutive ventricular events are VRS pacing pulses.
4 Single VRS Paces counter reports instances of single VRS pacing pulses per hour.

9 Configuring tachyarrhythmia detection

9.1 Detecting atrial tachyarrhythmias

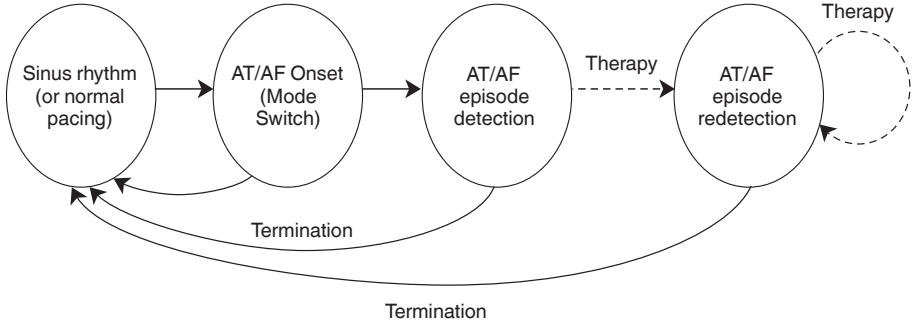
Atrial tachyarrhythmias are generally characterized by atrial rates that are faster than the ventricular rates. Atrial tachyarrhythmia can cause patient symptoms. When the device is in an atrial tracking mode, atrial tachyarrhythmia can also cause inappropriately fast ventricular pacing.

9.1.1 System solution: AT/AF Detection

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 AT/AF Detection is programmed to Monitor, the device switches to DDIR mode, if necessary, and collects atrial tachyarrhythmia episode data but does not deliver therapies.

9.1.2 Operation of AT/AF Detection

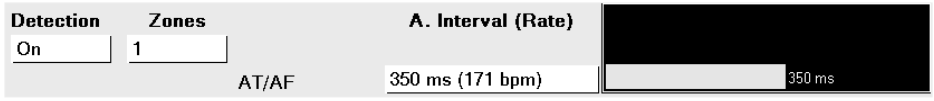
Figure 115. Overview of AT/AF Detection



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.

To program atrial tachyarrhythmia detection, select an AT/AF interval, labeled as A. Interval (Rate) on the programmer screen.

Figure 116. AT/AF Detection parameters



9.1.2.1 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 the Cardiac Compass Report.

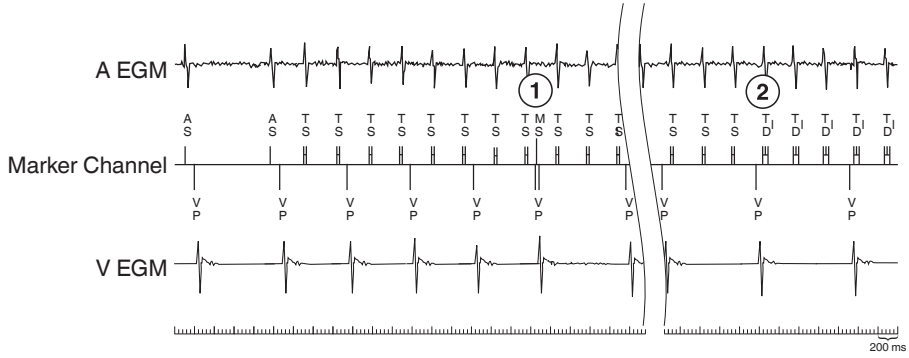
9.1.2.2 Detecting an atrial tachyarrhythmia episode

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 9.1.5, “Evaluation of AT/AF Detection”, page 242.

Figure 117. 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.

After detection, the device may deliver a programmed sequence of atrial therapies.

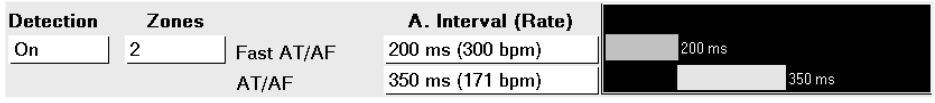
Notes:

- 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.

9.1.2.3 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.

Figure 118. AT/AF and Fast AT/AF Detection parameters



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.

9.1.2.4 Redetecting an atrial tachyarrhythmia

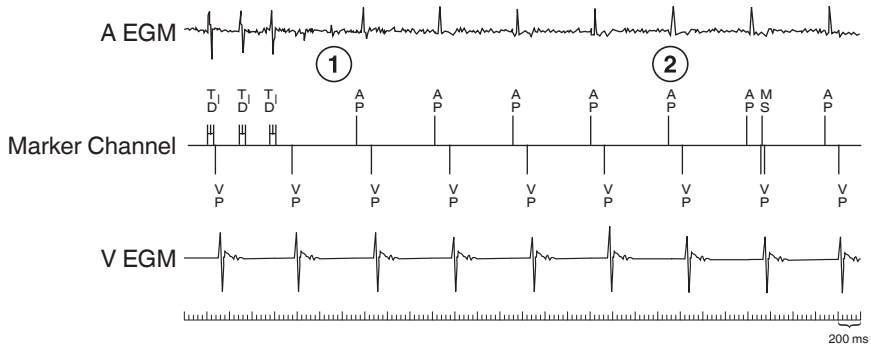
After a therapy sequence is delivered, the device must redetect the atrial tachyarrhythmia before applying another therapy sequence. The device applies a subsequent therapy sequence only when both of the following conditions are met:

- 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.

9.1.2.5 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 119. AT/AF termination



1 Atrial EGM shows that fast atrial rhythm has stopped.
2 There have been 5 consecutive intervals of 1:1 atrial-ventricular rhythm, with all 5 intervals being 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.

9.1.2.6 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.

9.1.3 Programming considerations for 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.

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.

9.1.4 Programming AT/AF Detection

9.1.4.1 Programming AT/AF Detection

Select Params icon
- ▷ AT/AF Detection <On>
- ▷ AT/AF Interval (Rate)

9.1.4.2 Programming AT/AF Detection for 2 detection zones

Select Params icon
- ⇒ AT/AF | Therapies…
  - ▷ Detection <On>
  - ▷ Zones <2>
  - ▷ Fast AT/AF A. Interval (Rate)
  - ▷ AT/AF A. Interval (Rate)

9.1.4.3 Programming AT/AF monitoring

Select Params icon
- ▷ AT/AF Detection <Monitor>
- ▷ AT/AF A. Interval (Rate)

9.1.5 Evaluation of AT/AF Detection

9.1.5.1 Quick Look II screen

Select Data icon
- ⇒ 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.

9.1.5.2 Data - Arrhythmia Episodes screen

Select Data icon

⇒ Clinical Diagnostics

⇒ Arrhythmia Episodes

The Data - 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.

Figure 120. Episode Plot

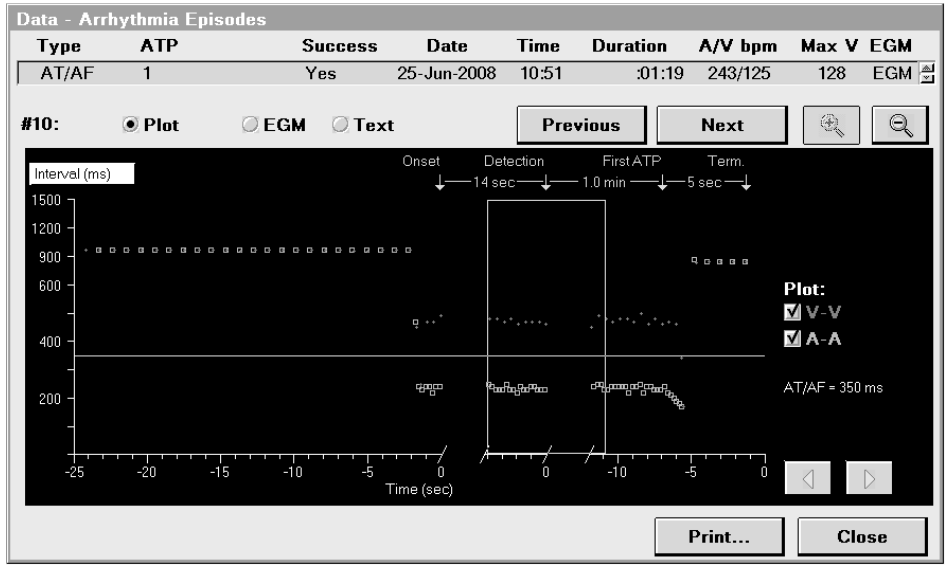


Figure 121. Episode EGM showing AT/AF Onset

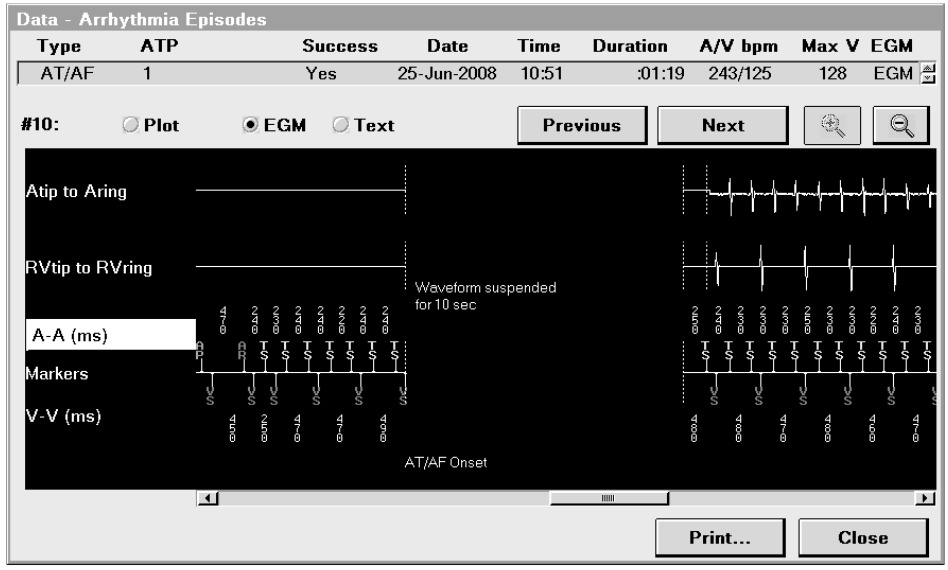
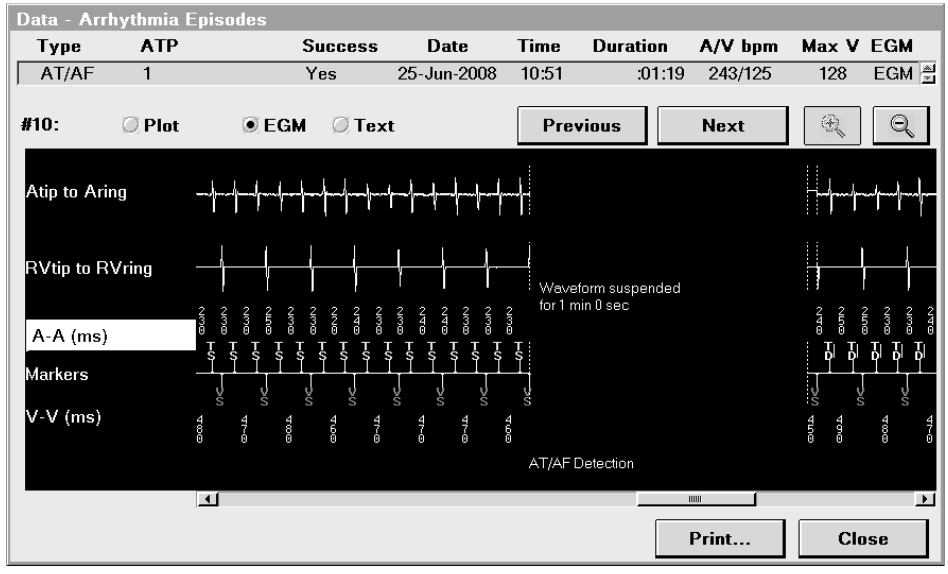


Figure 122. Episode EGM showing AT/AF Detection



9.1.5.3 Cardiac Compass Report

You can view or print Cardiac Compass Trends starting from the Data icon:

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Cardiac Compass Trends

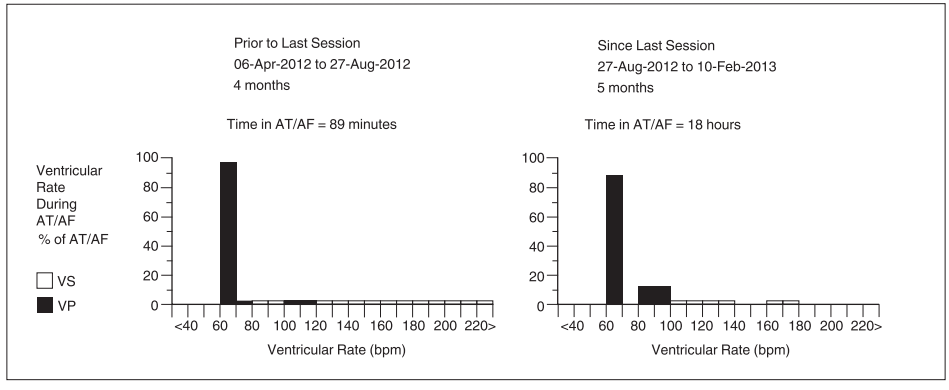
9.1.5.4 Rate Histograms Report

To view or print Rate Histograms from the Data icon:

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Rate Histograms

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

Figure 123. V. Rate During AT/AF Histogram



9.1.5.5 AT/AF episode counters

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Counters
    - ⇒ 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 7.5, “Viewing episode and therapy counters”, page 117.

9.2 Monitoring ventricular tachyarrhythmias

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

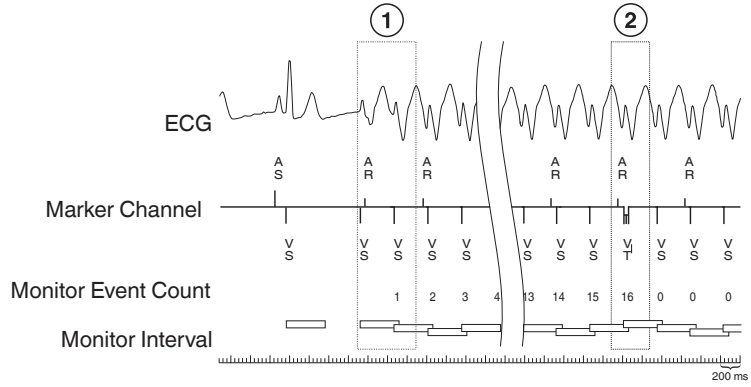
9.2.1 System solution: VT Monitor

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 Episode data for these episodes, and you can view and print this data from the Arrhythmia Episode and Flashback Memory displays.

9.2.2 Operation of VT Monitor

The device detects a ventricular tachyarrhythmia episode when 16 (for the Advisa DR MRI device) or 20 (for the Advisa SR MRI device) 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 124. 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 Advisa DR MRI 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 Advisa SR MRI 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.

9.2.2.1 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. For more information, see Section 7.4, “Viewing Arrhythmia Episodes data and setting data collection preferences”, page 110.

VT-NS – If at least 5 but fewer than 16 (for Advisa DR MRI) or 20 (for Advisa SR MRI) 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. For more information, see Section 7.4, “Viewing Arrhythmia Episodes data and setting data collection preferences”, page 110.

9.2.3 Programming VT Monitor

Select Params icon
- ▷ VT Detection <Monitor>
- ▷ VT Interval (Rate)

9.2.4 Evaluation of VT Monitor

9.2.4.1 Quick Look II Observations

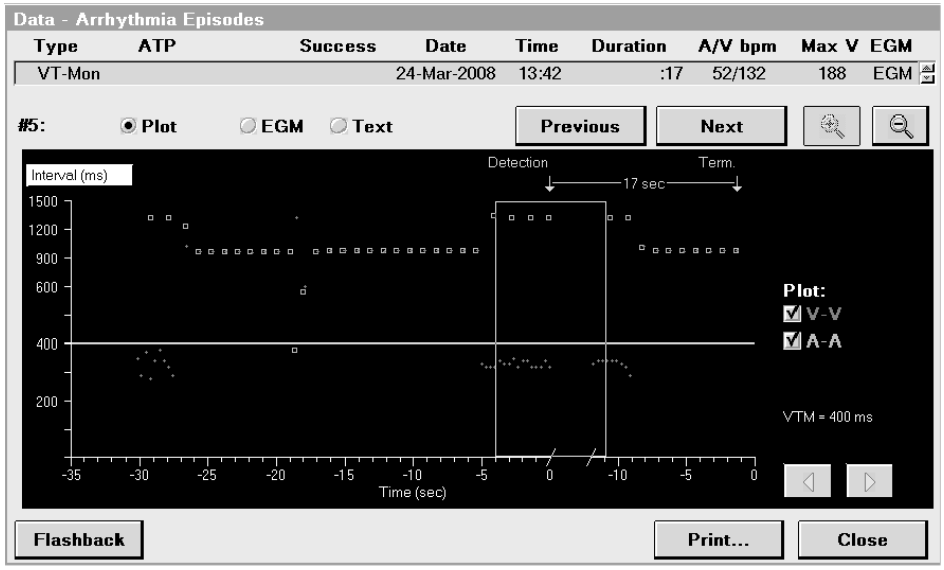
Select Data icon
- ⇒ Quick Look II

The Quick Look II screen shows the number of monitored VT episodes since the last session.

9.2.4.2 Data - Arrhythmia Episodes screen

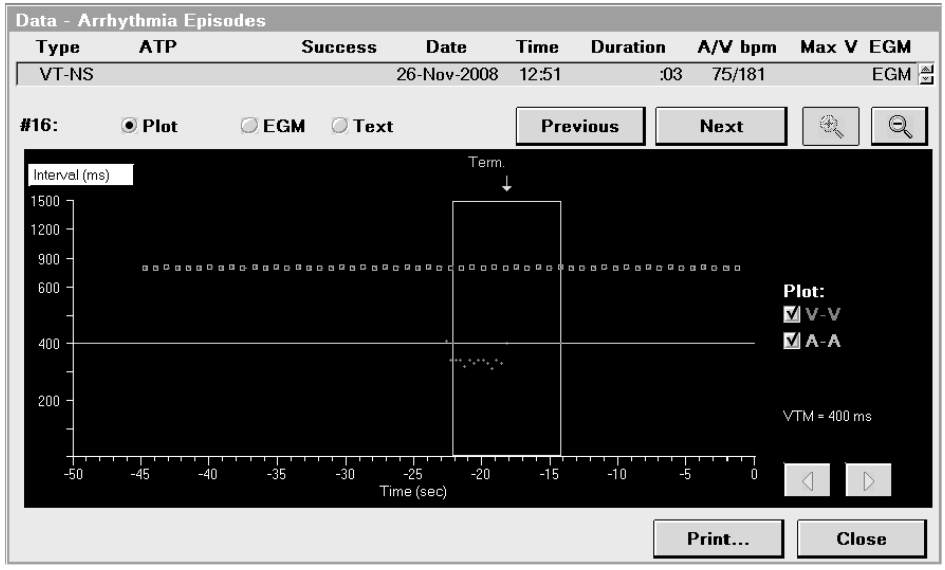
Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Arrhythmia Episodes

Figure 125. Episode Plot showing a VT Monitor episode



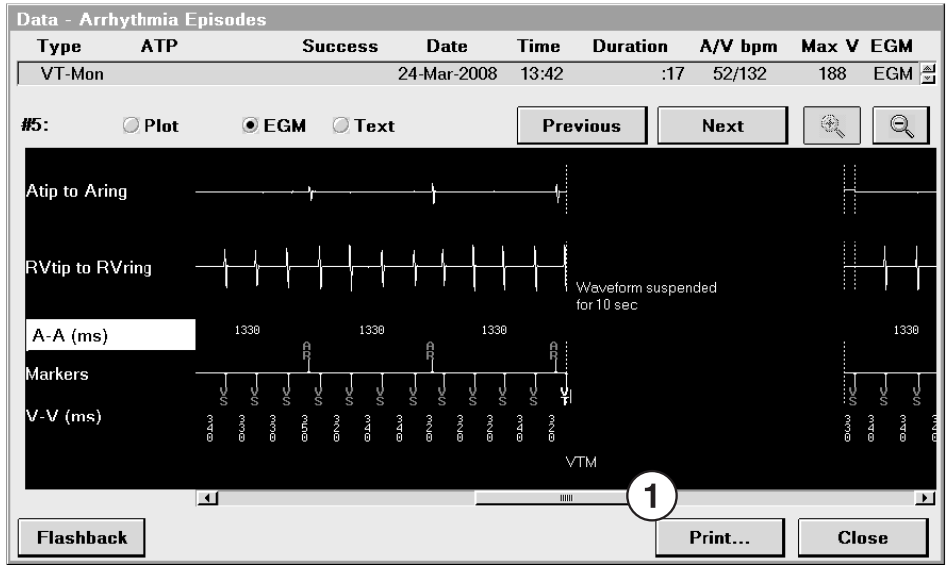
The Episode Plot record for a VT Monitor episode shows the detection and termination points.

Figure 126. Episode Plot showing a non-sustained VT Monitor episode



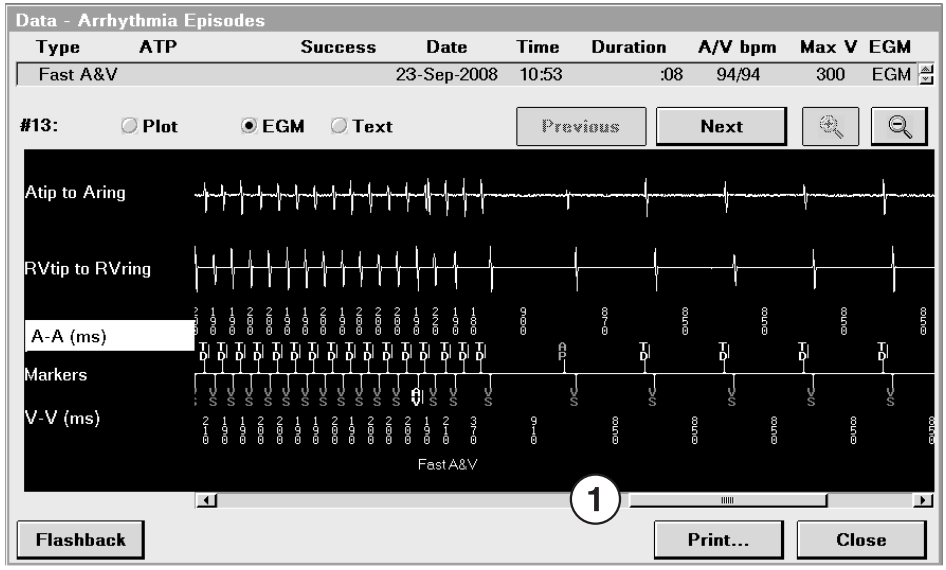
For an Advisa DR MRI device, the Episode Plot record for a non-sustained VT Monitor episode shows patterns of at least 5 but fewer than 16 events in the VT Monitor zone. For an Advisa SR MRI device, the Episode Plot record for a non-sustained VT Monitor episode shows patterns of at least 5 but fewer than 20 events in the VT Monitor zone.

Figure 127. Episode EGM showing a VT Monitor episode



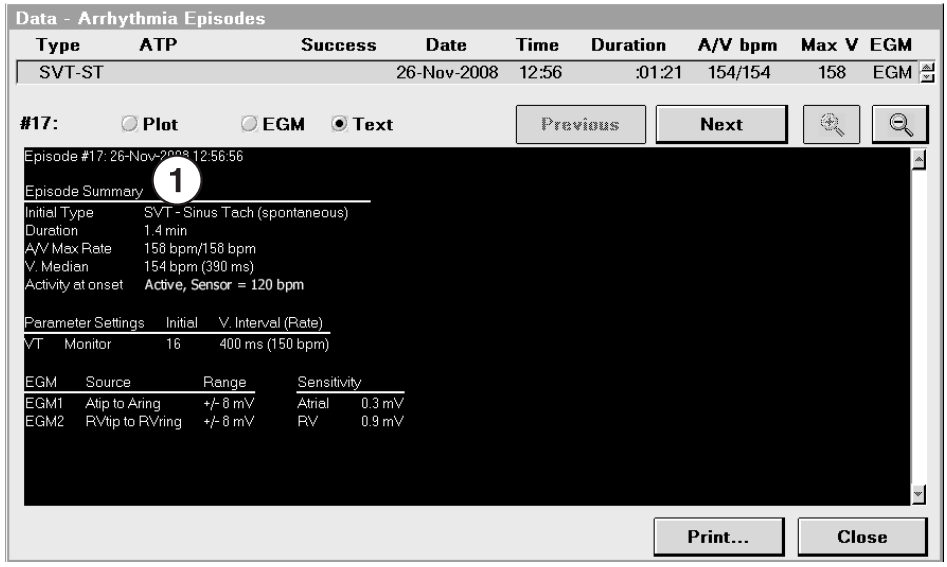
1 The Episode EGM record for a VT Monitor episode includes the Decision Channel annotation, VTM.

Figure 128. Episode EGM showing a Fast A&V episode



1 The Episode EGM record for a Fast A&V episode includes the Decision Channel annotation, Fast A&V.

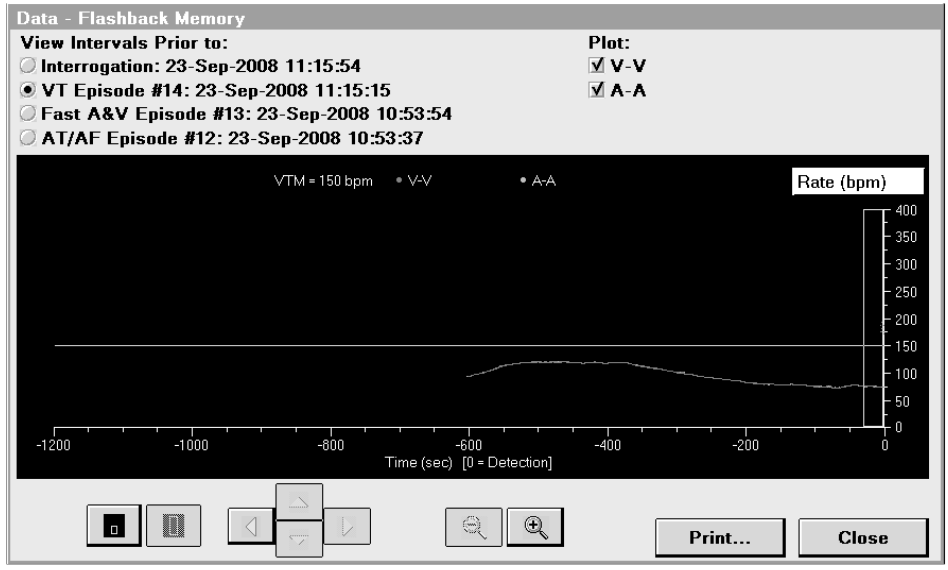
Figure 129. Episode Text showing a sinus tachycardia episode



1 The Episode Text record for a sinus or junctional tachycardia episode includes the text, SVT. No annotation appears on the Episode EGM Decision Channel.

9.2.4.3 Flashback Memory

Figure 130. Flashback Memory screen

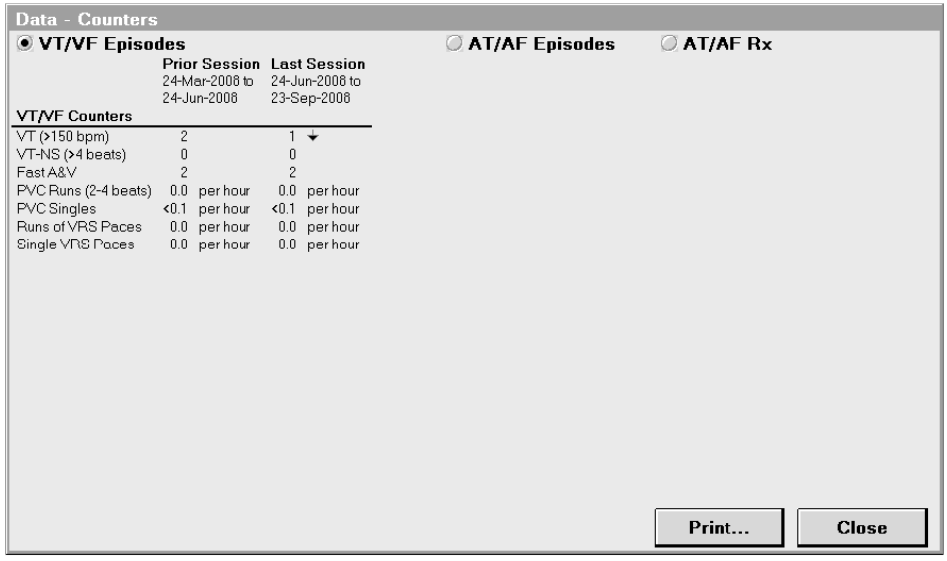


The Flashback Memory screen shows interval and marker data prior to the most recent occurrence of a VT or Fast A&V episode. Total elapsed time is plotted against interval length in milliseconds.

9.2.4.4 VT/VF episode counter

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Counters
    - ⇒ VT/VF Episodes

Figure 131. VT/VF episode counter



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.

9.3 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.

9.3.1 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.

9.3.2 How to suspend or resume detection with the programmer

Figure 132. [Suspend] and [Resume] buttons

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 a SUSPENDED annotation on the status bar.
2. To resume detection, select [Resume].

9.3.3 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, refer to Section A.4, “Magnet application”, page 290.
- A magnet can be used to suspend detection and initiate magnet mode only when there is no telemetry between the device and the programmer.

10 Configuring tachyarrhythmia therapies

10.1 Scheduling atrial therapies

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.

10.1.1 System solution: atrial therapy scheduling

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.

Refer to the following sections for information about atrial detection and therapies:

- Section 9.1, "Detecting atrial tachyarrhythmias", page 237
- Section 10.2, "Treating AT/AF episodes with antitachycardia pacing", page 262

10.1.2 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.

10.1.2.1 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.

10.1.2.2 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.

10.1.2.3 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.

10.1.2.4 Reactive ATP

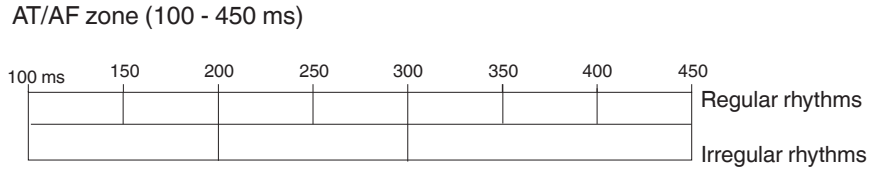
In some cases, the programmed set of atrial ATP therapies may not initially terminate an atrial tachyarrhythmia. Additional attempts at termination with the same set of atrial ATP therapies may be successful, particularly if the atrial rhythm changes. The Reactive ATP feature makes it possible for the device to repeat programmed sets of atrial ATP therapies in 2 different situations. Rhythm Change, one type of Reactive ATP, 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.

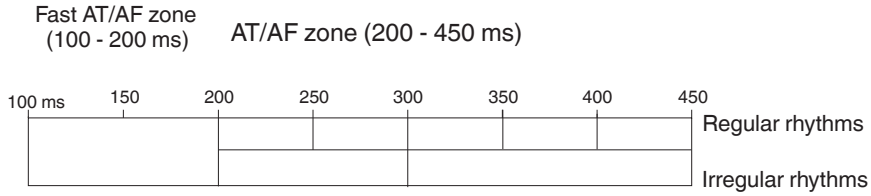
For 1 atrial detection zone, the number of regions depends on the programmed AT/AF Detection interval. Refer to Figure 133.

Figure 133. AT/AF zone subdivided for Rhythm Change (AT/AF only)



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 134. 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 134. AT/AF zone subdivided for Rhythm Change (AT/AF and Fast AT/AF)



Note: To view the number of atrial ATP therapies that were delivered for each region, view the Arrhythmia Episodes diagnostic. See Section 10.1.5.

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.

10.1.2.5 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.

The system also provides 2 programmable options that disable atrial therapies under certain situations. You can access these options by selecting “Stop Atrial Rx After Rx/Lead 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.

10.1.3 Programming considerations for atrial therapy scheduling

Atrial therapies and MRI SureScan – If the MRI SureScan feature is programmed to On, the device does not detect atrial and ventricular tachyarrhythmias or PVCs, 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.

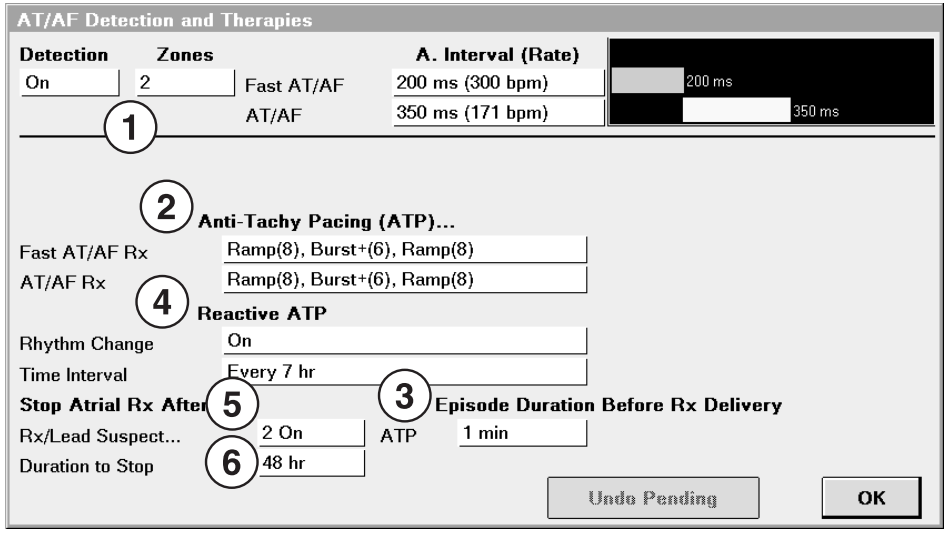
Atrial Lead Position Check – To ensure that the lead position check occurs, verify that the pacing mode includes atrial pacing. The lead position check does not occur if the programmed pacing mode is VVIR, VVI, VOO, DOO, or ODO.

Atrial Lead Position Check and Ventricular Safety Pacing – The lead position check cannot be enabled unless Ventricular Safety Pacing is enabled.

10.1.4 Programming atrial therapy scheduling

Select the Params icon to open the Parameters window. Program AT/AF Detection to On. Then, select the AT/AF therapies field (the last field in the row) to open the AT/AF Detection and Therapies window. Program atrial therapy scheduling parameters as outlined in the following steps:

1. Set the number of Zones to 1 or 2 as appropriate for the patient.
2. Select the desired ATP therapies.
3. Select the desired value for Episode Duration Before Rx Delivery (ATP).

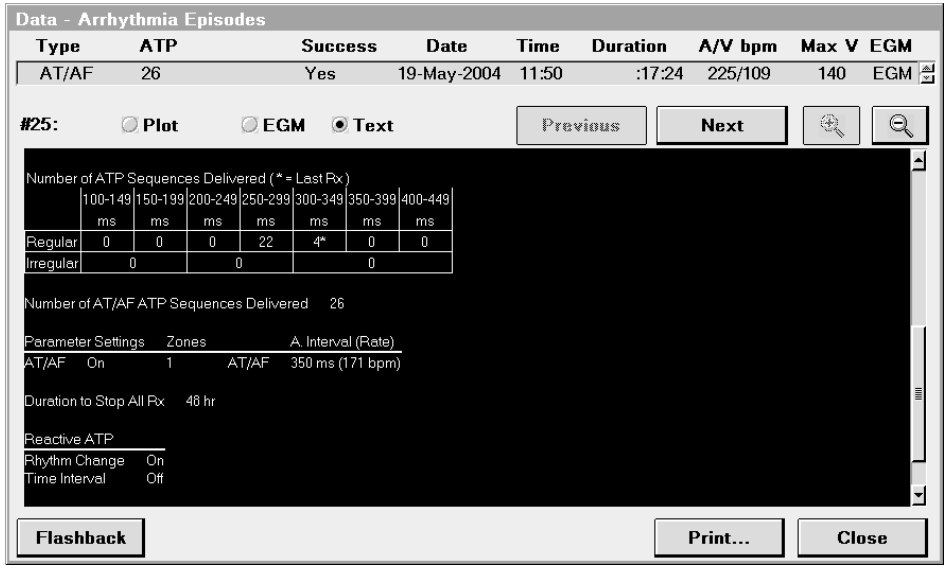


4. Select the desired values for Reactive ATP (Rhythm Change and Time Interval).
5. Select whether atrial therapies should be disabled if rate acceleration occurs or if the lead position is suspect.
6. Select the desired value for Duration to Stop.
7. Return to the Parameters screen and select [PROGRAM].

10.1.5 Evaluation of atrial therapy scheduling

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Arrhythmia Episodes
    - ⇒ Text

Figure 135. Data – Arrhythmia Episodes screen



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

10.2 Treating AT/AF episodes with antitachycardia pacing

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.

10.2.1 System solution: atrial antitachycardia pacing therapies

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 9.1, "Detecting atrial tachyarrhythmias", page 237.

10.2.2 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.

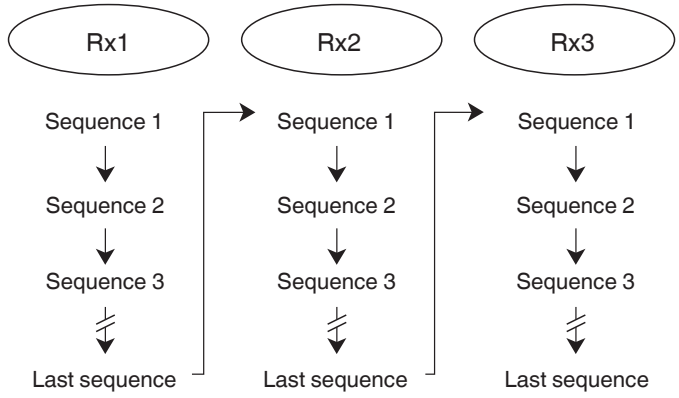
The device schedules the delivery of atrial therapies throughout a sustained AT/AF episode, based on the programmed settings. An ATP therapy may be aborted if no atrial event occurs within 500 ms after the therapy is scheduled.

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 136. Overview of atrial ATP therapy delivery



For an overview of atrial ATP sequence delivery, see Figure 137.

Note: VVI backup pacing is available during an atrial ATP therapy delivery. For more information, refer to Section 10.2.2.5.

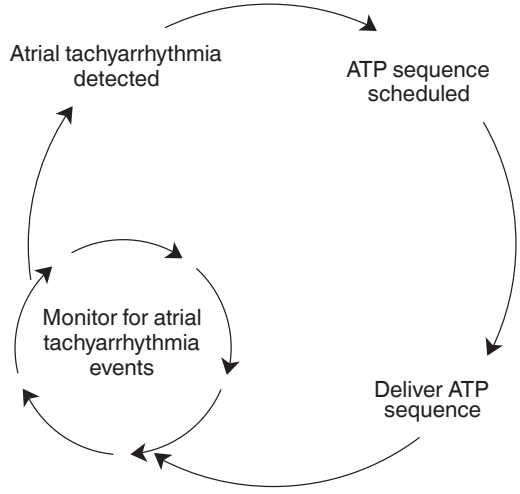
10.2.2.1 Atrial ATP therapy scheduling

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, refer to Section 10.1, “Scheduling atrial therapies”, page 257.

Figure 137. Overview of atrial ATP sequence delivery



10.2.2.2 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.

10.2.2.3 Operation of Burst+ pacing

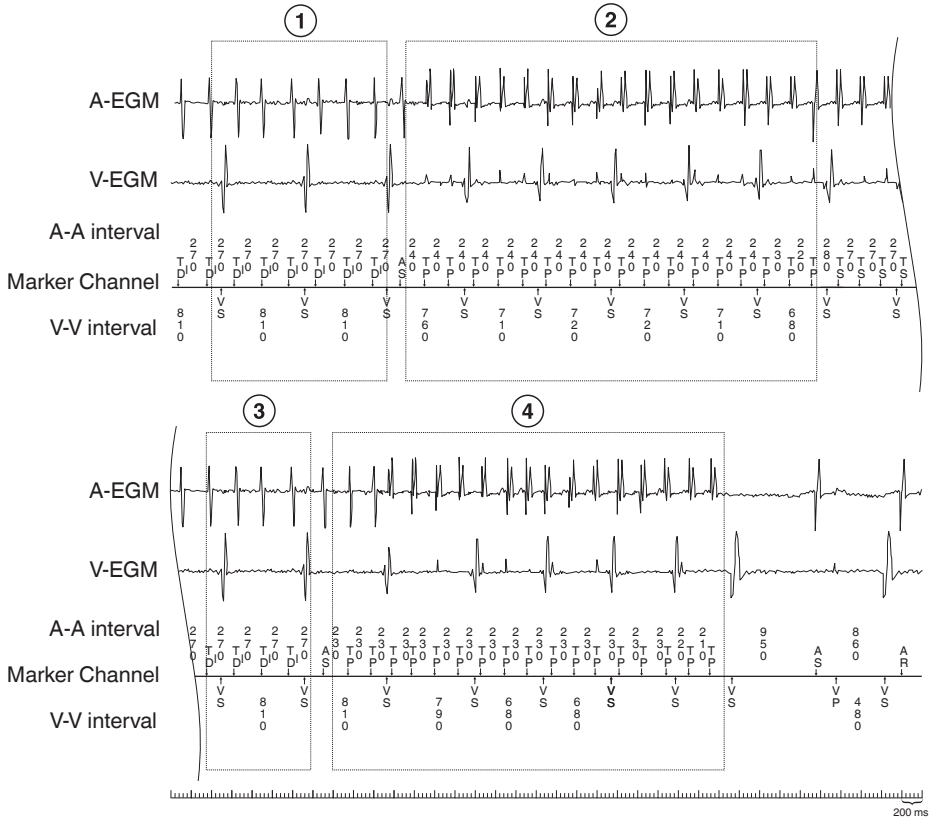
The programmable parameter Initial #S1 Pulses sets the number of Initial #S1 Pulses in each Burst+ therapy sequence. A-S1 Interval (%AA), S1-S2 (%AA), and S2-S3 Decrement are programmable parameters that determine the pacing intervals in a Burst+ sequence.

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 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 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 138. 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.

10.2.2.4 Operation of Ramp pacing

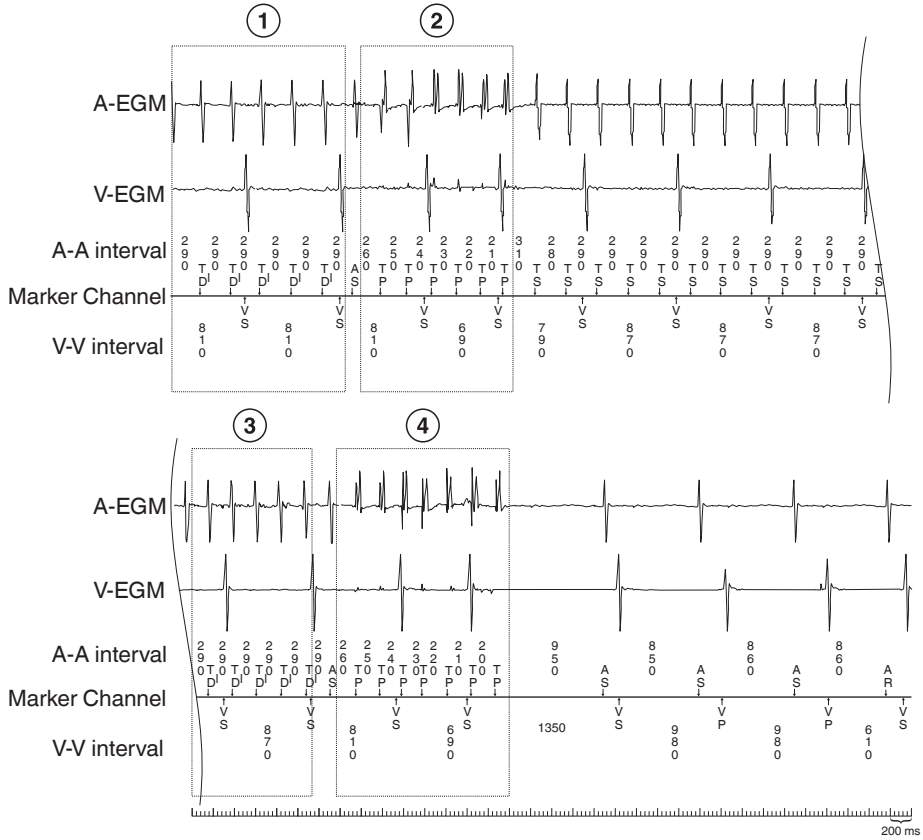
The Initial #S1 Pulses parameter sets the number of pulses in the first Ramp sequence. A-S1 Interval (%AA) and Interval Decrement are programmable parameters that determine the Ramp pacing intervals.

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 139. 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.

10.2.2.5 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.

10.2.2.6 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.

For information about programmable options that disable therapies, refer to Section 10.1, “Scheduling atrial therapies”, page 257.

10.2.3 Programming considerations for atrial ATP therapies

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.

10.2.4 Programming atrial ATP therapies

1. Select the Params icon to open the Parameters window.
2. Program AT/AF Detection to On.
3. Select the AT/AF therapies field (the last field in the row) to open the AT/AF Detection and Therapies window.
4. Select the Anti-Tachy Pacing (ATP)… field for Fast AT/AF Rx or AT/AF Rx to open the AT/AF Pacing Therapies window.

The following sections outline the steps for programming ATP therapies in the AT/AF zone, but you can program ATP therapies in the Fast AT/AF zone similarly, after selecting the Fast AT/AF Rx field in the AT/AF Detection and Therapies window.

10.2.4.1 Programming Burst+ pacing therapy

AT/AF Rx | Anti-Tachy Pacing (ATP)…
- ▷ AT/AF Rx Status <On>
- ▷ Therapy Type <Burst+>
- ▷ Initial #S1 Pulses
- ▷ A-S1 Interval (%AA)
- ▷ S1-S2 (%AA)
- ▷ S2-S3 Decrement
- ▷ Interval Decrement
- ▷ # Sequences

10.2.4.2 Programming Ramp pacing therapy

AT/AF Rx | Anti-Tachy Pacing (ATP)…

- ▷ AT/AF Rx Status <On>
- ▷ Therapy Type <Ramp>
- ▷ Initial #S1 Pulses
- ▷ A-S1 Interval (%AA)
- ▷ Interval Decrement
- ▷ # Sequences

10.2.4.3 Programming Shared A. ATP therapies

AT/AF Rx | Anti-Tachy Pacing (ATP)…

- ⇒ Shared A. ATP
  - ▷ A-A Minimum ATP Interval
  - ▷ A. Pacing Amplitude and Pulse Width
  - ▷ VVI Backup Pacing

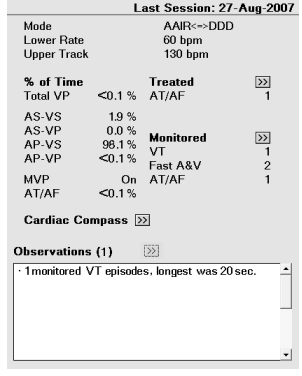
10.2.5 Evaluation of atrial ATP therapies

10.2.5.1 The Quick Look II screen

Select Data icon

- ⇒ Quick Look II

Figure 140. AT/AF information on the Quick Look II screen



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.

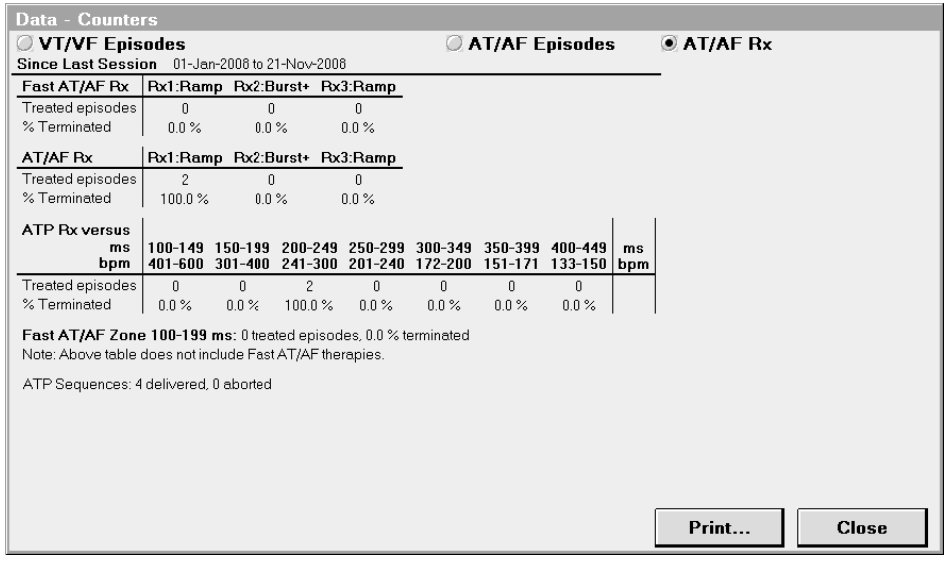
Quick Look II Observations – The Quick Look II Observations are based on an analysis of interrogated data since the last session and programmed parameters. You can select a specific observation and then select the Observations [>>] button to view related information.

10.2.5.2 AT/AF therapy counters

The AT/AF therapy counters provide information that helps you to evaluate the efficacy of atrial ATP therapies delivered since the last session.

Select Data icon
- ⇒ Clinical Diagnostics
  - ⇒ Counters
    - ⇒ AT/AF Rx

Figure 141. AT/AF therapy counters



The following therapy counter data is available for atrial ATP therapies:

AT/AF therapies – 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 therapies – 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.

11 Testing the system

11.1 Evaluating the underlying rhythm

The Underlying Rhythm Test allows you to evaluate the patient's intrinsic heart rhythm by temporarily inhibiting the pacing output of the device. During the Underlying Rhythm Test, the device is temporarily programmed to a nonpacing mode.

11.1.1 Considerations for evaluating the underlying rhythm

Caution: While the Underlying Rhythm Test is in progress, patients are not receiving pacing support. Pacing is inhibited as long as you press and hold the [INHIBIT Press and Hold] button. Carefully consider the implications of performing this test on pacemaker-dependent patients.

Manually lowering the pacing rate – For all patients, consider lowering the programmed Lower Rate and ensuring that the patient is at this rate before inhibiting pacing. These actions may help avoid sudden changes in the ventricular rate support.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Underlying Rhythm Test.

11.1.2 How to perform an Underlying Rhythm Test

1. Select Tests > Underlying Rhythm.
2. Press and hold [INHIBIT Press and Hold]. Pacing is inhibited until this button is released.
3. To print a recording of the heart's intrinsic rhythm, press the desired paper speed key on the printer or recorder. The ECG trace should not show any pacing.

11.2 Measuring pacing thresholds

The Pacing Threshold Test allows you to determine the patient's pacing stimulation thresholds. Pacing threshold information may be used to determine appropriate amplitude and pulse width settings to ensure capture while minimizing output to maximize battery longevity.

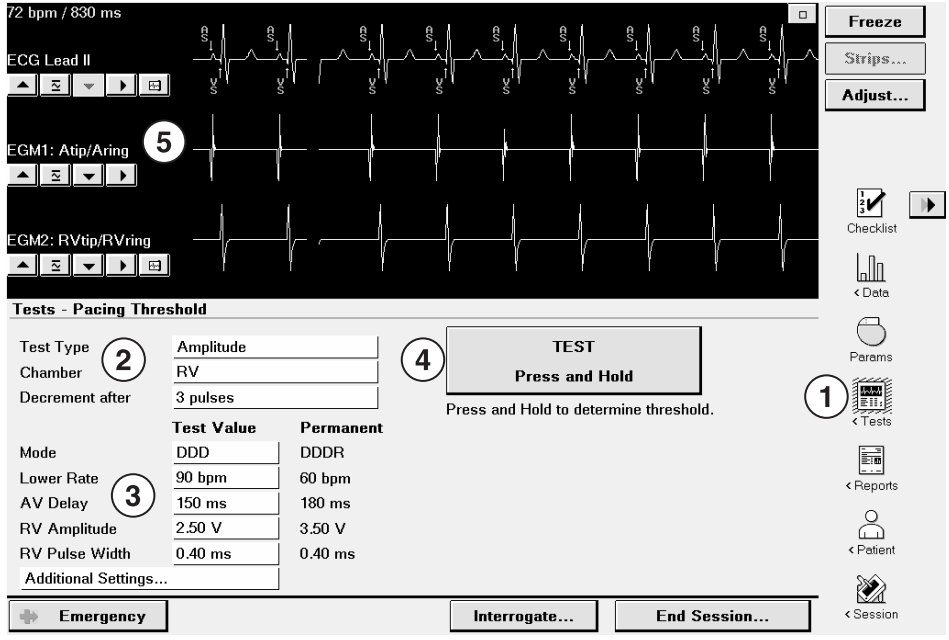
11.2.1 Considerations for measuring pacing thresholds

Selectable and default values – The selectable and default values provided by the Pacing Threshold Test depend on the programmed values for bradycardia pacing therapy.

Pacing threshold and safety margin – After performing a Pacing Threshold Test, make sure that the permanently programmed pulse width and amplitude parameters provide an adequate safety margin above the pacing threshold.

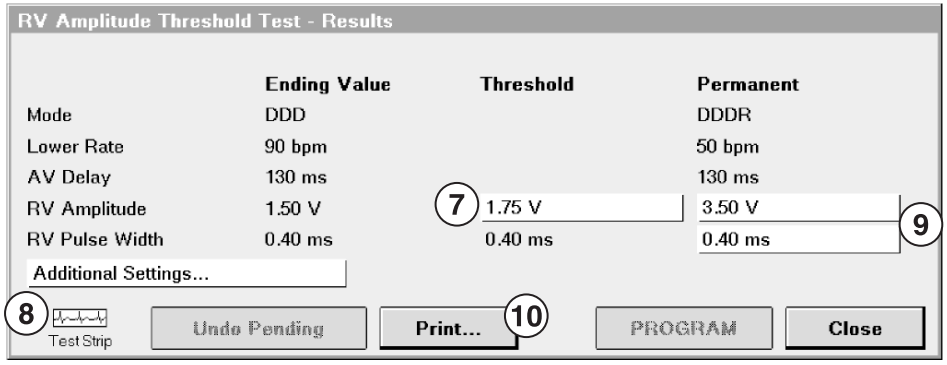
Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Pacing Threshold Test.

11.2.2 How to measure pacing thresholds



1. Select Tests > Pacing Threshold.
2. Select values for Test Type, Chamber, and Decrement after or accept the values displayed.
3. Select the starting Test Value for Mode, Lower Rate, AV Delay, Amplitude, and Pulse Width or accept the values displayed.
4. Press and hold [TEST Press and Hold].
5. Observe the Live Rhythm Monitor for loss of capture.

6. When capture is lost, immediately release [TEST Press and Hold]. The device resumes its original pacing values and displays the test results window.



7. To change the detected pacing threshold, select the appropriate value in the Threshold column.
8. To view a test strip from the Pacing Threshold Test, select the Test Strip icon. For more information, see Section 4.10, “Working with the Live Rhythm Monitor”, page 54.
9. To program new amplitude or pulse width values, select Amplitude or Pulse Width in the Permanent column in the test results window. The Capture window opens. In the Capture window, select the desired values and select [OK]. On the next window, select [PROGRAM].
10. To print a Pacing Threshold Test Report, select [Print…].

11.3 Measuring lead impedance

The Lead Impedance Test allows you to test the integrity of the implanted lead system by measuring the impedance of the atrial and ventricular pacing electrodes. Impedance measurements are made without delivering pacing pulses that capture the heart. The device makes these measurements by using low-voltage subthreshold pulses.

11.3.1 Considerations for measuring lead impedance

Sensing measurement pulses – During a sequence of lead impedance measurements, the device may sense the subthreshold test pulses as atrial refractory events or atrial sensed events. The test pulses may also cause very small variations on 1 or more of the EGM channels. Pulses delivered during a Lead Impedance Test do not capture the heart.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Lead Impedance Test.

11.3.2 How to measure lead impedance

1. Select Tests > Lead Impedance.
2. Select [START Measurement]. Wait for confirmation of programming and an in-progress message.
3. If necessary, end the test by selecting [STOP]. Lead impedance measurements are not updated from a test that is stopped.
4. When the test is complete, the new measured impedance values for the tested polarities are displayed. You may also view the measurements for all available lead polarities by selecting the All Measured Polarities [>>] button.

You may determine if the lead impedance has changed by comparing the measured values to the values reported on the Lead Impedance Trends screen and those measured during previous follow-up appointments (look in the patient's chart).

11.4 Performing a Sensing Test

The Sensing Test allows you to measure P-wave and R-wave amplitudes, which may be useful for assessing lead integrity and sensing performance. The Sensing Test allows you to temporarily program the Mode, AV Delay, and Lower Rate so that the device is not pacing the patient and increases the likelihood that sensed events will occur. After the test has started, you may continue to decrease the pacing rate until the intrinsic heart rhythm prevails. The device measures amplitudes only on intrinsic events.

11.4.1 Considerations for performing a Sensing Test

DOO, VOO, and AOO pacing modes – The Sensing Test cannot be performed if the programmed pacing mode is DOO, VOO, or AOO.

Pacing modes available – The pacing modes available under Test Value depend on the programmed pacing mode.

Patient comfort – During a Sensing Test, reduce the pacing rate gradually to minimize patient symptoms associated with abrupt changes in heart rate.

Automatic timeout – The Sensing Test ends automatically after a few seconds and restores the programmed settings if no intrinsic events occur and no changes are made to the pacing rate.

Comparison to sensing trends – Sensing amplitude measurements taken during a Sensing Test may include events that are atypical or a result of oversensing (for example PVCs or far-field R-waves). These events are excluded from the daily automatic sensing amplitude measurements the device collects and reports in the sensing amplitude trends.

Because of this difference in measurement operations, Sensing Test results may differ from those reported in the sensing amplitude trend data.

Maximum measured value – The maximum amplitude value that the Sensing Test can measure is 20 mV. If the amplitude is over 20 mV, the results are displayed as >20 mV.

Selecting sensitivity values – Do not adjust the values for A. Sensitivity and RV Sensitivity based on the results of the Sensing Test. For more information, see Section 8.1, “Sensing intrinsic cardiac activity”, page 140.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended during the Sensing Test.

11.4.2 How to perform a Sensing Test

Caution: Use caution when selecting temporary pacing settings for pacemaker-dependent patients. These patients may not receive adequate pacing support while amplitude measurements are being obtained.

1. Interrogate the device by selecting [Interrogate…].
2. Select Tests > Sensing.
3. Program the Test Value parameters for Mode and AV Delay or accept the values displayed.
4. Select [START Measurement].
5. Observe the Live Rhythm Monitor for an intrinsic rhythm. If consistent pacing is still occurring, decrease the Lower Rate.
6. If necessary, abort the test by selecting [STOP and Restore]. The temporary pacing settings of Mode, AV Delay, and Lower Rate return to the programmed values.

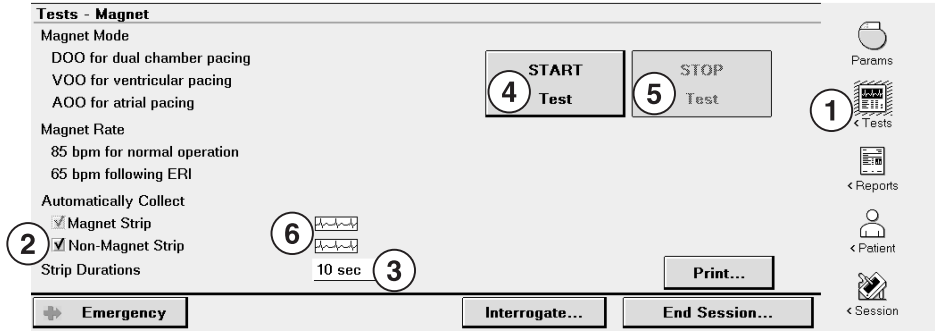
After the Sensing Test is complete, the measurement results are displayed on the test screen. To compare the Sensing Test measurements with the automatic daily sensing amplitude measurements, select the P/R Wave Amplitude Trends [>>] button.

11.5 Observing and documenting magnet mode operation

During magnet mode operation, the device provides asynchronous pacing at a fixed rate. While the device is in a telemetry session with the programmer, you cannot initiate magnet mode operation by placing a magnet over the device. To observe and document magnet mode operation using the programmer, you can use the Magnet test. The Magnet test simulates the presence of a magnet over the device, and can automatically record live rhythm monitor strips showing magnet mode and non-magnet mode operation.

For more information about magnet mode operation, see Section A.4, “Magnet application”, page 290 for Advisa DR and Section B.4, “Magnet application”, page 298 for Advisa SR.

11.5.1 How to perform a Magnet test



1. Select Tests > Magnet.
2. If you want the test to automatically record a strip showing non-magnet operation, select the Non-Magnet Strip check box.
3. Select a duration for the automatically collected strips.
4. Select [START Test].
5. If necessary, you can stop the Magnet test by selecting [STOP Test].

   Note: At any time during a Magnet test, lifting the programming head from over the patient’s pacemaker for at least 2 s restores operation of the pacemaker to its permanent status. This action should be taken in the event of programmer malfunction, loss of power, or the absence of an appropriate command confirmation.

6. To view and print the collected strips, select the Magnet Strip icon or the Non-Magnet Strip icon. The selected strip is displayed in the frozen strip viewing window. For more information, see Section 4.10, “Working with the Live Rhythm Monitor”, page 54.

11.6 Inducing an arrhythmia

The device provides several electrophysiology study (EP study) functions, including cardiac stimulation protocols that induce tachyarrhythmias. The available induction methods are 50 Hz Burst, Fixed Burst, and PES. These induction protocols may be used to induce arrhythmias during EP testing to evaluate the effectiveness of tachyarrhythmia therapies.

11.6.1 Considerations for inducing an arrhythmia

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Telemetry link – Make sure that there is a telemetry link between the device and the programmer before performing an EP study function. Successful interrogation or programming confirms proper communication between the device and the programmer.

Resuming detection – Tachyarrhythmia detection is automatically suspended during all EP study functions. If detection is manually suspended prior to the induction, it is not resumed automatically when the induction is delivered. All EP study inductions provide the option to resume detection automatically after the induction is delivered.

Select the check box for Resume at BURST or Resume at DELIVER to enable automatic resume for an induction. To resume detection after a manual therapy or after an induction delivered with automatic resume disabled, select [Resume] or remove the programming head from the implanted device.

Aborting an induction or therapy – As a safety measure, the programmer displays an [ABORT] button that may be selected to immediately abort any induction or tachyarrhythmia therapy in progress. A burst induction may also be aborted by removing the touch pen from the [Press and Hold] button. When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy in progress.

Temporary parameter values – The EP study functions use test values that do not change the programmed parameters of the device. The test values take effect when the induction or therapy begins. After the induction or therapy, the device reverts to its programmed parameter values for bradycardia pacing and tachyarrhythmia therapy.

Programmed parameters check – Before displaying an induction screen, the system verifies that the device is programmed to detect and treat an induced arrhythmia. If the detection or therapy features are not programmed appropriately, a warning message appears on the screen.

Programming head buttons – The Program button on the programming head is disabled during EP study inductions and manual therapies. Use the appropriate button on the programmer screen to deliver an induction or manual therapy. The Interrogate button on the programming head is disabled during EP study inductions only. Use the [Interrogate] button on the programmer screen to interrogate the device while the EP study induction screen is active.

11.6.2 Inducing AT/AF with an atrial 50 Hz Burst

You can use an atrial 50 Hz Burst to induce AT/AF. To induce AT/AF, the 50 Hz Burst induction delivers a rapid burst of AOO pacing pulses to the atrium. You can specify the amplitude and pulse width of these pulses, but the pacing interval is fixed at 20 ms.

As long as you press and hold the [50 Hz BURST Press and Hold] button on the programmer screen, the device continues delivering the induction (up to a maximum of 10 s).

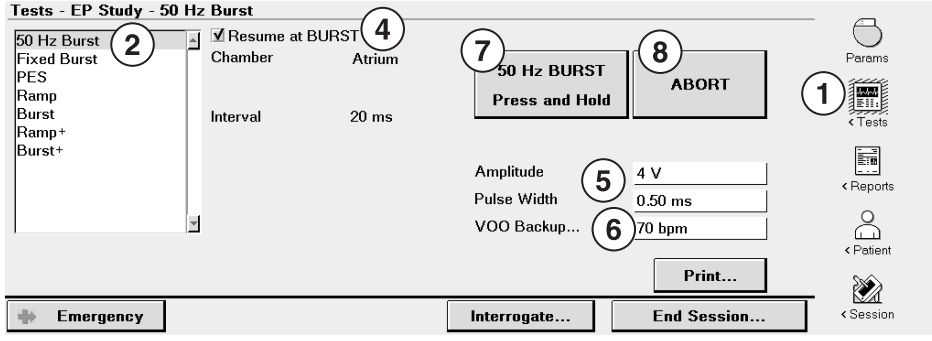
If you perform an atrial 50 Hz Burst induction, you may choose to have the device deliver VOO Backup pacing.

The atrial 50 Hz Burst can also be used to manually treat AF episodes.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

11.6.2.1 How to deliver an atrial 50 Hz Burst

Figure 142. Atrial 50 Hz Burst induction screen



1. Select Tests > EP Study.
2. Select 50 Hz Burst from the list of inductions and therapies.
3. If you want to treat the induced episode with a manual therapy, select [Suspend] to prevent automatic detection.

   Note: The [Suspend] button is located at the top of the 50 Hz Burst induction screen and is not shown in Figure 142.

4. Select the Resume at BURST check box for automatic detection and therapy, or clear the check box for manual therapy.

5. Accept the displayed test values or select new test values.
6. If you want to provide VOO Backup pacing during the pacing burst, select values for VOO Backup.
7. Press and hold [50 Hz BURST Press and Hold]. Release the button to end the induction.
8. If necessary, select [ABORT] to abort a therapy in progress.

11.6.3 Inducing AT or VT with Fixed Burst

You can use the Fixed Burst inductions to induce AT or VT. To induce atrial or ventricular tachyarrhythmias, the Fixed Burst induction delivers a set of asynchronous AOO or VOO pacing pulses at a uniform, selectable interval to the designated chamber. You can also specify the amplitude and pulse width of the pulses.

If you perform an atrial Fixed Burst induction, you may choose to have the device deliver VVI Backup pacing.

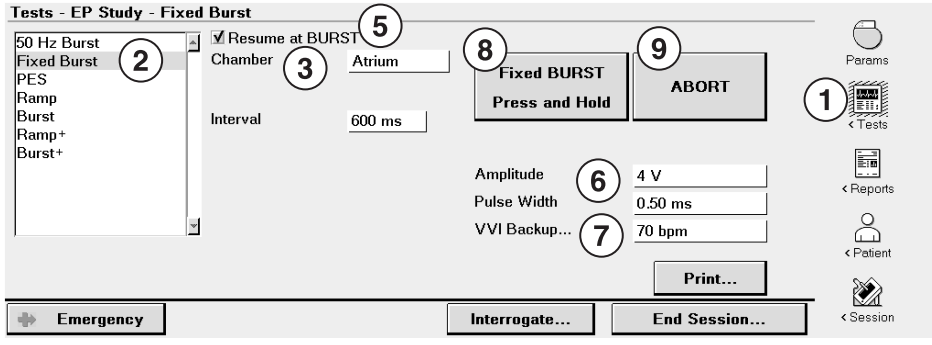
11.6.3.1 Considerations for inducing AT or VT with Fixed Burst

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Atrial Amplitude and VVI Backup pacing – VVI Backup pacing during an atrial Fixed Burst induction may be inhibited by crosstalk if the test value for atrial Amplitude is greater than 6 V.

11.6.3.2 How to deliver a Fixed Burst induction

Figure 143. Fixed Burst induction screen



1. Select Tests > EP Study.
2. Select Fixed Burst from the list of inductions and therapies.
3. If the Chamber Selection dialog box appears, select [Atrium] or [RV].
4. If you want to treat the induced episode with a manual therapy, select [Suspend] to prevent automatic detection.

   Note: The [Suspend] button is located at the top of the Fixed Burst induction screen and is not shown in Figure 143.

5. Select the Resume at BURST check box for automatic detection and therapy, or clear the check box for manual therapy.
6. Accept the displayed test values or select new test values.
7. If you want to provide VVI Backup pacing during an atrial induction, select values for VVI Backup.
8. Press and hold [Fixed BURST Press and Hold]. Release the button to end the induction.
9. If necessary, select [ABORT] to abort a therapy in progress.

11.6.4 Inducing AT or VT with Programmed Electrical Stimulation

You can use Programmed Electrical Stimulation (PES) to induce AT or VT. To induce atrial or ventricular tachycardias, PES delivers a selectable number of pacing pulses at the S1S1 interval and then delivers up to 3 asynchronous pacing pulses at S1S2, S2S3, and S3S4 intervals. You can specify the chamber, amplitude, pulse width, and pacing intervals for the induction.

If you perform an atrial PES induction, you may choose to have the device deliver VVI Backup pacing.

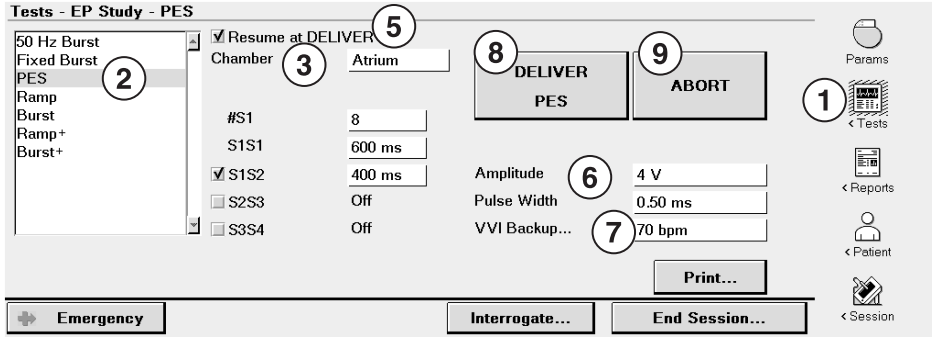
11.6.4.1 Considerations for inducing AT or VT with PES

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Atrial Amplitude and VVI Backup pacing – VVI Backup pacing during an atrial PES induction may be inhibited by crosstalk if the test value for atrial Amplitude is greater than 6 V.

11.6.4.2 How to deliver a PES induction

Figure 144. PES induction screen



1. Select Tests > EP Study.
2. Select PES from the list of inductions and therapies.
3. If the Chamber Selection dialog box appears, select [Atrium] or [RV].
4. If you want to treat the induced episode with a manual therapy, select [Suspend] to prevent automatic detection.

   Note: The [Suspend] button is located at the top of the PES induction screen and is not shown in Figure 144.

5. Select the Resume at DELIVER check box for automatic detection and therapy, or clear the check box for manual therapy.
6. Accept the displayed test values or select new test values.
7. If you want to provide VVI Backup pacing during an atrial induction, select values for VVI Backup.
8. Select [DELIVER PES]. Release the button to end the induction.
9. If necessary, select [ABORT] to abort a therapy in progress.

11.7 Delivering a manual therapy

Manual therapies are tachyarrhythmia therapies you initiate from the programmer. During EP testing, you can use manual therapies to provide backup therapy. At follow-up appointments, manual therapies may be helpful in assessing therapy effectiveness and making any necessary adjustments as part of chronic care.

The available manual therapies are Ramp, Burst, Ramp+, and Burst+.

11.7.1 Considerations

Warning: Monitor the patient carefully when delivering a manual therapy. Have an external defibrillator nearby and ready for immediate use. Potentially harmful tachyarrhythmias may occur during device testing.

Aborting an induction or a therapy – As a safety precaution, you can select the [ABORT] button displayed on the programmer to terminate any induction, manual therapy, or automatic therapy in progress. When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy already in progress.

Atrial Amplitude and VVI Backup pacing – If the test value for Atrial Amplitude is greater than 6 V, VVI Backup pacing during a manual atrial ATP therapy may be inhibited by crosstalk.

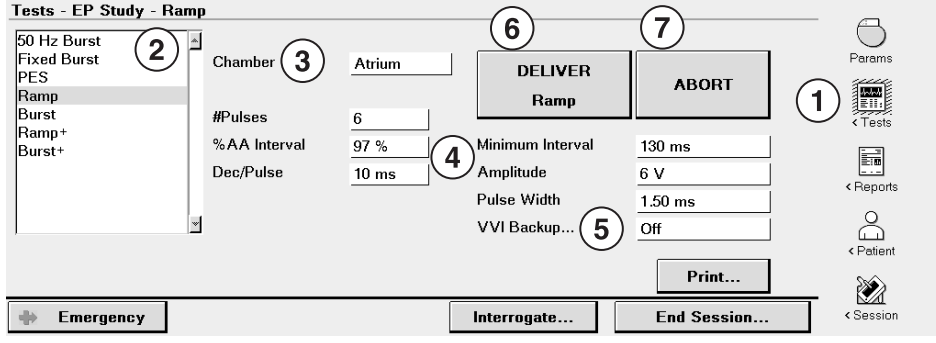
Detection suspended during manual therapy – Tachyarrhythmia detection is automatically suspended when delivering a manual therapy. Detection stays suspended until you select [RESUME] or the telemetry session between the programmer and device ends.

Programming head buttons – The Program button on the programming head is disabled during manual therapies. Use the appropriate on-screen [DELIVER] button to deliver a manual therapy.

Telemetry – Ensure that a telemetry link is established between the device and the programmer before you perform a manual therapy. Successful interrogation or programming confirms proper communication between the device and the programmer.

Temporary parameter values – The manual therapy functions use temporary values that do not change the programmed parameters of the device. The temporary values take effect when the manual therapy begins. After the manual therapy, the device reverts to its programmed parameter values for bradycardia pacing and tachyarrhythmia therapy.

11.7.2 How to deliver a manual therapy



1. Select Tests > EP Study.
2. Select the desired manual therapy from the list of inductions and therapies.
3. If the Select Chamber dialog box appears, select [Atrium] or [RV] as appropriate.
4. Accept the current test values or choose new test values.
5. To provide VVI Backup pacing during an atrial therapy, select VVI Backup… and set the VVI Backup pacing parameters.
6. Select [DELIVER].
7. If necessary, select [ABORT] to terminate the manual therapy.

11.7.3 Operation of manual therapies

In general, each manual therapy with a corresponding automatic therapy performs in the same manner as its automatic counterpart.

Antitachycardia pacing therapies – Manual Ventricular ATP therapies deliver one sequence of the selected therapy. For information about the operation of atrial Ramp and Burst+ therapies, see Section 10.2, “Treating AT/AF episodes with antitachycardia pacing”, page 262.

Note: The manual ventricular Ramp, Ramp+, and Burst ATP therapies are not available as automatic therapies.

Ventricular Ramp pacing therapy – Manual Ventricular Ramp pacing therapy delivers the selected number of pacing pulses in VVI mode. The pacing interval for the first pulse of the Ramp sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected %RR Interval. Each subsequent pulse in the sequence is delivered at progressively shorter intervals by subtracting the selected interval decrement (Dec/Pulse) from each pulse.

Ventricular Ramp+ pacing therapy – Manual Ventricular Ramp+ pacing therapy delivers the selected number of pacing pulses in VOO mode. The pacing interval for the first pulse of the Ramp+ sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected R-S1 (%RR). The second pulse is delivered at an interval determined using the selected S1-S2 (%RR) percentage. Any remaining pulses in the sequence are delivered at the selected S2-SN (%RR) percentage.

Ventricular Burst pacing therapy – Manual Ventricular Burst pacing therapy delivers the selected number of pacing pulses in VOO mode. The pacing interval for the Burst sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected %RR Interval. The pulses within the sequence are delivered at the same pacing interval.

A Advisa DR MRI - Quick reference

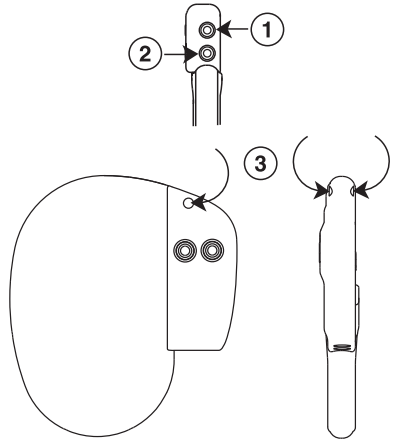
A.1 Physical characteristics

Table 11. Physical characteristics

Volume[a]	12.7 cm^3
Mass	22 g
H x W x D[b]	45 mm x 51 mm x 8 mm
Radiopaque ID[c]	PVX
Medtronic identifier	
Surface area of titanium device can	32.2 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium silver vanadium oxide with carbon monofluoride

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Figure 145. Connector and suture hole



1 IS-1 connector port, A
2 IS-1 connector port, V
3 Suture hole

A.2 Replacement indicators

The battery voltage and messages about replacement status appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT), Elective Replacement Indicator (ERI), and the End of Service (EOS) conditions are listed in Table 12.

Table 12. Replacement indicators

Recommended Replacement Time (RRT)	≤ 2.83 V on 3 consecutive daily automatic measurements
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

RRT date – The programmer displays the date when the battery reached RRT on the Quick Look II and Battery and Lead Measurements screens.

Replace at EOS – If the programmer indicates that the device is at EOS, replace the device immediately.

RRT operation – When the device reaches RRT, it continues to operate with its programmed parameters. However, placing a magnet over the device initiates asynchronous pacing at 65 bpm rather than at 85 bpm.

ERI operation – When the device reaches ERI, it automatically changes the value of several parameters as shown in Table 13.

Table 13. Parameter settings after ERI

Pacing Mode	VVI
Lower Rate	65 bpm
RV Amplitude	as programmed
RV Pulse Width	as programmed
Rate Hysteresis	Off
Sleep	Off
V. Rate Stabilization	Off
AT/AF Detection	Monitor[a]
Pre-arrhythmia EGM	Off[b]

[a] When AT/AF Detection is set to Monitor, AT/AF therapies are not available.
[b] Pre-arrhythmia EGM cannot be reprogrammed after ERI.

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.

Note: When MRI SureScan is on, battery measurements are taken, but the device does not report RRT, EOS, or ERI until MRI SureScan has been programmed to Off.

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 6 months assuming the following conditions: 100% DDD pacing at 60 bpm, 2.5 V atrial and RV pacing amplitude; 0.4 ms pulse width; and 600 Ω pacing load. The EOS may be indicated before the end of 6 months if the device exceeds these conditions.

A.3 Projected service life

The projected service life in years for the device is shown in Table 14, page 289. The data is based on pacing outputs programmed to the specified amplitude and 0.4 ms pulse width and 60 bpm pacing rate.

The service life of the device is affected by the programmed settings for certain features, such as Pre-arrhythmia EGM storage.

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. These values should not be interpreted as precise numbers.

Delivery of atrial antitachycardia pacing therapy does not appreciably alter the longevity, considered with the inhibition of atrial pacing during the AT/AF episode.

Table 14. Projected service life in years

Pacing	Pre-arrhythmia EGM storage[a]	500 Ω pacing impedance		600 Ω pacing impedance		900 Ω pacing impedance	
		2.5 V	3.5 V	2.5 V	3.5 V	2.5 V	3.5 V
DDD, 0%	Off	11.8	11.8	11.8	11.8	11.8	11.8
	On	11.6	11.6	11.6	11.6	11.6	11.6
DDD, 15%	Off	11.2	10.6	11.3	10.8	11.4	11.0
	On	11.0	10.4	11.1	10.6	11.2	10.9
DDD, 50%	Off	10.0	8.6	10.3	8.9	10.7	9.7
	On	9.9	8.5	10.1	8.8	10.5	9.5
AAI<=>DDD (MVP Mode) 50% Atrial, 5% Ventricular	Off	10.8	9.8	10.9	10.1	11.2	10.5
	On	10.6	9.7	10.7	9.9	11.0	10.4
DDD, 100%	Off	8.7	6.7	9.1	7.2	9.8	8.2
	On	8.6	6.6	8.9	7.1	9.6	8.0

[a] The data provided for programming Pre-arrhythmia EGM storage to On is based on a 6-month period (two 3-month follow-up intervals) over the life of the device. Additional use of Pre-arrhythmia EGM storage reduces projected service life by approximately 27% or 3.2 months per year.

Note: These projections are based on typical shelf storage time (5 months). Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 10.1%.

Table 15. Projected service life in years per conditions specified in EN 45502-2-1:2003

	500 Ω ± 1% pacing impedance	
Pacing	**2.5 V**	**5.0 V**
DDDR, 100%	7.9[a]	3.3[a]

[a] Data storage and diagnostic functions applicable to the pacing mode are On. Pulse width is set at 0.5 ms and pacing rate is 70 bpm.

A.4 Magnet application

When a magnet is placed near the device, the pacing mode changes from the programmed mode to DOO, VOO, or AOO, and the pacing rate changes to 85 bpm or 65 bpm as described at the end of this section. Placing a magnet near the device suspends tachyarrhythmia detection. When the magnet is removed, the device returns to its programmed operation.

Note: Magnet operation does not occur if telemetry between the device and programmer is established or if MRI SureScan is on.

The pacing mode will be DOO when the programmed pacing mode is a dual chamber mode or an MVP mode (AAIR<=>DDDR, AAI<=>DDD), VOO when the programmed pacing mode is a single chamber ventricular mode, and AOO when the programmed pacing mode is a single chamber atrial mode.

The pacing rate will be 85 bpm (710 ms) if the device conditions are normal and it will be 65 bpm (920 ms) if a Recommended Replacement Time (RRT) indicator or an electrical reset has occurred.

A.5 Stored data and diagnostics

Table 16. Arrhythmia episode data storage

Episode type	Capacity
Monitored VT episode log	100 entries
Monitored VT episode EGM, markers, and intervals	5 min
Non-sustained VT episode log	15 entries
Non-sustained VT episode EGM, markers, and intervals	2 min
Fast A&V episode log	15 entries
Fast A&V episode EGM, markers, and intervals	2 min
Treated AT/AF episode log	100 entries
Treated AT/AF episode EGM, markers, and intervals	8.25 min
Monitored AT/AF episode log	50 entries

Table 16. Arrhythmia episode data storage (continued)

Episode type	Capacity
Monitored AT/AF episode EGM, markers, and intervals	3 min
SVT episode log	25 entries
SVT episode EGM, markers, and intervals	2.5 min
Rate Drop Response episode log, markers, and intervals	10 entries
Patient activated episode log	50 entries
Flashback memory interval data before each of the following events: • Interrogation • VT Monitor Episode • Fast A&V Episode • AT/AF Episode	2000 events (includes both A- and V-events)

Table 17. VT/VF episode counters

The VT/VF episode counters are maintained for the current follow-up session and the previous follow-up session.	
Counts of each type of VT/VF episode	• VT • VT-NS (>4 beats) • Fast A&V • PVC Runs (2–4 beats) • PVC Singles • Runs of VRS Paces • Single VRS Paces

Table 18. AT/AF episode counters

The AT/AF episode counters are maintained for the current follow-up session and the previous follow-up session.	
AT/AF summary data	• % of Time AT/AF • Average AT/AF time/day • Monitored AT/AF Episodes • Treated AT/AF Episodes • Pace-Terminated Episodes • % of Time Atrial Pacing • % of Time Atrial Intervention • AT-NS (>6 beats)
Number of AT/AF episodes	• Grouped by duration[a] • Grouped by start time[a]

[a] This counter includes any instance when the device identifies AT/AF Onset. Therefore, the total number of episodes in this counter may exceed the number of detected AT/AF episodes recorded by the device.

Table 19. AT/AF therapy counters

The AT/AF therapy counters are maintained for the current follow-up session and the previous follow-up session.	
Number of AT/AF episodes treated and the percentage of episodes terminated	• Grouped by detection zone and therapy • Grouped by atrial cycle length
Counts of different types of AT/AF therapy	• ATP sequences – delivered – aborted

Table 20. Battery and lead measurement data

The device automatically and continuously monitors its battery and lead status throughout the life of the device. You may print and view the following data:

- Battery Voltage
- Remaining Longevity
  - Estimated at
  - Minimum
  - Maximum
- Sensing Integrity Counter
  - Short V-V Intervals
- Atrial Lead Position check
- Lead Impedance
  - A. Pacing
  - RV Pacing
- Sensing
  - P-Wave Amplitude
  - R-Wave Amplitude

Table 21. Lead performance trend data

For 14 days, the device stores daily measurements. After 14 days, the device compresses each full week of data into a weekly sample for up to 80 weeks. Beyond 82 weeks, data is maintained on a first-collected, first-deleted basis.

- A. Pacing Impedance
  - Bipolar
  - Unipolar
  - Uni/Bi
- RV Pacing Impedance
  - Bipolar
  - Unipolar
  - Uni/Bi
- Capture Threshold
  - Atrial
  - RV
- P/R Wave Amplitude
  - P-wave
  - R-wave

Table 22. Cardiac Compass trends data

Cardiac Compass trend data is available on the programmer screen or as a printed report. The report shows up to 14 months of long-term clinical trends. Each report contains the following information:

- Programming, interrogation, and remote session events with date and event annotations
- AT/AF total minutes or hours per day
- Ventricular rate during AT/AF
- Percent pacing per day
- Average ventricular rate (day and night rates)
- Patient activity
- Heart rate variability

Table 23. Rate Histograms data

Rate histogram data is available only as a printed report. The report shows the distribution of atrial and ventricular rates recorded since the last patient session and in the period before the last session.

The histograms show the percentage of total time paced or sensed for the following event sequences:[a]	• Total VP • AS-VS • AS-VP • AP-VS • AP-VP
The histograms show the rate distribution of paced and sensed events for the following conditions:	• Atrial rate[b] • Ventricular rate • Ventricular rate during AT/AF

[a] If the programmed pacing mode during the reporting period was a dual chamber mode, the report displays the AS-VS, AS-VP, AP-VS, and AP-VP event sequence data. If a single chamber mode was programmed, the report displays the percent of time spent pacing and sensing. MVP modes (AAIR<=>DDDR and AAI<=>DDD) are considered dual chamber modes for this purpose.

[b] If more than 2% of atrial sensed events are identified as far-field R-waves, the general percentage range (either “2% to 5%” or “>5%”) is reported above the atrial rate histogram.

B Advisa SR MRI - Quick reference

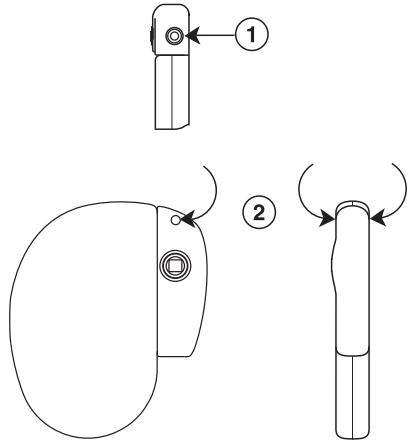
B.1 Physical characteristics

Table 24. Physical characteristics

Volume[a]	11.9 cm^3
Mass	21 g
H x W x D[b]	42 mm x 51 mm x 8 mm
Radiopaque ID[c]	PVX
Medtronic radiopaque identifier[c]	
Surface area of titanium device can	32.2 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium silver vanadium oxide with carbon monofluoride

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Figure 146. Connector and suture hole



1 IS-1 connector port, V
2 Suture hole

B.2 Replacement indicators

The battery voltage and messages about replacement status appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT), Elective Replacement Indicator (ERI), and the End of Service (EOS) conditions are listed in Table 25.

Table 25. Replacement indicators

Recommended Replacement Time (RRT)	≤ 2.83 V on 3 consecutive daily automatic measurements
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

RRT date – The programmer displays the date when the battery reached RRT on the Quick Look II and Battery and Lead Measurements screens.

Replace at EOS – If the programmer indicates that the device is at EOS, replace the device immediately.

RRT operation – When the device reaches RRT, it continues to operate with its programmed parameters. However, placing a magnet over the device initiates asynchronous pacing at 65 bpm rather than at 85 bpm.

ERI operation – When the device reaches ERI, it automatically changes the value of several parameters as shown in Table 26.

Table 26. Parameter settings after ERI

Pacing Mode	VVI
Lower Rate	65 bpm
RV Amplitude	as programmed
RV Pulse Width	as programmed
Rate Hysteresis	Off
Sleep	Off
V. Rate Stabilization	Off
Pre-arrhythmia EGM	Off[a]

[a] Pre-arrhythmia EGM cannot be reprogrammed after ERI.

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.

Note: When MRI SureScan is on, battery measurements are taken, but the device does not report RRT, EOS, or ERI until MRI SureScan has been programmed to Off.

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 6 months assuming the following conditions: 100% VVI pacing at 60 bpm, 2.5 V RV pacing amplitude; 0.4 ms pulse width; and 600 Ω pacing

load. The EOS may be indicated before the end of 6 months if the device exceeds these conditions.

B.3 Projected service life

The projected service life in years for the device is shown in Table 27. The data is based on pacing outputs programmed to the specified amplitude and 0.4 ms pulse width and 60 bpm pacing rate.

The service life of the device is affected by the programmed settings for certain features, such as Pre-arrhythmia EGM storage.

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. These values should not be interpreted as precise numbers.

Table 27. Projected service life in years

Pacing	Pre-arrhythmia EGM storage[a]	500 Ω pacing impedance		600 Ω pacing impedance		900 Ω pacing impedance	
		2.5 V[b]	3.5 V[b]	2.5 V[b]	3.5 V[b]	2.5 V[b]	3.5 V[b]
VVI, 0%	Off	13.9	13.9	13.9	13.9	13.9	13.9
	On	13.6	13.6	13.6	13.6	13.6	13.6
VVI, 15%	Off	13.5	13.1	13.5	13.2	13.6	13.4
	On	13.3	12.9	13.3	13.0	13.4	13.2
VVI, 50%	Off	12.7	11.5	12.8	11.8	13.1	12.4
	On	12.5	11.3	12.6	11.6	12.9	12.2
VVI, 100%	Off	11.7	9.8	11.9	10.2	12.5	11.1
	On	11.5	9.6	11.8	10.1	12.3	11.0

[a] The data provided for programming Pre-arrhythmia EGM storage to On is based on a 6-month period (two 3-month follow-up intervals) over the life of the device.
[b] 0.4 ms pulse width, 60 bpm when pacing and 70 bpm when sensing, and 5-month shelf life.

Note: These projections are based on typical shelf storage time (5 months). Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 10.1%.

Table 28. Projected service life in years per conditions specified in EN 45502-2-1:2003

Pacing	500 Ω ± 1% pacing impedance	
	2.5 V	5.0 V
VVIR, 100%	10.8[a]	5.7[a]

[a] Data storage and diagnostic functions applicable to the pacing mode are On. Pulse width is set at 0.5 ms and pacing rate is 70 bpm.

B.4 Magnet application

When a magnet is placed near the device, the pacing mode changes from the programmed mode to VOO. When the magnet is removed, the device returns to its programmed operation.

The pacing rate will be 85 bpm (710 ms) if the device conditions are normal and it will be 65 bpm (920 ms) if a Recommended Replacement Time (RRT) indicator or an electrical reset has occurred.

Note: Magnet operation does not occur if telemetry between the device and programmer is established or if MRI SureScan is on.

B.5 Stored data and diagnostics

Table 29. Arrhythmia episode data storage

Episode type	Capacity
Monitored VT episode log	100 entries
Monitored VT episode EGM, markers, and intervals	5 min
Non-sustained VT episode log	15 entries
Non-sustained VT episode EGM, markers, and intervals	2 min
Patient activated episode log	50 entries
Flashback memory interval data before each of the following events: • Interrogation • VT Monitor Episode	2000 events

Table 30. VT/VF episode counters

The VT/VF episode counters are maintained for the current follow-up session and the previous follow-up session.	
Counts of each type of VT/VF episode	• VT • VT-NS (>4 beats) • PVC Runs (2–4 beats) • PVC Singles • Runs of VRS Paces • Single VRS Paces

Table 31. Battery and lead measurement data

The device automatically and continuously monitors its battery and lead status throughout the life of the device. You may print and view the following data:

- Battery Voltage
- Remaining Longevity
  - Estimated at
  - Minimum
  - Maximum
- Sensing Integrity Counter
  - Short V-V Intervals
- Lead Impedance
  - RV Pacing
- Sensing
  - R-Wave Amplitude

Table 32. Lead performance trend data

For 14 days, the device stores daily measurements. After 14 days, the device compresses each full week of data into a weekly sample for up to 80 weeks. Beyond 82 weeks, data is maintained on a first-collected, first-deleted basis.

- RV Pacing Impedance
  - Bipolar
  - Unipolar
  - Uni/Bi
- Capture Threshold
  - RV
- P/R Wave Amplitude
  - R-wave

Table 33. Cardiac Compass trend data

Cardiac Compass Trends data is available on the programmer screen or as a printed report. The report shows up to 14 months of long-term clinical trends. Each report contains the following information:

- Programming, interrogation, and remote session events with date and event annotations
- Percent pacing per day
- Average ventricular rate (day and night rates)
- Patient activity
- Heart rate variability

Table 34. Rate Histograms data

Rate histogram data is available on the programmer screen or as a printed report. The report shows the distribution of ventricular rates recorded since the last patient session and in the period before the last session.	
The histograms show the percentage of total time paced or sensed for the following event sequences:	• VS • VP

C Advisa DR device parameters

C.1 Emergency settings

Table 35. Emergency VVI settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude[a]	6 V
RV Pulse Width[a]	1.5 ms
RV Pace Polarity	Unipolar
V. Blank Post VP	240 ms
Rate Hysteresis	Off
V. Rate Stabilization	Off
MRI SureScan	Off

[a] If the programmed RV Amplitude is 8 V, VVI pacing is delivered at 8 V with a pulse width of 1.2 ms.

C.2 Tachyarrhythmia detection parameters

Table 36. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
AT/AF Detection	On; Monitor◈	Monitor	Monitor
Zones	1◈; 2	—	—
AT/AF Interval (Rate)[a]	150; 160 … 350◈ … 450 ms	350 ms	350 ms
Fast AT/AF Interval (Rate)[a]	150; 160 … 200◈ … 250 ms	200 ms	200 ms
VT Monitor	Monitor◈; Off	Monitor	Off
VT Monitor Interval (Rate)[a]	280; 290 … 400◈ … 500 ms	400 ms	400 ms
RV Sensitivity[b,e,f]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Bipolar: 0.9◈ mV Unipolar: 2.80◈ mV	0.9 mV	2.8 mV
Atrial Sensitivity[b,c,d]	0.15; 0.3; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV Bipolar: 0.3◈ mV Unipolar: 0.45◈ mV	0.3 mV	0.45 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[c] With a 20 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.4 times the rated sine^2 sensing threshold.
[d] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in bipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 1.8 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 1.8 mV or higher.
[e] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.
[f] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 2.0 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 2.0 mV or higher.

C.3 Atrial tachyarrhythmia therapy parameters

Table 37. Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
Anti-Tachy Pacing (ATP)			
Fast AT/AF Rx Status	On; Off◈	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: Ramp◈	—	—
AT/AF Rx Status	On; Off◈	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: Ramp◈	—	—
Burst+ parameters			
Initial # S1 Pulses	1; 2 … 15◈; 20; 25	—	—
A-S1 Interval (%AA)	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
S1-S2 (%AA)	28; 31; 34; 38; 41 … 59; 63; 66; 69 … 84◈; 88; 91; 94; 97%; Off	—	—
S2-S3 Decrement	0; 10◈; 20 … 80 ms; Off	—	—
Interval Decrement	0; 10◈; 20; 30; 40 ms	—	—
# Sequences	1; 2 … 6◈ … 10	—	—

Table 37. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Ramp parameters			
Initial # S1 Pulses	1; 2 … 6◈ … 15; 20; 25	—	—
A-S1 Interval (% AA)	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
Interval Decrement	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 8◈; 9; 10	—	—
Stop Atrial Rx After (shared)			
Rx/Lead Suspect…			
Disable Atrial ATP if it accelerates V. rate?	Yes◈; No	Yes	Yes
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes◈; No	No	No
Duration to Stop	12; 24; 48◈; 72 hr; None	48 hr	48 hr
Episode Duration Before Rx Delivery			
Episode Duration Before ATP	0; 1◈; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr	1 min	1 min
Reactive ATP			
Rhythm Change	On◈; Off	On	On
Time Interval	Off; 2; 4; 7◈; 12; 24; 36; 48 hr	Off	Off
Shared A. ATP			
A-A Minimum ATP Interval[a]	100; 110; 120; 130◈ … 400 ms	150 ms	150 ms
A. Pacing Amplitude	1; 2 … 6◈; 8 V	6 V	6 V
A. Pacing Pulse Width	0.1; 0.2 … 1.5◈ ms	1.5 ms	1.5 ms
VVI Backup Pacing	Off; On (Always); On (Auto-Enable)◈	On (Auto-Enable)	On (Auto-Enable)
VVI Backup Pacing Rate	60; 70◈ … 120 bpm	70 bpm	70 bpm

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

C.4 Pacing parameters

Table 38. Modes, rates, and intervals

Parameter	Programmable values	Shipped	Reset
Mode	DDDR; DDD; AAIR<=>DDDR◈; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO	AAI<=>DDD	VVI
Mode Switch	On◈; Off	On	Off
Lower Rate[a]	30; 35 … 60◈; 70; 75 … 150 bpm	60 bpm	65 bpm
Upper Tracking Rate	80; 85 … 130◈ …175 bpm; 180; 190 … 210 bpm	130 bpm	120 bpm
Paced AV	30; 40 … 180◈ … 350 ms	180 ms	180 ms
Sensed AV	30; 40 … 150◈ … 350 ms	150 ms	150 ms
PVARP	Auto◈; 150; 160 … 500 ms	Auto	Auto
Minimum PVARP	150; 160 … 250◈ … 500 ms	250 ms	250 ms
A. Refractory Period	150; 160 … 310◈ … 500 ms	310 ms	310 ms

[a] The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.

Table 39. Atrial parameters

Parameter	Programmable values	Shipped	Reset
Atrial Amplitude[a]	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[g]	3.5 V	—
Atrial Pulse Width[b]	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	—
Atrial Sensitivity[c,d,f]	0.15; 0.3; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV Unipolar: 0.45◈ mV Bipolar: 0.3◈ mV	0.3 mV	0.45 mV
Atrial Pace Polarity	Bipolar; Unipolar	Configure[e]	—
Atrial Sense Polarity	Bipolar; Unipolar	Configure[e]	Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When tested per CENELEC standard EN 45502-2-1:2003, the tolerance (+40%/-30% for voltages less than 2.0, and ±30% for voltages greater than or equal to 2.0) is applied not to the programmed setting, but to the calculated amplitude A, which depends on the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$

[b] When tested per CENELEC standard EN 45502-2-1:2003, the measured pulse width W depends on the load Rload (in Ohms) and programmed pulse width W_p (in seconds): $W \leq W_p + 34\ \mu s$ and $W \geq$ the smaller of (W_p - 16 µs) or (124 µs + (4 µs x Rload)).

[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[d] With a 20 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.4 times the rated sine^2 sensing threshold.

[e] “Configure” is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

[f] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in bipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 1.8 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 1.8 mV or higher.
[g] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.

Table 40. RV parameters

Parameter	Programmable values	Shipped	Reset
RV Amplitude[a]	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[g]	3.5 V	6 V
RV Pulse Width[b]	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	1.5 ms
RV Sensitivity[c,d,f]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Unipolar: 2.80◈ mV Bipolar: 0.90◈ mV	0.90 mV	2.80 mV
RV Pace Polarity	Bipolar; Unipolar	Configure[e]	Unipolar
RV Sense Polarity	Bipolar; Unipolar	Configure[e]	Unipolar
RV Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When tested per CENELEC standard EN 45502-2-1:2003, the tolerance (+40%/-30% for voltages less than 2.0, and ±30% for voltages greater than or equal to 2.0) is applied not to the programmed setting, but to the calculated amplitude A, which depends on the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$
[b] When tested per CENELEC standard EN 45502-2-1:2003, the measured pulse width W depends on the load Rload (in Ohms) and programmed pulse width W_p (in seconds): $W \leq W_p + 34\ \mu s$ and $W \geq$ the smaller of (W_p - 16 µs) or (124 µs + (4 µs x Rload)).
[c] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.
[d] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[e] "Configure" is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.
[f] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 2.0 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 2.0 mV or higher.
[g] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

Table 41. Atrial Capture Management parameters

Parameter	Programmable values	Shipped	Reset
Atrial Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
Atrial Amplitude Safety Margin	1.5x; 2.0x◈; 2.5x; 3.0x	2.0x	2.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5◈; 2.0; 2.5; 3.0; 3.5 V	1.5 V	1.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120◈; 150 days	120 days	120 days

Table 42. RV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
RV Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
RV Amplitude Safety Margin	1.5x; 2.0x◈; 2.5x; 3.0x	2.0x	2.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0◈; 2.5; 3.0; 3.5 V	2 V	2 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120◈; 150 days	120 days	120 days

Table 43. Blanking periods

Parameter	Programmable values	Shipped	Reset
PVAB Interval	10; 20 … 150◈ … 300 ms	150 ms	150 ms
PVAB Method	Partial◈; Partial+; Absolute	Partial	Partial
A. Blank Post AP	150; 160 … 200◈ … 250 ms	200 ms	240 ms
A. Blank Post AS	100◈; 110 … 170 ms	100 ms	100 ms
V. Blank Post VP	150; 160 … 200◈ … 320 ms	200 ms	240 ms
V. Blank Post VS	120◈; 130 … 170; 200; 220; 250; 280; 300; 320 ms	120 ms	120 ms

Table 44. Rate Response Pacing parameters

Parameter	Programmable values	Shipped	Reset
Upper Sensor Rate	80; 85 … 130◈ … 175 bpm	130 bpm	120 bpm
ADL Rate	60; 65 … 95◈ … 170 bpm	95 bpm	95 bpm
Rate Profile Optimization	On◈; Off	On	Off
ADL Response	1; 2; 3◈; 4; 5	3	3
Exertion Response	1; 2; 3◈; 4; 5	3	3
Activity Threshold	Low◈; Medium Low; Medium High; High	Low	Medium Low
Activity Acceleration	15; 30◈; 60 s	30 s	30 s

Table 44. Rate Response Pacing parameters (continued)

Parameter	Programmable values	Shipped	Reset
Activity Deceleration	Exercise◈; 2.5; 5; 10 min	Exercise	5 min
ADL Setpoint	5; 6 … 40; 42 … 80	18	18
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 180	40	40

Table 45. Rate Adaptive AV parameters

Parameter	Programmable values	Shipped	Reset
Rate Adaptive AV	Off◈; On	Off	On
Start Rate	50; 55 … 90◈ … 145 bpm	80 bpm	60 bpm
Stop Rate	55; 60 … 130◈ … 175 bpm	130 bpm	120 bpm
Minimum Paced AV	30; 40 … 140◈ … 200 ms	140 ms	140 ms
Minimum Sensed AV	30; 40 … 110◈ … 200 ms	110 ms	110 ms

Table 46. Atrial Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
A. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ … 150 bpm	100 bpm	100 bpm
Interval Percentage Increment	12.5; 25◈; 50%	25%	25%

Table 47. Atrial Preference Pacing parameters

Parameter	Programmable values	Shipped	Reset
A. Preference Pacing	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ … 150 bpm	100 bpm	100 bpm
Interval Decrement	30; 40; 50◈ … 100; 150 ms	50 ms	50 ms
Search Beats	5; 10◈ … 25; 50	10	5

Table 48. Post Mode Switch Overdrive Pacing (PMOP) parameters

Parameter	Programmable values	Shipped	Reset
Post Mode Switch	On; Off◈	Off	Off
Overdrive Rate	70; 75; 80◈ … 120 bpm	80 bpm	65 bpm
Overdrive Duration	0.5; 1; 2; 3; 5; 10◈; 20; 30; 60; 90; 120 min	10 min	10 min

Table 49. Conducted AF Response parameters

Parameter	Programmable values	Shipped	Reset
Conducted AF Response	On; Off◈	Off	Off
Response Level	Low; Medium◈; High	Medium	Medium
Maximum Rate	80; 85 … 110◈ … 130 bpm	110 bpm	110 bpm

Table 50. Ventricular Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
V. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ …120 bpm	100 bpm	120 bpm
Interval Increment	100; 110 … 150◈ … 400 ms	150 ms	150 ms

Table 51. Rate Drop Response parameters

Parameter	Programmable values	Shipped	Reset
Rate Drop Response[a]	On; Off◈	Off	Off
Detection Type	Drop◈; Low Rate; Both	Drop	Drop
Drop Size	10; 15 … 25◈ … 50 bpm	25 bpm	25 bpm
Drop Rate	30; 40 … 60◈ … 100 bpm	60 bpm	60 bpm
Detection Window	10; 15; 20; 25; 30 s 1◈; 1.5; 2; 2.5 min	1 min	1 min
Detection Beats	1; 2; 3◈ beats	3 beats	3 beats
Intervention Rate	70; 75 … 100◈ … 150 bpm	100 bpm	100 bpm
Intervention Duration	1; 2◈ … 15 min	2 min	2 min

[a] When Rate Drop Response is set to On, the lower rate is automatically set to 45 bpm.

Table 52. Sleep parameters

Parameter	Programmable values	Shipped	Reset
Sleep	On; Off◈	Off	Off
Sleep Rate	30; 35 … 50◈; 55; 60; 70; 75 … 100 bpm	50 bpm	50 bpm
Bed Time	00:00; 00:10 … 22:00◈ … 23:50	22:00	22:00
Wake Time	00:00; 00:10 … 07:00◈ … 23:50	07:00	07:00

Table 53. Non-Competitive Atrial Pacing (NCAP) parameters

Parameter	Programmable values	Shipped	Reset
Non-Comp Atrial Pacing	On◈; Off	On	On
NCAP Interval	200; 250; 300◈; 350; 400 ms	300 ms	300 ms

Table 54. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
MRI Pacing Mode	DOO; AOO; VOO; ODO	—	—
MRI Pacing Rate	30; 35 … 60; 70; 75 … 120 bpm	—	—

Table 55. Additional pacing features

Parameter	Programmable values	Shipped	Reset
PMT Intervention	On; Off◈	Off	Off
PVC Response	On◈; Off	On	On
V. Safety Pacing	On◈; Off	On	On
Rate Hysteresis	Off◈; 30; 40 … 80 bpm	Off	Off

C.5 Data collection parameters

Table 56. Data collection parameters

Parameter	Programmable values	Shipped	Reset
EGM 1 Source	Can to RVring; Can to Aring; RVtip to RVring; Atip to RVring; Atip to Aring◈; Aring to RVring; RVtip to Can; Atip to Can	Atip to Aring	Atip to Aring
EGM 1 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 2 Source	Can to RVring; RVtip to RVring◈; RVtip to Can	RVtip to RVring	RVtip to RVring
EGM 2 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 3 Source	Can to RVring◈; Can to Aring; RVtip to RVring; Atip to RVring; Atip to Aring	Can to RVring	Can to RVring
EGM 3 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
Monitored	EGM1 and EGM2◈; EGM1 and EGM3; EGM2 and EGM3	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off◈; On – 1 month; On – 3 months; On Continuous	Off	Off
AT/AF Daily Burden	0.5; 1; 2; 6◈; 12; 24 hr	6	6
Avg. V. Rate During AT/AF Burden	0.5; 1; 2; 6◈; 12; 24 hr	6	6
Avg. V. Rate During AT/AF V. Rate	90; 100◈ … 150 bpm	100 bpm	100 bpm
Device Date/Time[a]	(enter time and date)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

[a] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

C.6 System test parameters

Table 57. System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	Atrium; RV
Decrement after	2; 3 … 15 pulses
Mode[a] (RV test)	VVI; VOO; DDI; DDD; DOO
Mode[a] (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate	30; 35 … 60; 70; 75 … 150[c] bpm
RV Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
A. Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
AV Delay[b]	30; 40 … 350 ms
V. Pace Blanking	150; 160 … 320 ms
A. Pace Blanking	150; 160 … 250 ms
PVARP	150; 160 … 500 ms
Pace Polarity	Unipolar; Bipolar
Sensing Test parameters	
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay[b]	30; 40 … 350 ms
Lower Rate[c]	30; 35 … 60; 70; 75 … 120 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] The selectable values for this parameter depend on the programmed Lower Rate.
[c] When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.

C.7 EP Study parameters

Table 58. 50 Hz Burst induction parameters

Parameter	Selectable values
50 Hz Burst induction parameters	
Resume at Burst	Enabled◈; Disabled
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈…1.50 ms
VOO Backup	On; Off◈
Pacing Rate	60; 70◈…120 bpm

Table 58. 50 Hz Burst induction parameters (continued)

Parameter	Selectable values
V. Amplitude[a]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 … 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Table 59. Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled◈; Disabled
Chamber	RV; Atrium
Interval	100; 110 … 600◈ ms
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms
VVI Backup (for atrial Fixed Burst)[a]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm
V. Amplitude[b]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[b]	0.10; 0.20 … 1.50 ms

[a] Crosstalk may occur when atrial pacing amplitude is greater than 6 V.
[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Table 60. PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled◈; Disabled
Chamber	RV; Atrium
#S1	1; 2 … 8◈ … 15
S1S1	100; 110 … 600◈ … 2000 ms
S1S2	Off; 100; 110 … 400◈ … 600 ms
S2S3	Off◈; 100; 110 … 600 ms
S3S4	Off◈; 100; 110 … 600 ms
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 …0.50◈ … 1.50 ms
VVI Backup (for atrial PES)[a]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm
V. Amplitude[b]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[b]	0.10; 0.20 … 1.50 ms

[a] Crosstalk may occur when atrial pacing amplitude is greater than 6 V.
[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Table 61. Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (atrial ATP)	100; 110; 120; 130◈ … 400 ms
Minimum Interval (ventricular ATP)	150; 160 … 200◈ … 400 ms
Amplitude	1; 2 … 6◈; 8 V
Pulse Width	0.10; 0.20 …1.50◈ ms
VVI Backup (for atrial ATP therapy)[a]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm
V Amplitude[b]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V Pulse Width[b]	0.10; 0.20 … 1.50 ms

[a] Crosstalk may occur when atrial pacing amplitude is greater than 6 V.
[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Table 62. Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	Atrium; RV
RV Ramp therapy parameters	
# Pulses	1; 2 … 6◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88; 91; 94; 97◈%
Dec/Pulse	0; 10◈; 20; 30; 40 ms
Atrial Ramp therapy parameters	
# Pulses	1; 2 … 6◈ … 15; 20; 30 … 100
%AA Interval	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91; 94; 97◈%
Dec/Pulse	0; 10◈; 20; 30; 40 ms

Table 63. Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 … 8◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%

Table 64. Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3◈ … 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 … 75◈ … 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69◈ … 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66◈ … 84; 88; 91; 94; 97%

Table 65. Manual Burst+ therapy parameters

Parameter	Selectable values
#S1 Pulses	1; 2 … 6◈ … 15; 20; 30 … 100
%AA Interval	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%
S1S2	Off; 28; 31; 34; 38; 41 … 59; 63; 66 … 84◈; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20◈ … 80 ms

C.8 Nonprogrammable parameters

Table 66. Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
Fixed blanking periods	
Atrial blanking after a paced ventricular event (bipolar atrial sensing)	30 ms
Atrial blanking after a paced ventricular event (unipolar atrial sensing)	40 ms
Ventricular blanking after a paced atrial event (bipolar ventricular sensing)	30 ms[a]
Ventricular blanking after a paced atrial event (unipolar ventricular sensing)	40 ms
Fixed bradycardia pacing parameters	
Ventricular Safety Pacing intervals[b]	110 ms
PVARP value applied by PVC Response and PMT Intervention[c]	400 ms
NCAP value applied by PVC Response and PMT Intervention[d]	400 ms
Fixed automatic atrial ATP therapy parameters	
VVI Backup Pacing amplitude	6 V
VVI Backup Pacing pulse width	1.5 ms
Fixed EP study parameters	
50 Hz burst pacing interval	20 ms
Hardware parameters	
Pacing rate limit[e] (protective feature)	171 bpm[f]
Input impedance	150 kΩ minimum
Recommended Replacement Time (RRT)	
Battery Voltage Threshold	≤ 2.83 V

[a] 35 ms when the ventricular pacing amplitude is programmed to 8 V.
[b] The VSP interval may be shortened from 110 ms to 70 ms automatically by the device at higher pacing rates when necessary to help support ventricular tachycardia detection.

[c] PVARP is extended to 400 ms only if the current PVARP is less than 400 ms.
[d] The NCAP extension applies only if NCAP is enabled.
[e] Does not apply during ATP therapies or ventricular safety pacing.
[f] If either the Upper Tracking Rate or the Upper Sensor Rate (whichever is greatest) is programmed to a value greater then 150 bpm and less than or equal to 180 bpm, the pacing rate limit is 200 bpm. If the Upper Tracking Rate is programmed to a value greater than 180 bpm, the pacing rate limit is 230 bpm.

D Advisa SR MRI device parameters

D.1 Emergency settings

Table 67. Emergency VVI settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude[a]	6 V
RV Pulse Width[a]	1.5 ms
RV Pace Polarity	Unipolar
V. Blank Post VP	240 ms
Rate Hysteresis	Off
V. Rate Stabilization	Off
MRI SureScan	Off

[a] If the programmed RV Amplitude is 8 V, VVI pacing is delivered at 8 V with a pulse width of 1.2 ms.

D.2 Tachyarrhythmia detection parameters

Table 68. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
VT Monitor	Monitor◈; Off	Monitor	Off
VT Monitor Interval (Rate)[a]	280; 290 … 360◈ … 500 ms	360	360
RV Sensitivity[b,c,d]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Bipolar: 0.90◈ mV Unipolar: 2.80◈ mV	0.90 mV	2.80 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[c] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.
[d] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 2.0 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 2.0 mV or higher.

D.3 Pacing parameters

Table 69. Modes, rates, and intervals

Parameter	Programmable values	Shipped	Reset
Mode	VVIR◈; VVI; VOO; OVO	VVI	VVI
Lower Rate[a]	30; 35 … 60◈; 70; 75 … 150 bpm	60 bpm (1000 ms)	65 bpm (923 ms)

[a] The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.

Table 70. RV parameters

Parameter	Programmable values	Shipped	Reset
RV Amplitude[a]	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[b]	3.5 V	6 V
RV Pulse Width[c]	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	1.5 ms
RV Sensitivity[d,e,f]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Unipolar: 2.80◈ mV Bipolar: 0.90◈ mV	0.90 mV	2.80 mV
RV Pace Polarity	Bipolar; Unipolar	Configure[g]	Unipolar
RV Sense Polarity	Bipolar; Unipolar	Configure[g]	Unipolar
RV Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When tested per CENELEC standard EN 45502-2-1:2003, the tolerance (+40%/-30% for voltages less than 2.0, and ±30% for voltages greater than or equal to 2.0) is applied not to the programmed setting, but to the calculated amplitude A, which depends on the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$

[b] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

[c] When tested per CENELEC standard EN 45502-2-1:2003, the measured pulse width W depends on the load Rload (in Ohms) and programmed pulse width W_p (in seconds): $W \leq W_p + 34\ \mu s$ and $W \geq$ the smaller of (W_p - 16 µs) or (124 µs + (4 µs x Rload)).

[d] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times the rated sine^2 sensing threshold.

[e] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 2.0 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 2.0 mV or higher.

[f] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[g] “Configure” is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

Table 71. RV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
RV Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
RV Amplitude Safety Margin	1.5x; 2.0x◈; 2.5x; 3.0x	2.0x	2.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0◈; 2.5; 3.0; 3.5 V	2 V	2 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120◈; 150 days	120 days	120 days

Table 72. Blanking periods

Parameter	Programmable values	Shipped	Reset
V. Blank Post VP	150; 160 … 200◈ … 320 ms	200 ms	240 ms
V. Blank Post VS	120◈; 130 … 170; 200; 220; 250; 280; 300; 320 ms	120 ms	120 ms

Table 73. Rate Response Pacing parameters

Parameter	Programmable values	Shipped	Reset
Upper Sensor Rate	80; 85 … 130◈ … 175 bpm	130 bpm	120 bpm
ADL Rate	60; 65 … 95◈ … 170 bpm	95 bpm	95 bpm
Rate Profile Optimization	On◈; Off	On	Off
ADL Response	1; 2; 3◈; 4; 5	3	3
Exertion Response	1; 2; 3◈; 4; 5	3	3
Activity Threshold	Low◈; Medium Low; Medium High; High	Low	Medium Low
Activity Acceleration	15; 30◈; 60 s	30 s	30 s
Activity Deceleration	Exercise◈; 2.5; 5; 10 min	Exercise	5 min
ADL Setpoint	5; 6 … 40; 42 … 80	18	18
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 180	40	40

Table 74. Conducted AF Response parameters

Parameter	Programmable values	Shipped	Reset
Conducted AF Response	On; Off◈	Off	Off
Response Level	Low; Medium◈; High	Medium	Medium
Maximum Rate	80; 85 … 110◈ … 130 bpm	110 bpm	110 bpm

Table 75. Ventricular Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
V. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ …120 bpm	100 bpm	120 bpm
Interval Increment	100; 110 … 150◈ … 400 ms	150 ms	150 ms

Table 76. Sleep parameters

Parameter	Programmable values	Shipped	Reset
Sleep	On; Off◈	Off	Off
Sleep Rate	30; 35 … 50◈; 55; 60; 70; 75 … 100 bpm	50 bpm	50 bpm
Bed Time	00:00; 00:10 … 22:00◈ … 23:50	22:00	22:00
Wake Time	00:00; 00:10 … 07:00◈ … 23:50	07:00	07:00

Table 77. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
MRI Pacing Mode	VOO; OVO	—	—
MRI Pacing Rate	30; 35 … 60; 70; 75 … 120 bpm	—	—

Table 78. Additional pacing features

Parameter	Programmable values	Shipped	Reset
Rate Hysteresis	Off◈; 30; 40 … 80 bpm	Off	Off

D.4 Data collection parameters

Table 79. Data collection parameters

Parameter	Programmable values	Shipped	Reset
EGM 1 Source	Can to RVring; RVtip to RVring◈; RVtip to Can	RVtip to RVring	RVtip to RVring
EGM 1 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 2 Source	Can to RVring; RVtip to RVring; RVtip to Can◈	RVtip to Can	RVtip to Can
EGM 2 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 3 Source	Can to RVring◈; RVtip to RVring; RVTip to Can	Can to RVring	Can to RVring
EGM 3 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
Monitored	EGM1 and EGM2◈; EGM1 and EGM3; EGM2 and EGM3	EGM1 and EGM2	EGM1 and EGM2

Table 79. Data collection parameters (continued)

Parameter	Programmable values	Shipped	Reset
Pre-arrhythmia EGM	Off◈; On - 1 month; On - 3 months; On Continuous	Off	Off
Device Date/Time[a]	(enter time and date)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

[a] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

D.5 System test parameters

Table 80. System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	RV
Decrement after	2; 3 … 15 pulses
Mode[a] (RV test)	VVI; VOO
Lower Rate	30; 35 … 60; 70; 75 … 150 bpm
RV Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
V. Pace Blanking	150; 160 … 320 ms
Pace Polarity	Unipolar; Bipolar
Sensing Test parameters	
Mode[a]	VVI; OVO
Lower Rate	30; 35 … 60; 70; 75 … 120 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.

D.6 EP Study parameters

Table 81. Fixed Burst induction parameters

Parameter	Selectable values
Interval	100; 110 … 600◈ ms
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms

Table 82. PES induction parameters

Parameter	Selectable values
#S1	1; 2 … 8◈ … 15
S1S1	100; 110 … 600◈ … 2000 ms
S1S2	Off; 100; 110 … 400◈ … 600 ms
S2S3	Off◈; 100; 110 … 600 ms
S3S4	Off◈; 100; 110 … 600 ms
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 …0.50◈ … 1.50 ms

Table 83. Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (ventricular ATP)	150; 160 … 200◈ … 400 ms
Amplitude	1; 2 … 6◈; 8 V
Pulse Width	0.10; 0.20 …1.50◈ ms

Table 84. Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	RV
RV Ramp therapy parameters	
# Pulses	1; 2 … 6◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88; 91; 94; 97◈%
Dec/Pulse	0; 10◈; 20; 30; 40 ms

Table 85. Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 … 8◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%

Table 86. Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3◈ … 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 … 75◈ … 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69◈ … 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66◈ … 84; 88; 91; 94; 97%

D.7 Nonprogrammable parameters

Table 87. Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
Hardware parameters	
Pacing rate limit[a] (protective feature)	171 bpm[b]
Input impedance	150 kΩ minimum
Recommended Replacement Time (RRT)	
Battery Voltage Threshold	≤ 2.83 V

[a] Does not apply during ATP therapies.
[b] If the Upper Sensor Rate is programmed to a value greater than 150 bpm the pacing rate limit is set to 200 bpm.

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 (ADL) – level of patient movement during basic life tasks such as dressing, eating, or housekeeping.

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 Interval – programmable interval used to define the AT/AF Detection zone. The median atrial interval must be shorter than this value for an AT/AF episode to be detected.

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 tracking – dual chamber pacing operation that paces the ventricle in response to atrial events.

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.

capture – depolarization of cardiac tissue by an electrical stimulus delivered by a cardiac device.

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 Report – on screen or printed report of up to 14 months of long-term clinical trends, such as frequency of arrhythmias, heart rates, and device therapies.

Checklist – interactive list of programmer screens that helps users operate the programmer more efficiently. Clinicians can set up their own checklists or use a Medtronic standard checklist supplied with the programmer.

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 status indicators – programmer warnings, such as “Warning - Device Electrical Reset,” that describe problems with device memory or operation.

electrical reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to electrical reset values. This operation triggers a device status indicator.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that can interfere with device operations, such as sensing, or can 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 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.

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.

impedance – total opposition that a circuit presents to electrical current flow; the device lead impedances can be measured to assess lead system integrity.

Interrogate – command to transmit the device parameter settings and stored data to the programmer.

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.

Live Rhythm Monitor – configurable programmer window that displays ECG, Marker Channel with marker annotations, and telemetered EGM waveform trace. It also displays the patient heart rate and interval in the upper left corner of the window.

longevity – number of years before the device battery reaches the recommended replacement time (RRT) voltage. This is also referred to as “projected service life”.

manual operations – device functions that can only be initiated using the programmer in a patient session (for example, EP study functions or manual system tests).

Marker Channel telemetry – telemetered symbols that annotate the device sensing, pacing, detection, and therapy operations.

median atrial interval – the seventh in a numerically ordered list of the 12 most recent A-A intervals.

Mode Switch – a 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.

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 – 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.

nominal – parameter value that is suggested by Medtronic and may be acceptable for the majority of patients.

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.

projected service life – estimated number of years before the device battery reaches the Recommended Replacement Time (RRT) voltage.

Prolonged Service Period (PSP) – estimated number of months the device will operate once RRT has been reached.

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.

radiopaque ID – a small metallic plate (inside the connector block of the device) featuring the Medtronic-identifier symbol and a unique code for identifying the device or device family under fluoroscopy.

Rate Adaptive AV (RAAV) – dual chamber pacing feature that automatically shortens the AV interval at elevated rates to help maintain 1:1 tracking and AV synchrony.

Rate Histograms – on screen or printed report 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 Response – feature that adjusts the cardiac pacing rate in response to changes in sensed patient activity.

Recommended Replacement Time – see "RRT".

refractory period – time interval during which the device senses events normally but classifies them as refractory and responds to them in a limited way.

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.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

telemetry – transmission of data between the device and the programmer by radio waves.

tracking – see “atrial tracking”.

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 ventricular asystole due to inappropriate inhibition of ventricular pacing.

waveform – graphic plot of electrical activity, for example, intracardiac EGM or surface ECG trace.

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